

EU EMERGENCY RESPONSE UPDATE

KEY POLICY & REGULATORY DEVELOPMENTS

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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

- European Commission publishes Annual Competition Report for 2023
- 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

Trade / Export Controls

- Council of the European Union adopts Critical Raw Materials Act
- Joint Statement on 11th EU-US Energy Council
- Council of the European Union prolongs individual sanctions in context of Russia's war against Ukraine

Medicines and Medical Devices

- Council and Parliament reach provisional political agreement on European Health Data Space
- Commission publishes Communication on boosting biotechnology and biomanufacturing

Cybersecurity, Privacy & Data Protection

- European Commission welcomes provisional political agreement on proposed Cyber Solidarity Act and targeted amendment to Cybersecurity Act
- Council of the European Union adopts legal framework on European Digital Identity

COMPETITION & STATE AID

Competition

European Commission publishes 2023 Report on Competition Policy (see [here](#))

On 6 March 2024, the European Commission published the Annual Competition Report for 2023, presenting the key policy developments and legislative initiatives undertaken last year, as well as a selection of important enforcement actions.*

In presenting the Report for 2023, Margrethe Vestager, Executive Vice-President and Commissioner for Competition remarked that in taking stock of 2023, *“it is hard to untangle our achievements from the continued effects of crisis. The war in Ukraine followed immediately on the back of the global pandemic, and the effects of both continued to play out, forcing the European Commission to divide our attention between - on the one hand - continuing crisis measures, and - on the other hand - making progress on our longer-term policy goals.”*

The Report states that EU competition policy was one of many tools viewed as successfully used for the continued crisis response, economic recovery, and promoting the green and digital transitions, and notably:

- On the [crisis front](#), State aid control experienced another exceptional year, with some 220 decisions taken under the COVID-19 Temporary Crisis Framework (TCF) and the TCF/Temporary Crisis and Transition Framework (TCTF) that followed Russia’s war on Ukraine. The overall budget that Member States notified to the Commission under such State aid measures amounted to some €77.94 billion.
- On the [green transition](#), State aid under the TCTF provides wide-ranging support to the EU’s decarbonization and climate efforts, e.g., by supporting Europe’s steel industry towards renewable hydrogen, offshore wind projects, and assisting coal miners as the EU transitions away from fossil fuels. The Commission also published new [Guidelines on horizontal cooperation agreements](#), clarifying how companies could legally cooperate in pursuing environmental improvements in their industry.
- On the [digital transition](#), the pandemic accelerated this process, adding to the urgency for the EU to seek to implement the right policies in pursuit of the goal of ensuring safe and competitive digital markets. In this respect, for example:
 - According to the Report, important progress was made on the [Digital Markets Act](#), under which the Commission has designated six digital platforms as “gatekeepers,” covering a total of 22 core platform services** (see also [Jones Day EU Emergency Response Update No. 102 of 3 May 2023](#)). By requiring gatekeepers to comply with the full list of obligations (e.g., providing business users with access to the data generated by their activities on their platforms), the Commission believes that the DMA will bring broader choice and freedom for consumers and business users of these services.
 - Work continued on [Important Projects of Common European Interest](#) (IPCEI) including the approval of up to €1.2 billion of State aid for research, development and [first industrial](#)

deployment of advanced cloud and edge computing technologies involved seven member States and 19 companies – including SMEs. These ground-breaking projects are intended to enable significant advances in data processing technologies, and produce positive spillover effects for the EU as a whole.

- According to the Report, significant progress was also made on the Foreign Subsidies Regulation (FSR), which started to apply in 2023. In the Commission's view, the FSR will help level the playing field in relation to companies that receive subsidies from outside the EU, given the Commission's power to investigate this aid with the aim of ensuring that such aid does not create distortions in the EU. If the Commission deems that such distortions arise, the Commission can impose fines, remedies, and even block transactions (see also [Jones Day EU Emergency Response Update No. 110 of 23 November 2023](#)).

The Report's accompanying Staff Working Document (see [here](#)) further details (i) the main legislative and policy developments in 2023 across the State aid, antitrust (including cartels), and mergers, as well developments related to modernizing and optimizing enforcement capacity and (ii) specific enforcement actions in a sectoral overview, including Commission decisions taken pursuant to the State aid rules adopted to mitigate the economic impact due to the COVID-19 pandemic and Russia's war against Ukraine.

The Commission also released an infographic of key milestones for 2023 (see [here](#)).

* For the Annual Competition Report for 2022, see [Jones Day EU Emergency Response Update No. 101 of 19 April 2023](#).

** *The DMA aims to prevent the imposition of unfair conditions on businesses and end users by those designated as "gatekeepers" (i.e., large digital platforms deemed as significantly impacting the internal market, serving as an important gateway for business users to reach their end users, and which enjoy, or will foreseeably enjoy, an entrenched and durable position) that provide a "core platform service" (e.g., online search engines; online social networking services, web browsers, virtual assistants).*

State aid

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

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).

Among the most recently approved State aid schemes under the TCTF (up to 2 April 2024):

- €900 million French State aid scheme to support the production of energy and fuel from biomass and renewable hydrogen to foster the transition to a net-zero economy.
- Amendment to an existing Italian scheme, including a €150 million budget increase, to support companies in the agricultural, forestry,

dependencies (see [here](#))

fishery and aquaculture sectors in the region of Friuli Venezia Giulia, in the context of Russia's war against Ukraine/

- €86.9 million (BGN 170 million) Bulgarian scheme to support farmers in the context of Russia's war against Ukraine.
- €750 million Italian scheme to support small and medium-sized companies ("SMEs") and mid-caps companies in the context of Russia's war against Ukraine.
- €1.1 billion Italian scheme to support investments for the production of equipment necessary to foster the transition towards a net-zero economy.
- €90 million French scheme aimed at supporting organic farming producers in the context of Russia's war against Ukraine.
- €61.3 million (BGN 120 million) Bulgarian scheme to support farmers, producers of grain and oil crops, in the context of Russia's war against Ukraine.
- €3 billion Romanian State aid scheme to support onshore wind and solar photovoltaic installations to foster the transition to a net-zero economy.
- €350 million Portuguese State aid scheme to support investments in equipment necessary to foster the transition to a net-zero economy.
- €164 million (RON 815.5 million) Romanian scheme to support the agricultural primary production sector in the context of Russia's war against Ukraine.

TRADE / EXPORT CONTROLS

Council of the European Union adopts Critical Raw Materials Act (see [here](#))

On 18 March 2024, the Council of the European Union adopted the Critical Raw Materials Act, which establishes a regulatory framework to support the development of domestic capacities and strengthen sustainability of the EU's supply chains for critical raw materials (CRMs) that are essential to many strategic sectors, including the net zero industry, digital, aerospace, and defence sectors (see also [Jones Day EU Emergency Response Update No. 104 of 10 July 2023](#)).

To recall, the Act built on actions initiated under the Commission's 2020 Action Plan on critical raw materials (see also [Jones Day COVID-19 EU Update No. 21 of 8 September 2020](#)) and the EU's need to mitigate supply chain risks related to strategic dependencies, as highlighted by shortages triggered by the COVID-19 pandemic (e.g. for semiconductor chips) and the energy crisis following Russia's invasion of Ukraine.

The Council emphasized that the Act addresses the demand for rare earths, which is expected to surge as the EU divests from fossil fuels and pivots to clean energy systems that require more minerals, e.g., the local production of batteries and solar panels.

The Act seeks to ensure the EU's access to a secure and sustainable supply of CRMs, and in particular sets out the following:

- Identifies 34 CRMs, among which 17 are identified as strategic raw materials (SRMs, i.e., materials expected to grow exponentially in terms

of supply, with complex production requirements, and thus facing a higher risk of supply issues). This strategic raw material list will be reviewed at least every 3 years.

- Sets clear benchmarks for domestic capacities along the strategic raw material supply chain by 2030, including:
 - Significantly increasing EU capacities for each strategic raw material by 2030, such that EU capacity approaches or reaches the following benchmark capabilities:
 - (i) EU extraction capacity to extract the ores, minerals or concentrates needed to produce at least 10% of the EU's annual consumption of strategic raw materials, to the extent that the EU's reserves allow for this;
 - (ii) EU processing capacity to produce at least 40% of the EU's annual consumption of strategic raw materials; and
 - (iii) EU recycling capacity to produce at least 25% of the EU's annual consumption of strategic raw materials.
- Setting clear benchmarks for diversifying EU supply, such that by 2030, the EU is not dependent on a single third country for more than 65% of its supply of any strategic raw material, unprocessed and at any stage of processing. However, special consideration will be given to countries with whom the EU has established a Strategic Partnership,** a free trade agreement, or other forms of cooperation covering raw materials, as they provide greater assurances regarding supply risks.
- Easing administrative burdens and simplifying permitting procedures for CRM projects in the EU, e.g., Member States will create single points of contact per administrative level and stage in the CRM value chain. Selected strategic projects will also benefit from support for access to finance and shorter permitting timeframes.
- Continuing to seek mutually beneficial partnerships with emerging markets and developing economies towards diversifying investment and promoting stability in international trade.

Next steps. Following the Council's approval of the European Parliament's position, the Act has been adopted. After signing by the President of the European Parliament and the President of the Council, the Act will be published in the Official Journal of the European Union and will enter into force on the twentieth day following its publication.

* *Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020 (see [here](#)).*

** *The Act defines "Strategic Partnership" as a commitment between the EU and a third country, or Overseas Countries and Territories (OCT) to increase cooperation related to the raw materials value chain that is established through a non-binding instrument setting out concrete actions of mutual interest, which facilitate beneficial outcomes for both partners.*

Joint Statement on 11th EU-US Energy Council (see [here](#))

On 15 March 2024, the EU and US issued a Joint Statement following the 11th EU-US Energy Council in Washington, D.C..*

Established in 2009, the Council is the main transatlantic coordination forum on strategic energy issues at the political and technical levels. Additionally, the Joint Energy Security Task Force, created in March 2022 by Presidents von der Leyen and Biden, has accompanied the Council in playing an important role in supporting the swift elimination of the EU's reliance on Russian fossil fuels by diversifying its natural gas supplies, taking steps to minimize the sector's climate impact, and reducing the overall demand for natural gas (see also [Jones Day EU Emergency Response Update No. 101 of 19 April 2023](#)).

The Joint Statement emphasized, in particular, the vital role of energy systems with diverse and resilient supply chains (rather than over-relying on a single supplier for fuels, critical raw materials and minerals, or other inputs) in reducing dependencies and countering attempts to weaponize energy. Among the Joint Statement's highlights:

- On reinforcing support for Ukraine and eliminating the threat of Russia weaponizing energy, the Council notably:
 - Welcomed Ukraine's formal membership in the European Network of Transmission System Operators for Electricity (ENTSO-E) and the milestone completion of required actions to enable its permanent synchronization with continental Europe's power systems to boost regional energy security and support Ukraine and Europe in accelerating the broader energy transition.
 - Recalled the growing number of cyber and physical threats to energy infrastructure and plans to continue related cooperation to bolster resilient energy systems, including in the context of the ongoing synchronization of the Baltic States' electricity networks with the Continental European Network (see [here](#)).
 - Reiterated its commitment to confront, with adequate measures, Russia's efforts to destabilize the global energy markets and to circumvent sanctions.
 - Recalled the strategic importance of energy relations with partner countries in regions such as the Caspian Sea, Black Sea, Eastern Mediterranean, and North Africa in attaining energy diversification, security, resilience and sustainability.
- On energy policy, technology, and innovation, the Council noted the crucial importance of diversifying and securing supply chains for critical minerals and raw materials as well as voluntary stockpiling necessary for the energy transition to climate-neutrality and reinforced the value of EU-US collaboration in fora such as the Minerals Security Partnership (MSP) and its newly established MSP Forum (see [here](#)).
- On strengthening cooperation to advance the global energy transition, the Council affirmed the EU and US intention to continue to deepen their strategic relationship to ensure energy security, align policies, and enhance cooperation on technologies and innovation, with the aim of accelerating the global transition to net-zero greenhouse gas emissions by 2050.

* *Chaired by US Deputy Secretary of State Kurt Campbell, US Deputy Secretary of Energy David M. Turk, European Commissioner for Energy Kadri*

Simson, and EEAS (European External Action Service, the EU's diplomatic service) Acting Deputy Secretary General Bélen Martínez Carbonell)

Council of the European Union prolongs individual sanctions in context of Russia's war against Ukraine (see [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 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 12 March 2024, the Council decided to prolong by six months (until 15 September 2024) individual sanctions targeting those responsible for undermining or threatening the territorial integrity, sovereignty and independence of Ukraine. Such restrictions are subject to renewal every six months.

These sanctions will continue to apply to 1706 individuals and 419 entities, many of which are targeted in response to Russia's war against Ukraine. Such restrictive measures concern asset freezes, travel restrictions for natural persons, the freezing of assets, and a ban on making funds or other economic resources available to the listed individuals and entities..

In the context of this sanctions review, the Council also decided against renewing the listings of three individuals and removed nine deceased persons from the list.

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 13th package of sanctions was adopted by the Council on 23 February 2024 (see also [Jones Day EU Emergency Response Update No. 112 of 24 February 2024](#)).*

A consolidated latest version of all Commission FAQs on implementation of sanctions adopted following Russia's military aggression against Ukraine is available [here](#).

** An in-depth analysis of the 13th 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)).*

MEDICINES AND MEDICAL DEVICES

Council and Parliament reach provisional political

On 15 March 2024, the European Parliament and Council reached a provisional political agreement on the proposed Regulation on the European Health Data Space ("proposed EHDS").

agreement on European Health Data Space (see [here](#))

The European Commission released the proposed EHDS in May 2022 ([here](#)), which seeks to create a common space in which individuals can easily control their electronic health data (“EHD”) and to enable researchers, innovators and policy makers use this electronic data in a trusted and secure way through the use of common rules, standards, infrastructures and a governance framework (see also [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)).

On facilitating access to EHD, which includes both personal and non-personal data, the proposed EHDS distinguishes between processing EHD for (i) primary use for the provision of healthcare services and (ii) secondary use for societal benefits in areas such as research, innovation, policy-making and regulatory activities other than the initial purposes for collecting the data.

The provisional political agreement, in particular, amended several aspects of the proposed EHSD, such as by:

- Introducing an opt-out mechanism for natural persons for the primary and secondary use of their personal EHD, subject to certain exceptions in which Member States could override such opt-out for specific reasons (e.g., for public-interest, policy-making or statistics purposes);
- Easing administrative burdens by allowing Member States to establish trusted data holders that can securely process requests for access to health data;
- Introducing more specific provisions for protecting intellectual property rights, trade secrets and regulatory data protection rights. For example, data holders must notify whether their data sets contains protected data, and health data access bodies must take measures to protect that data and must refuse access if there is a risk of infringing those rights;
- Requiring personal EHD to be stored and processed within the European Union (“EU”), except if a GDPR (General Data Privacy Directive) adequacy decision allows such storage and processing in a third country; and
- Allowing Member States to establish stricter measures governing access to certain kinds of sensitive data (such as genetic data) for research purposes.

The European Parliament and the Council must now formally adopt the Regulation, which would then become applicable in different stages, according to use case and data type.

Commission publishes Communication on boosting biotechnology and biomanufacturing (see [here](#))

On 20 March 2024, the Commission published a Communication on “Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU”, which addresses the following in particular:

Opportunities. The Communication emphasizes that biotechnology (i.e., application of science and technology to living organisms to alter materials for the production of knowledge goods and services) and biomanufacturing (i.e., use and conversion of biotechnology and biological resources into chemicals, products and energy) can contribute to solving many societal and environmental challenges, such as those related to human health,

climate change mitigation and adaptation, access to and sustainable use of natural resources, and food supply and security.

In the health sector, for example, mRNA therapeutics enabled the discovery of mRNA-based vaccines for COVID-19, and RNA therapeutics are being developed to treat cancer as well as rare and cardiovascular diseases. Biotechnology can further help to address challenges linked to aging (such as disease prevention and personalized medicines), antimicrobial resistance, and the security of supply of both innovative and generic medicines.

Challenges and solutions. However, the Communication states that various challenges face the EU biotechnology and biomanufacturing sector, including regulatory complexity and difficulties for research and technology to transfer to the market. In response, the Commission has identified specific action items aimed at releasing the full potential of these sectors.

In this respect, the Commission will:

- Assess how to further streamline EU legislation to reduce fragmentation, explore potential simplification, and shorten the time for biotech innovations to reach the market. The resulting study would lay the foundations for a potential EU Biotech Act;
- Further promote the establishment of regulatory sandboxes for testing novel solutions in a controlled environment for a limited amount of time and under regulatory supervision as a way of bringing more of such solutions quickly to the market;
- Continue to encourage developing and updating EU standards for biotechnology and biomanufacturing;
- Support the development of advanced generative AI models for healthcare, leveraging data and tools such as multi-modal data and human health “Virtual Human Twin” modelling (see [here](#)), existing cross-border data infrastructures and other relevant data sources; and
- Explore opportunities to launch international biotech and biomanufacturing partnerships with key international partners, such as the US, India, Japan, and South Korea.

More information about the Communication can be found in the accompanying Q&A ([here](#)) and factsheet ([here](#)).

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission welcomes provisional political agreement on proposed Cyber Solidarity Act and targeted amendment to Cybersecurity Act (see [here](#))

On 6 March 2024, the European Commission welcomed the provisional political agreement between the Parliament and Council of the European Union on the following:

(1) The proposed Cyber Solidarity Act, which aims to strengthen cyber resilience in the European Union (see also [Jones Day EU Emergency Response Update No. 101 of 19 April 2023](#)). The proposed Act is one of the building blocks towards EU cyber resilience, along with the EU Cyber Resilience Act* and the EU NIS 2 Directive.**

The proposed Act seeks to strengthen solidarity at the EU level to better detect, prepare and respond to cyberthreats and incidents. It comes at a

critical time for EU cybersecurity, as geopolitical events continue to impact the EU's cyber threat landscape.

The proposed Act, to recall, would establish the following mechanisms in particular:

- A European Cybersecurity Alert System, consisting of a network of National and Cross-border Cyber Hubs to provide real-time situational awareness and enable authorities and other relevant entities to effectively respond to possible cyber threats and incidents.
- A Cybersecurity Emergency Mechanism, which aims to provide enhanced preparedness and response capabilities to significant and large-scale cyber incidents. The mechanism will support three main areas: (i) preparedness actions, (ii) the new EU Cybersecurity Reserve (i.e., a mechanism consisting of incident response services from trusted providers ready to intervene at the request of Member States, EU institutions, or third countries), and (iii) financial support for mutual assistance.
- A European Cybersecurity Incident Review Mechanism, which aims to review and assess significant cyber incidents after they have occurred in order to provide recommendations to improve cybersecurity resilience in the EU.

(2) The targeted amendment to the Cybersecurity Act of 2019, which introduced a harmonized European system for the cybersecurity certification of ICT products, services and processes. The targeted amendment aims to strengthen the EU's cyber resilience by providing for the future adoption of European certification schemes for "managed security services" provided by specialized companies to customers and which are important for preventing, detecting, responding, and recovering from cybersecurity incidents. Managed security services provide, for example, incident handling, penetration testing, and security audits; however, such services are also a target for malicious actors seeking to penetrate the sensitive environments of their clients

The certification of such managed security services would reinforce cybersecurity in the EU by enhancing trust and transparency in these services. This will notably help to provide a framework for establishing trusted providers in the above-referred EU Cybersecurity Reserve under the Cyber Solidarity Act. The certification schemes are expected to promote comparability between providers and prevent fragmentation of the EU, particularly as certain Member States have already commenced the adoption of national certification schemes for managed security services.

Next steps. Both provisional political agreements are now subject to formal approval by the European Parliament and the Council. Following their formal adoption, they will be published in the Official Journal of the EU and will enter into force on the 20th day after publication.

* *Proposed Regulation on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020.*

** *Directive (EU) 2022/2555 of 14 December 2022 on measures for a high common level of cybersecurity across the Union.*

Council of the European Union adopts legal framework on European Digital Identity (see [here](#))

On 6 March 2024, the Council of the European Union adopted the Regulation on a new framework on a secure and trustworthy European Digital Identity (“eID,” see also [Jones Day COVID-19 Update No. 78 of 4 March 2022](#) and [Jones Day COVID-19 Update No. 74 of 24 January 2022](#)).

To recall, the new eID wallets will enable all citizens to access online services with their national digital identification throughout the EU in a secure and trustworthy way, without unnecessary personal data sharing or using private identification methods.

The Regulation amends the eIDAS Regulation*, providing changes such as the following:

- Requiring Member States to make a digital identity wallet available to its citizens by 2026.
- Requiring Member States to accept digital identity wallets from other Member States.
- Adding sufficient safeguards to avoid discrimination against anyone choosing not to use the digital identity wallet.
- Introducing the wallet’s business model (issuance, use, and revocation to be free of charge).
- Requiring each Member State to provide free-of-charge validation mechanisms to verify the authenticity and validity of the wallet and of the relying parties’ identity.

Upon the Council’s adoption of the eID Regulation, Mathieu Michel, Belgian Secretary of State for Digitization, Administrative Simplification, Privacy and the Buildings Administration, stated: “*The adoption of the European digital identity regulation is a milestone in our society’s digital transformation. Enabling citizens to have a unique and secure European digital wallet while remaining in full control of their personal data is a key step forward for the EU ...*”.

Next steps. Following its publication in the Official Journal of the EU, the Regulation will enter into force on the 20th day after publication and will be fully implemented by 2026.

* [Regulation \(EU\) No 910/2014](#) on electronic identification and trust services for electronic transactions.

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