

# EU EMERGENCY RESPONSE UPDATE

## KEY POLICY & REGULATORY DEVELOPMENTS

No. 111 | 29 December 2023

This regular alert covers key regulatory developments related to EU emergency responses, including in particular to Russia's war of aggression against Ukraine, COVID-19, and cyber threats. It does not purport to provide an exhaustive overview of developments.

*This regular update expands from the previous COVID-19 Key EU Developments – Policy & Regulatory Updates (last issue [No. 99](#)).*

### LATEST KEY DEVELOPMENTS

#### Competition & State Aid

- Commission publishes Competition Policy – 2023 at a glance
- European Commission launches Chips Joint Undertaking
- European Commission approves further schemes under Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies
- European Commission approves further scheme to compensate for damage due to COVID-19 crisis

#### Trade / Export Controls

- Council of the European Union expands sanctions against Russia and Iran
- European Declaration on Quantum Technologies released
- Council of the European Union extends emergency regulations on security of supply and energy prices

#### Medicines and Medical Devices

- EMA publishes report on COVID-19 Lessons Learned
- European Commission, EMA, and HMA publish first version of Union list of critical medicines

#### Cybersecurity, Privacy & Data Protection

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- Council of the European Union agrees on common position on proposed Cyber Solidarity Act

## COMPETITION & STATE AID

### Competition

#### Commission publishes Competition Policy – 2023 at a glance (see [here](#))

On 21 December 2023, the European Commission published its Competition Policy – 2023 at a glance.\*

This infographic reported on the following in particular:

- State aid: some 620 decisions, among which over 220 decisions under the State aid temporary frameworks in response to the Ukraine crisis, accelerating the green transition and reducing fuel dependencies;
- Merger enforcement: 333 final decisions, including, in particular, 1 prohibition decision; and 9 commitment decisions;
- Antitrust enforcement: 7 unannounced inspections; 6 Statement of Objections; 5 final decisions; and total fines of €465 million.

\* For the Competition Policy “at a glance” of 2022 and 2021, see respectively [here](#) and [here](#).

### State aid

#### European Commission launches Chips Joint Undertaking (see [here](#))

On 30 November 2023, the Commission formally launched the Chips Joint Undertaking (Chips JU) under the European Chips Act.\* Both measures entered into force on 21 September 2023.

To recall, the Chips Act is part of the Commission’s package of measures released in February 2022 (see [here](#)) aimed at ensuring the EU’s security of supply and technological leadership in the field of semiconductors. (Micro-)chips or semiconductors are key building blocks for digital products, e.g., smartphones, computers, and medical equipment (see also [Jones Day EU Emergency Response Update No. 107 of 29 September 2023](#)).

On State aid aspects, in light of steep barriers to entry and the capital intensity of the chips sector, the Commission has noted that private investment in chips manufacturing facilities may likely require public support. In this respect, the Commission may consider approving State aid to such facilities under Article 107(3)(c) TFEU, weighing relevant positive effects (e.g., the chips facility is “first-of-a-kind” in Europe and would strengthen security of supply).

The Chips JU is the primary component of the [Chips for Europe Initiative](#) (anticipated total budget of €15.8 billion until 2030), which aims at supporting large-scale technological capacity building and is one of the Chips Act’s main pillars.

As a public-private partnership involving the EU, Member States and the private sector (anticipated budget of nearly €11 billion by 2030), the Chips JU will support activities such as:

- Supporting the development of advanced technology and engineering capacities for quantum chips; and
- Establishing advanced pilot production lines to accelerate technology development. The Commission also announced, on the same day, the first call for such projects with €1.67 billion of EU funding available and expected matching Member State funds, in view of reaching €3.3 billion, in addition to private funds. Among the pilot projects envisaged:
  - Leading-edge nodes at and below 2 nanometres (nm)\*\*: This project will focus on developing cutting-edge technology for advanced semiconductors at the size of 2 nm and below (1 nm is one billionth of a meter), which will play essential roles in numerous applications, from computing to communication devices, transport systems and critical infrastructure;
  - Wide bandgap semiconductors: This project will focus on materials that allow electronic devices to operate at much higher voltage, frequency and temperature than standard silicon-based devices. Wide bandgap and ultra-wide bandgap semiconductors are essential to developing highly efficient power, lighter weight, lower costs and radio-frequency electronics.

The deadline for calls for proposals for these pilot lines is early March 2024. For information on the application process for these calls for proposals and the pilot lines to be deployed, see [here](#).

In addition, on the same day, the European Semiconductor Board held its first meeting. To recall, the Board is the advisory body serving as the primary coordination mechanism between the Commission (serving as Chair), Member States, and stakeholders for mapping/monitoring the EU's semiconductor value chain and preventing/responding to semiconductor crises with ad hoc emergency measures (e.g., information requests, priority-rated orders, and common purchasing). For more information, see [here](#).

\* [Regulation on the Chips JU](#) of 25 July 2023 enabling the Chips JU's establishment; [Regulation \(EU\) 2023/1781](#) of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem.

\*\* The Commission has noted Europe's limited chip manufacturing capabilities, which are mainly in mature production nodes (at 22 nm and above), but none in leading-edge nodes (at 7 nm and below). Smaller nodes deliver higher performance and power efficiency, but are also more complex and expensive to produce (see [Communication on A Chips Act for Europe](#) of 8 February 2022).

**European Commission approves further schemes under Temporary Crisis and Transition Framework to**

The Commission approved additional measures under the State aid Temporary Crisis and Transition Framework (TCTF) to support the economy in the context of Russia's invasion of Ukraine and in sectors key to accelerating the green transition and reducing fuel dependencies (as most lately amended on 20 November 2023).

**support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies (see [here](#))**

Among the most recently approved State aid schemes under the TCTF (up to 29 December 2023):

- Extension and modification of a French aid scheme aimed at supporting small and medium-sized enterprises (SMEs), as well as micro-enterprises, in the context of Russia's war against Ukraine, such as by extending the duration of the regime from 31 December 2023 to 30 June 2024 and a budget increase from €3.5 billion to €4.2 billion.
- €120 million Bulgarian measure to support Bulgargaz EAD, the public supplier of natural gas in Bulgaria, in the context of Russia's invasion of Ukraine.
- €260 million German scheme to support the installation of electrolyzers for the production of renewable hydrogen and hydrogen storage to foster the transition to a net-zero economy.
- €150 million Greek scheme to support energy-intensive companies facing increased energy costs in the context of Russia's war against Ukraine.
- €50 million Belgian measure to support the production of batteries and electrolyzers in Wallonia needed to promote the transition to a net-zero emissions economy.
- €140 million Portuguese scheme to support the production of renewable hydrogen and biomethane to foster the transition to a net-zero economy.
- €1 billion Slovak scheme to support investments in equipment necessary to foster the transition to a net-zero economy.
- €23 million (£20 million) UK scheme to support companies in Northern Ireland in the context of Russia's war against Ukraine, in line with EU State aid rules made applicable by the [Windsor Framework](#) (formerly the Protocol on Ireland and Northern Ireland).
- €4.12 billion French scheme to support the rollout of offshore wind energy to foster the transition to a net-zero economy.

**European Commission approves further scheme to compensate for damage due to COVID-19 crisis (see [here](#))**

The Commission has adopted a significant number of State aid measures under Article 107(2)(b), Article 107(3)(b), and the State aid COVID Temporary Crisis Framework adopted in March 2020 under Article 107(3)(b) TFEU. With certain exceptions, the Temporary Crisis Framework applied until 30 June 2022.\*

Among the latest schemes (up to 29 December 2023):

- €51.4 million French scheme aimed at compensating the Régie Autonome des Transports Parisiens ("RATP") for the restrictive measures by the government to limit the spread of the virus during the coronavirus pandemic.
- €833 million (SEK 9.5 billion) Danish and Swedish State aid measure to recapitalize SAS, which suffered substantial losses due to the coronavirus outbreak and the travel restrictions that Denmark, Sweden and other countries imposed to limit the spread of the virus.

This approval followed the Commission's in-depth investigation subsequent to the EU General Court's (GC) annulment, in May 2023, of the Commission's initial approval in August 2020 of the aid scheme. In now approving the aid, the Commission determined that SAS had put forward measures, viewed as compliant with the COVID Temporary Crisis Framework, to address the GC's reasons for annulment.

*\* Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments as a stimulus to overcome an investment gap accumulated in the economy due to the crisis (until 31 December 2023) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies.*

*The Temporary Framework had also provided for a flexible transition, under clear safeguards, in particular for the conversion and restructuring options of debt instruments (e.g., loans and guarantees) into other forms of aid, such as direct grants, until 30 June 2023.*

## TRADE / EXPORT CONTROLS

### **Council of the European Union expands sanctions against Russia and Iran (see [here](#) and [here](#))**

The EU relies on restrictive measures (sanctions) as one of its tools to advance its Common Foreign and Security Policy (CFSP) objectives, such as safeguarding EU's values, fundamental interests, and security; preserving peace; and supporting democracy and the rule of law.

Sanctions include measures such as travel bans (prohibition on entering or transiting through EU territories); asset freezes; prohibition on EU citizens and companies from making funds and economic resources available to the listed individuals and entities; ban on imports and exports (e.g., no exports to Iran of equipment that might be used for internal repression or for monitoring telecommunications), and sectoral restrictions.

Among the most recent developments to the EU sanctions regimes:

**Russia:** On 18 December 2023, the Council adopted a 12th package of sanctions,\* which focuses on imposing further import and export bans on Russia and closing loopholes, including measures such as:

- Import restrictions, e.g.:
  - Import ban on Russian diamonds, including a direct ban on non-industrial natural and synthetic diamonds and diamond jewellery exported from Russia (as of 1 January 2024); an indirect ban on Russian diamonds polished in a third country, including jewellery incorporating diamonds originating in Russia (as of 1 March 2024); and a ban on lab-grown diamonds, jewellery, and watches containing diamonds (as of 1 September 2024).
  - Import ban on raw materials for steel production, processed aluminium products and other metal goods.
- Export restrictions, e.g.:

- Additional export restrictions on dual-use and advanced technological and industrial goods worth an estimated €2.3 billion per year.
- Extending prohibitions on the provision of services to include providing software for the management of enterprises and software for industrial design and manufacture to the Russian government or Russian companies.
- Addition of 29 Russian and third country entities to the list of those directly supporting Russia's military and industrial complex in its war of aggression against Ukraine. They will be subject to tighter export restrictions concerning dual use goods and technologies, as well as goods and technology that may contribute to the technological enhancement of Russia's defense and security sector (including entities registered in Uzbekistan and Singapore).
- Energy measures, such as a new import ban on liquified petroleum gas (LPG), impacting annual imports worth over €1 billion, with grandfathering of existing contracts for a period of maximum 12 months.

Within this 12th package of sanctions, the Council also added over 140 additional individuals and entities (including actors in the Russian military and defence (e.g., military industry companies and private military companies), actors from the IT sector and other important economic actors involved in the circumvention of EU restrictive measures) to the list of those subject to asset freezes, and EU citizens and companies are forbidden from making funds and economic resources available to them. Natural persons are additionally subject to a travel ban, which prevents them from entering or transiting through EU territories.

Altogether, EU restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine now apply to over 1,900 individuals and entities.

The European Commission's Q&A on the 12th package of sanctions provides further details (see [here](#)).

The Council's overview of EU sanctions against Russia over Ukraine (since 2014) is also available [here](#). To recall, EU restrictive measures taken against Russia, as first introduced in 2014 in response to Russia's actions destabilizing the situation in Ukraine, have significantly expanded following Russia's military aggression against Ukraine, starting in February 2022 with the so-called first package of sanctions (see [here](#)). The 11th package of sanctions was adopted by the Council on 23 June 2023 (see also [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)).

*\* An in-depth analysis of the 12th package of sanctions against Russia is available from the authors of the EU Emergency Update (see contact details below for Nadiya Nychay (Brussels) and Rick van 't Hullenaar (Amsterdam)).*

Iran. In the context of Russia's invasion of Ukraine, the EU has also adopted sanctions against Iran, and most lately:

- Iran. On 11 December 2023, the Council imposed restrictive measures against 6 persons and 5 entities involved in Iran's

development and production of unmanned aerial vehicles (UAV) used in Russia's war against Ukraine.

These are the first listings under the new framework for restrictive measures in view of Iran's military support of Russia's war against Ukraine, which notably prohibits exports from the EU to Iran of components used to produce Unmanned Aerial Vehicles (UAVs) (see also [Jones Day EU Emergency Response Update No. 105 of 31 August 2023](#)). These new listings complement the previous four rounds of listings on Iranian drones already adopted under other sanctions regimes.

For an [overview of EU restrictive measures against Iran](#), see [here](#).

**European Declaration on Quantum Technologies released (see [here](#))**

On 6 December 2023, the Council of the European, under the Spanish Presidency, published the European Declaration on Quantum Technologies, which aims at creating a world-class quantum technology ecosystem across Europe and making Europe the world's "quantum valley" and global leader in quantum excellence and innovation.

Backdrop. The Declaration affirms the strategic importance of quantum technologies for the EU's scientific and industrial competitiveness. Quantum technologies are also a high priority for the EU's sovereignty, as highlighted in particular in:

- The Joint Communication on European Economic Security Strategy of 20 June 2023 ([here](#)), which addresses Europe's shortcomings in adequate preparedness for new and emerging risks (see also [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)); and
- The Recommendation of 3 October 2023 on critical technology areas for the EU's economic security for further risk assessment with Member States ([here](#)) (see also [Jones Day EU Emergency Response Update No. 108 of 16 October 2023](#) and [Jones Day Alert, "European Commission Signals Increased Scrutiny in Semiconductors, AI, Quantum Technologies, and Biotechnologies," October 2023](#)).

Key measures. The Declaration's signatory Member States\* agree to working together and with the European Commission, such as by:

- Coordinating efforts to accelerate the transition from "lab-to-fab" (i.e., from research (lab) to design/manufacture (fab)); filling gaps in Europe's supply chain; and facilitating the transformation of high-quality European quantum research into marketable devices and applications with substantial economic and societal value;
- Further developing all areas of the European quantum ecosystem, especially by supporting startups and scale-ups, as well as encouraging private funding, including urging large companies across industrial sectors to invest in quantum;
- Supporting further public investments in European innovation in quantum; and
- Aligning internationally-focused measures to reinforce the EU's economic security, identifying key opportunities and threats, and targeting potential EU-level agreements and collaboration

opportunities in quantum with third countries and international organizations.

Next steps. The signatory Member States agree to regularly discuss the Declaration's objectives and to collaborating together and with the European Commission to develop a corresponding action plan with concrete targets.

The Commission encourages other Member States to join this common effort.

\* *Initial signatories include: Denmark, Finland, France, Germany, Greece, Hungary, Italy, Slovenia, and Sweden.*

**Council of the European Union extends emergency regulations on security of supply and energy prices (see [here](#))**

On 22 December 2023, the Council of the European Union prolonged a package of emergency regulations on security of supply and energy prices.

To recall, this package of three emergency measures sought to counter the energy crisis caused by Russia's war against Ukraine (see also [Jones Day COVID-19 Update No. 95 of 9 January 2023](#)):

1. Regulation on establishing temporary measures on enhancing solidarity through better coordination of gas purchases, reliable price benchmarks and exchanges of gas across borders ([Council Regulation \(EU\) 2022/2576 of 19 December 2022](#)):

The Regulation aims at containing high energy prices and improving supply security, including through measures for strengthening solidarity in case of emergency and gas supply shortage, enhancing coordination of joint gas purchases, limiting gas and electricity price volatility, and setting reliable gas price benchmarks.

In particular, to support organizing demand aggregation and joint purchasing of gas, the [EU Energy Platform](#) (a European Commission-led coordination mechanism to secure the supply of gas, LNG, and hydrogen) plays a pivotal role in working with Member States and industry (see also [Jones Day COVID-19 Update No. 82 of 15 April 2022](#)).

*The Regulation is now extended until 31 December 2024.*

An infographic on EU gas market measures to secure and share supply provides further details (see [here](#)).

2. Regulation on laying down a framework to accelerate the deployment of renewable energy ([Council Regulation \(EU\) 2022/2577 of 22 December 2022](#)):

The Regulation seeks to lower the EU's dependence on Russian fossil fuels and further advance the EU's climate objectives, notably by accelerating the permit-granting process and deployment of renewable energy projects. The Regulation, in particular, targets technologies capable of swift implementation in the short term and with considerable potential for reducing gas consumption.

*Certain amended provisions of the Regulation are now extended until 30 June 2025.*

3. Regulation establishing a temporary Market Correction Mechanism to protect against excessively high gas prices ([Council Regulation \(EU\) 2022/2578 of 22 December 2022](#)):

The Regulation establishes a market correction mechanism (MCM), a system of temporary measures to prevent excessively high gas prices in the EU. The MCM is activated when prices on the main European gas exchange, the Dutch Title Transfer Facility (TTF)\* rise above certain levels and significantly exceed a reference price reflecting global liquefied natural gas (LNG) price trends.

An infographic on the MCM provides further details (see [here](#)).

*The Regulation is now extended until 31 January 2025.*

Progress report. The European Commission's [State of the Energy Union Report 2023](#) (October 2023) indicates certain progress arising from the EU's joint actions to address the energy crisis, such as:

- Reduced dependence on Russia, including by diversifying energy imports (e.g., increasing LNG and natural gas imports, notably from Norway, the United States, and Azerbaijan), with the overall share of Russian gas (LNG and piped natural gas) in total EU gas imports falling to 15% (from 45-50% in the pre-crisis years).
- Lowered energy demand, with Member States collaborating to reduce energy demand. Gas consumption dropped by over 18% in 2022 and 2023, compared to the previous five years.
- Swifter deployment of renewables, with 2022 as a record year for solar energy (41 GW (gigawatts) of photovoltaic capacity installed, i.e., 60% more than in 2021 (26 GW)). In May 2022, for the first time ever, more electricity was generated in the EU from wind and solar power than from fossil fuels.

*\* The TTF is a "hub" or a "virtual trading point" of a so-called entry / exit system, where market players can transfer gas between each other. In addition to the Dutch TTF, other main gas hubs in Europe include, e.g., German Trading Hub Europe (THE); French Gas exchange point - North (PEG); Belgian Zeebrugge (Beach).*

## MEDICINES AND MEDICAL DEVICES

**EMA publishes report on COVID-19 Lessons Learned** (see [here](#))

On 1 December 2023, the European Medicines Agency (EMA) published "COVID-19 Lessons Learned – Joint report on the response to the Public Health Emergency".

The Report reflects the findings of a joint review of the activities and overall response to the emergency of the European Medicines Regulatory Network (EU Network (comprised of the medicines regulatory authorities of the Member States (NCAs), European Commission, and the EMA)), which played a key role during the pandemic. The report covers activities during

the pandemic's public health emergency phase, i.e., between 30 January 2020 and 5 May 2023.

The Report highlights various unprecedented challenges related to the prolonged COVID-19 crisis, the activities and resources that enabled effective response to the emergency, and recommendations on improving crisis response. In this respect, the Report focuses on ten areas of activity of the EU Network, such as:

- Crisis preparedness:
  - Given the scale and duration of the global and sudden crisis, which surpassed existing pandemic preparedness plans and crisis management structures, the EU Network set up specific new governance structures such as the EMA COVID-19 Steering Group. The EMA's mandate was also extended in January 2022 to formalize its role and interaction with NCAs in assessing and responding to shortages across the EU.
  - Lessons learned include, e.g.: the importance of further strengthening horizon scanning of potential health threats and relevant medical countermeasures, which the EMA's Emergency Task Force's ([ETF](#)) is pursuing as part of its role in crisis preparedness.
- Support to development and approval of medicines:
  - The EU Network rapidly activated a set of agile support measures for research and development, including enhanced and proactive pre-submission dialogue with developers of COVID-19 medicines and waived fees for EMA scientific advice (SA). Sufficiently mature medicinal products benefited from an expedited formal EMA SA, with timelines reduced from the standard 40-70 days to no more than 20 days.
  - Lessons learned include, e.g.: importance in crisis situations of regulators providing feedback and engaging in regular dialogue with medicines developers, as now strengthened and formalized through the ETF in EMA's extended mandate. Informal communications with developers, academic groups and international stakeholders are essential to adequately determine the level of regulatory support needed.
- Regulatory framework and procedures:
  - Use of the [rolling review](#), which the EMA's health threats plan had already foreseen as an appropriate tool for exceptional cases and which enabled a fast track assessment of medicines and rapid approval.
  - Lessons learned include, e.g.: stepwise early review of available data should be considered for a limited number of high priority medicinal products that address unmet patient needs outside of the context of public health threats.
- Clinical trials and real-world evidence:
  - The EU Network provided medicines developers with urgent guidance on how to conduct clinical trials during the pandemic (e.g., where participants could no longer attend follow up appointments in person), and the EMA issued [guidance on methodological aspects](#) on acceptance of data generated in an emergency context.

- Lessons learned include, e.g.: with the rising use of real-world data and evidence, it is necessary to continue increasing expertise on their use in the EU Network, including by investing in human resources; and ongoing efforts should be pursued, such as under the [EMA Big Data Workplan 2022-2025](#), to develop capacity to access and analyze individual patients' data from clinical trials.

The Report concludes with identifying both:

- Areas that performed well (e.g., close cooperation and coordination among EMA, NCAs, the European Commission, ECDC (European Centre for Disease Prevention and Control), international partners, and reinforced stakeholder engagement; and
- Areas requiring further improvement (e.g., extending development and access of real-world data sources with relevant and granular information, improving IT systems for processing these data, and reinforcing networks of expertise).

**European Commission, EMA, and HMA publish first version of Union list of critical medicines ([here](#))**

On 12 December 2023, the European Commission, EMA, and HMA (Member States' Heads of Medicines Agencies) published the first version of the European Union list of critical medicines (Union List).

The need to secure the supply of medicines across the EU and avoid shortages is an important part of the European Health Union and has been highlighted as key in the EU Pharmaceutical Strategy for Europe and the new EU pharmaceutical legislation proposal (see also [Jones Day COVID-19 Update No. 27 of 18 November 2020](#) and [Jones Day EU Emergency Response Update No. 102 of 3 May 2023](#)). The Union List is also part of the EU's efforts to strengthen its resilience and strategic autonomy in the face of geopolitical and unexpected challenges.

This first version of the Union List contains more than 200 active substances used in medicines for humans, covering a wide range of therapeutic areas, including vaccines and medicines for rare diseases (see [here](#)).

The Union List identifies medicines that are critical for health systems across the EU/EEA and for which continuity of supply should always be guaranteed for European patients. A medicine is considered critical if used in serious diseases and not readily replaced by other medicines, as determined under a strict methodology that was developed in consultation with key stakeholder groups, including patients' and healthcare professionals' organizations and industry associations (see [here](#)).

The EMA also specified the following in particular for medicines on the Union List:

- Inclusion on the list does not mean that such medicines are likely to experience a shortage in the short term, but that prevention of shortages is particularly important, as a shortage could significantly harm patients and raise serious challenges to health systems;
- Such medicines can continue to be prescribed and used as usual by patients and healthcare professionals. Additional reporting requirements for marketing authorization holders and national competent authorities will be established and become effective once the proposed pharmaceutical legislation becomes applicable.

- The Union List will be used to support and expedite the Commission's analysis of vulnerabilities in the supply chains of critical medicines. The Commission and EMA, together with the Member States through the [Executive Steering Group on Shortages and Safety of Medicinal Products](#), may propose measures to address those vulnerabilities.

Publication of the Union List does not impact existing or to-be-established national lists of critical medicines. The Union List will be broadened in 2024 and then updated annually.

## CYBERSECURITY, PRIVACY & DATA PROTECTION

### Data Act published in Official Journal of the EU (see [here](#))

On 22 December 2023, the Data Act was published in the Official Journal of the EU (*Regulation (EU) 2023/2854 of 13 December 2023 on harmonized rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828*).

To recall, the Data Act sets out rules on fair access to and use of personal and non-personal data across all economic sectors generated by connected products and digital related services (see also *Jones Day Alert, [EU Releases Data Act to Facilitate Access and Use of Data, January 2024 and Jones Day COVID-19 Update No. 77 of 23 February 2022](#)*).

In particular, the Data Act:

- Introduces rules on business-to-business and business-to-consumer access to data. In particular, manufacturers and service providers must:
  - Design products and provide services in such a manner that generated data are directly accessible to users, and
  - Provide information to users on generated data, its accessibility, and users' rights.
- Prohibits use of unfair contractual terms on data sharing, setting out a list of terms deemed as unfair (e.g., a term enabling the party that unilaterally imposed the term to terminate the contract at unreasonably short notice). These measures seek to prevent abuse of contractual imbalances in data sharing contracts due to unfair terms imposed by a party with significantly stronger bargaining position.
- Establishes restrictions to non-EU governmental access and international transfers of non-personal data, by requiring providers of data processing services to take technical, organizational and legal measures to prevent unlawful access and transfers.
- Introduces requirements to enable switching between providers of cloud services and of other data processing services, by requiring providers to take all reasonable measures to facilitate the process of achieving functional equivalence in the use of the new service.
- Sets out interoperability requirements for participants in data spaces that offer data or data services, data processing service providers, and vendors of applications using smart contracts.

Under the Data Act, EU Member States are required to lay down rules on penalties for violations of the Data Act, and EU data protection authorities may impose administrative fines as provided in the EU General Data Protection Regulation (“GDPR”) for certain infringements of the Data Act.

Next steps. Following the Data Act's entry into force on 11 January 2024, most of its provisions will become applicable on 12 September 2025.

However, the obligation to make product data and related service data accessible to the user will become applicable on 12 September 2026. The rules on unfair contractual terms shall apply (i) from 12 September 2025 to contracts concluded after 12 September 2025, and (ii) from 12 September 2027 for contracts concluded on or before 12 September 2025, provided that they are (a) of indefinite duration or (b) set to expire at least 10 years from 11 January 2024.

**Council of the European Union agrees on common position on proposed Cyber Solidarity Act (see [here](#))**

On 20 December 2023, the Council reached a [common position](#) on the proposed Cyber Solidarity Act (*Regulation laying down measures to strengthen solidarity and capacities in the Union to detect, prepare for and respond to cybersecurity threats and incidents, and amending Regulation (EU) 2021/694*), see also [Jones Day COVID-19 Update No. 101 of 19 April 2023](#)).

As stated in the proposed Act, the magnitude, frequency and impact of cybersecurity incidents are rising, including supply chain attacks aiming at cyberespionage, ransomware or disruption. The threat of potential large-scale incidents causing significant disruption or damage to critical infrastructures demands heightened preparedness of the EU's cybersecurity framework. The proposed Act notes that such threats reach beyond Russia's war against Ukraine\* and are likely to persist given the multiplicity of state-aligned, criminal and hacktivist actors involved in current geopolitical tensions.

To recall, the proposed Act seeks to strengthen EU's solidarity and capacities to detect, prepare for and respond to cybersecurity threats and incidents, by introducing:

- A European Cyber Shield, a pan-European infrastructure composed of national and cross-border of Security Operations Centres (“SOCs”), to be tasked with improving the detection, analysis and response to cyber threats;
- A Cybersecurity Emergency Mechanism to improve preparedness and response to cybersecurity incidents, e.g., through a new EU cybersecurity reserve consisting of incident response services from private sector trusted providers who are pre-contracted and therefore ready to intervene, at the request of a Member State or EU institutions, bodies, and agencies, in case of a significant or large-scale cybersecurity incident; and
- A Cybersecurity Incident Review Mechanism to assess significant or large-scale incidents, as performed by ENISA (EU Agency for Cybersecurity), in the form of an incident review report to the computer incident response teams (“CSIRTs”) network, the EU Cyber Crises Liaison Organisation Network (“EU-CyCLONE”), and with the Commission to support them in carrying out their tasks.

The Council's common position maintains the general orientation of the Commission's proposed Act, but sets forth various amendments, such as:

- Modifying and aligning certain definitions with other legislation, and primarily the recent NIS2 Directive (*Directive 2022/2555 on measures for a high common level of cybersecurity across the Union*), which replaced the previous NIS1 Directive and expanded the list of critical entities and sectors that must take risk-management measures (see also *Jones Day Alert, "EU Adopts Enhanced Legal Framework to Provide for High Common Level of Cybersecurity", December 2022, [here](#)*);
- Emphasizing the voluntary nature of Member State involvement in the mechanisms established in the proposed Act; and
- Strengthening and clarifying the role of ENISA.

Next steps. The Council's common position ("negotiating mandate") will allow the Council to enter into negotiations with the European Parliament on reaching a final version of the proposed Act.

*\* In presenting the proposed Act, the Commission had noted that Russia's war against Ukraine was accompanied by a strategic use of hostile cyber operations, marking a significant shift in the EU's collective cybersecurity crisis management landscape and requiring urgent action.*

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