

EU EMERGENCY RESPONSE UPDATE

KEY POLICY & REGULATORY DEVELOPMENTS

No. 104 | 10 July 2023

This regular alert covers key regulatory developments related to EU emergency responses, including in particular, to COVID-19, Russia's war of aggression on against Ukraine, 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](#)).

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COMPETITION & STATE AID

Competition

European Commission adopts rules for implementing the Foreign Subsidies Regulation (see [here](#))

On 10 July 2023, the Commission adopted the Implementing Regulation* detailing the procedural aspects of implementing the [Foreign Subsidies Regulation](#) (FSR), which entered into force on 12 January 2023.

To recall, the FSR affords the European Commission with extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market, which have fallen outside of the existing EU State aid, merger control and antitrust framework (see also *Jones Day Alert, "EU Foreign Subsidies Regulation Filings Mandatory Starting in October 2023"* of December 2022, [here](#)).

In proposing the FSR, the Commission argued that the COVID economic crisis had led to higher levels of subsidization worldwide. The Commission's Impact Assessment on the proposed FSR (see [here](#)) also contended that the problem of distortive foreign subsidies is becoming more pressing in the context of acquisitions, public procurement and other market situations.

The FSR, in particular, sets out notification obligations for companies:

- **Mandatory notification for concentrations.** In mergers and acquisitions ("concentrations") facilitated by foreign subsidies, the acquirer must submit a prior notification to the Commission when:
 - the acquired company, one of the merging parties, or the joint venture is established in the EU and generates an EU turnover of at least €500 million; and
 - where the parties to the transaction were granted combined aggregate foreign financial contributions of at least €50 million over the past 3 years.
- **Mandatory public procurement notification.** Bidders in public procurement procedures must disclose any foreign subsidies received by submitting a prior notification to the Commission when:
 - the estimated contract value is at least €250 million; and
 - the bid involves combined aggregate foreign financial contribution of at least €4 million per non-EU country over the past 3 years.

The Implementing Regulation notably sets out the information that notifying parties must include in the notification forms. According to the Commission, in particular, the Implementing Regulation seeks to address public consultation feedback on limiting the administrative burden related to notifications.

As concerns foreign financial contributions deemed as the most likely to distort the internal market under Article 5 FSR (e.g., contributions granted to ailing undertakings, directly facilitating a concentration, or unlimited guarantees for an undertaking's debts or liabilities):

- For concentrations, companies must provide detailed information on all financial contributions of an individual amount of at least €1 million, granted to the parties to the transaction in the 3 years prior to the

conclusion of the agreement, the announcement of the public bid, or the acquisition of a controlling interest.

- For public procurement procedures, companies must provide detailed information on all financial contributions of at least €1 million individually granted to the notifying party/parties in the 3 years prior to the notification.

Furthermore, the Implementing Regulation provides detailed rules on, e.g.:

- the Commission's investigation process (including procedures for companies to follow for submitting commitments to address the Commission's potential concerns);
- the parties' procedural rights on the protection of confidential information, access to files, and submission of observations; and
- the calculation and suspension of time limits for providing information and submitting commitments.

Next steps. The FSR applied as from 12 July 2023. As of 12 October 2023, companies must notify concentrations and participation in public procurement procedures involving foreign financial contributions and meeting the relevant notification thresholds.

The Commission's [technical Q&A document](#) provides further details and guidance on applying the FSR.

** Commission Implementing Regulation (EU) 2023/1441 of 10 July 2023 on detailed arrangements for the conduct of proceedings by the Commission pursuant to Regulation (EU) 2022/2560 on foreign subsidies distorting the internal market*

Executive Vice-President and Competition Commissioner Margrethe Vestager seeks to lead European Investment Bank (see [here](#))

In June 2023, Executive Vice-President and Competition Commissioner Margrethe Vestager announced that the Danish government had put her forward as a potential candidate for President of the European Investment Bank (EIB). The current EIB President, Werner Hoyer, finishes his term on 31 December 2023.

Commissioner Vestager has served in her role at the Commission since 2014, notably dealing in recent years with the economic impact of the COVID-19 pandemic and Russia's war on Ukraine. During her tenure, some commentators have also viewed the Commission as arguably becoming the world's most prominent antitrust enforcer, focusing on digital markets, sustainability issues, and growing protectionism.

The role of EIB President is anticipated by some commentators to become increasingly important as multilateral banks are more often sought to fund infrastructure projects and development in pursuit of the green transition.

The finance ministers of the EU Member States will select the new EIB President, either by consensus or by a vote, to serve a six-year term. The goal is reportedly to agree on a name by consensus at an informal meeting of Member State finance ministers in mid-September 2023 in Spain.

** The EIB, the lending arm of the European Union, is the world's largest multilateral financial institution (balance sheet of over €544 billion) and one of the largest providers of climate finance.*

State Aid

European Commission prolongs the possibility to grant operating aid to certain regional airports (see [here](#))

On 7 July 2023, the Commission extended the possibility (until 4 April 2027) to grant operating aid to certain regional airports under the 2014 Guidelines on State aid to airports and airlines. The Guidelines otherwise remain applicable and without further changes.

The 2014 Guidelines enable Member States to grant, subject to certain conditions:

- Operating aid to regional airports with under 3 million passengers annually, in view of becoming cost-covering. The Guidelines had set a ten-year transition period (initially set to expire on 4 April 2024) during which such aid can be declared compatible with the internal market.
- Operating aid under a more favorable regime (i.e., with higher aid levels) to airports with up to 700,000 passengers annually, which face greater difficulties in becoming cost-covering. This possibility was also set to expire on 4 April 2024.

In prolonging such operating aid by three years, the Commission noted the presence of exceptional circumstances. The European aviation sector has faced the dual crises of the (i) COVID-19 pandemic and the resulting sharp decrease in traffic at EU airports; and (ii) energy crisis triggered by Russia's war against Ukraine, which has significantly increased the energy costs of airport operators. In particular, regional airports have been facing lower revenues and higher costs, which have negatively impacted their profitability. The Commission indicated that such circumstances could lead to closures of certain regional airports, which could then detrimentally impact connectivity across the EU.

In 2022, the Commission launched a public consultation on its intention to address the situation of regional airports. Most respondents indicated that extending operating aid under the 2014 Guidelines was needed to counterbalance the pandemic's impact on the ability of regional airports to become cost-covering. The public consultation replies are [here](#).

European Commission approves further schemes under new Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies (see [here](#))

The Commission approved additional measures under the new State aid Temporary Crisis and Transition Framework (new 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 (applied as from 9 March 2023, see also [Jones Day COVID-19 EU Update No. 99 of 17 March 2023](#)).

Among the most recently approved State aid schemes under the new TCTF (from 15 June 2023 to 10 July 2023):

- €718 million Czech scheme to support companies in the heat sector in the context of Russia's war against Ukraine
- Re-introduction of two Italian schemes to support companies in the context of Russia's war against Ukraine, with an overall budget of €600 million, including a number of modifications to the original schemes, such as higher aid ceilings

- Two Italian schemes, with a total budget of around €535 million, to support labor costs of companies in the context of Russia's war against Ukraine
- €7 million Cypriot scheme to support sheep and goat breeders in the context of Russia's war against Ukraine
- €1.1 billion (approximately HUF 436 billion) Hungarian scheme to support electricity storage facilities to foster the transition to a net-zero economy
- €77.1 million (HUF 29 billion) Hungarian scheme to support companies active in the agriculture, fishing and food industry in the context of Russia's war against Ukraine
- Amendment to an existing Croatian scheme to support the liquidity of exporting companies in the context of Russia's war against Ukraine, including an overall budget increase from previously approved €552 million to around €747 million; and an adjustment of the maximum aid ceilings
- €42 million Lithuanian scheme to support companies in the context of Russia's war against Ukraine
- €5 million French scheme aimed at supporting starch potato producers in the context of the war waged by Russia against Ukraine
- €10 million Estonian scheme to support producers of agricultural and food products in the context of Russia's war against Ukraine

TRADE / EXPORT CONTROLS

European Commission publishes Communication on 2023 Strategic Foresight Report (see [here](#))

On 6 July 2023, the European Commission published the Communication on the “2023 Strategic Foresight Report: sustainability and wellbeing at the heart of Europe's Open Strategic Autonomy.” This is the fourth of such annual Strategic Foresight Reports, which aim at guiding the Commission's priorities and work programmes.

The 2023 Report focuses on key challenges facing Europe's transition towards sustainability, such as:

- The rise of geopolitics and reconfigured globalization. Global crises have strained the globalization model; notably, Russia's war against Ukraine has challenged the foundations of multilateralism, and the pandemic also highlighted the vulnerability of global supply chains. Growing geo-economic tensions are further increasing the risk of trade restrictions and supply chain disruptions, which could aggravate the EU's strategic dependencies (e.g., access to critical raw materials needed for the twin green/digital transitions) and the challenges facing the EU's strategic sectors (from batteries to microchips);
- The quest for a sustainable economy and well-being. Ensuring a sustainable economic model and the well-being of Europeans requires fundamental change. For instance, in pursuing net-zero industry and in the face of mounting global competition, Europe's open strategic autonomy must be strengthened through increased support for R&D and strategic net-zero technologies, as well as greater investment in areas of critical importance where the EU displays high dependencies.

The 2023 Report then sets out 10 action areas to address economic and social challenges for the sustainability transition, including in particular:

- Leveraging the Single Market to promote a resilient net-zero economy to achieve open strategic autonomy, including economic security, e.g., by:
 - further developing tools to assess future dependencies across strategic sectors (such as health, food, digital technologies, energy, space, water); and
 - optimizing the use of trade defence instruments, the regulation on foreign subsidies, and procurement instruments.
- Reinforcing the EU's offer on the global stage to strengthen cooperation with key partners, as geoeconomics are increasingly calling for combining agile approaches and strategic partnerships e.g., by:
 - building on the existing free trade agreement model to create new, more flexible, and targeted types of partnership agreements to explore with the European Neighbourhood,* Africa, Asia, or Latin America;
 - creating a green transatlantic marketplace facilitating access to incentive schemes and preventing discrimination in view of promoting green investments and sustainable production.

Next steps. The Commission aims to continue mainstreaming strategic foresight into EU policymaking and strengthening its ability to tackle potential future crises and challenges. The Commission will also draw from lessons learned and consider future foresight priorities.

Additionally, work carried out by a foresight cluster of Member States led by Spain, together with the Commission's 2023 Strategic Foresight Report, will inform discussions during an informal European Council in Granada in October 2023.

The Commission will also co-host, with the European Parliament, the annual European Strategy and Analysis System (ESPAS) conference on 14 November 2023.

** The European Neighbourhood Policy (ENP) is the foreign policy framework aimed at closer partnership between the EU and its Eastern and Southern neighbors, composed of 16 countries such Armenia, Egypt, Georgia, Israel, Jordan, Republic of Moldova, Morocco, Tunisia, Ukraine.*

Council of the European Union adopts its negotiating position on proposed Critical Raw Materials Act (see [here](#))

On 30 June 2023, the Council of the European Union adopted its negotiating position on the proposed Critical Raw Materials Act,* which aims at providing a regulatory framework to support the development of domestic capacities and strengthen sustainability of the EU's supply chains for critical raw materials (CRMs) (see also [Jones Day COVID-19 EU Update No. 99 of 17 March 2023](#)).

In unveiling the proposed Act, to recall, the Commission noted that the initiative built on, in particular, 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](#)). The Commission also further

emphasized 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 stated that while it shares the objectives of the Commission's proposed Act, its negotiating position sought more ambitious action, such as:

- elevating targets for EU processing, e.g., at least 50% (instead of 40%) of the EU's annual consumption of raw materials is to come from EU processing;
- raising targets for EU recycling capacity, e.g., at least 20% (instead of 15%) of the EU's annual consumption of raw materials is to come from domestic recycling;
- more frequently updating the list of critical and strategic raw materials (at least every three years, instead of every four years); and
- facilitating permit procedures for strategic projects.

The Council's formalized negotiating position provides the Council presidency with a mandate for negotiations with the European Parliament (EP), which will commence once the EP adopts its own position.

** 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](#)).*

Council of the European Union authorizes Critical Minerals Agreement negotiations with US (see [here](#))

On 20 July 2023, the Council of the European Union adopted a Decision authorizing the European Commission to open negotiations, on behalf of the EU, with the US on a Critical Minerals Agreement (CMA). The Decision's addendum sets out the Commission's directives for negotiating the CMA (see [here](#)).

The CMA seeks to enhance EU-US supply chains in critical raw materials necessary for producing electric vehicle batteries. The EU exported €8.3 billion worth of critical raw materials relevant to the electric vehicle battery industry in 2022. The CMA also aims at easing some of the negative repercussions on EU industry of the US Inflation Reduction Act (US IRA),* adopted on 16 August 2022.

The CMA would grant the EU an equivalent status to US free trade agreement partners for the purpose of the Clean Vehicle Credit** under the US IRA. As stated by the Commission, such equivalent status is intended to enable EU firms to compete on a level playing field with US and third country competitors on the US market, such as Chile, the Republic of Korea, and Japan.

Additionally, the CMA would reinforce the Commission's proposed [Critical Raw Materials Act](#) (see above item on proposed Act) and proposed [Net Zero Industry Act](#), which aim to ramp up EU manufacturing of key carbon neutral technologies.

According to the directives for negotiation, the CMA should notably:

- strengthen trade in and diversification of international supply chains of critical minerals and promote the adoption of electric vehicle battery

technologies by formalizing the shared commitment to facilitate trade, and promote fair competition and market-oriented conditions for trade in critical minerals;

- fully align with World Trade Organization rules and the objectives pursued in the EU's proposed Critical Raw Materials Act, in terms of ensuring the EU's access to a secure and sustainable supply of critical raw materials; and
- promote high levels of environmental protection and protection of workers in the critical minerals sector and foster corporate social responsibility across critical minerals supply chains.

Next steps. The Commission will engage in formal negotiations with the US, in view of concluding the CMA in the near term.

Once negotiations are finalized, the Council would need to adopt the CMA, which would also require the European Parliament's consent.

** The IRA aims to curb inflation and to invest in domestic clean energy production. The law, which represents the largest initiative to address climate change in US history, targets a reduction of around 40% of greenhouse gas emissions in 2030 as compared to 2005.*

*** The Clean Vehicle Credit is a subsidy for the purchase of qualifying battery or fuel-cell operated vehicles in the form of a tax credit. To qualify for the full subsidy, a vehicle must, among other things, be equipped with a battery that has had at least some of its critical mineral content either recycled in North America or extracted and processed in the US or a country with which the US has a Free Trade Agreement or a CMA.*

MEDICINES AND MEDICAL DEVICES

EMA announces phasing out of extraordinary regulatory flexibilities for medicines during COVID-19 pandemic (see [here](#))

On 7 July 2023, the European Medicines Agency (EMA) announced that the EMA, European Commission, and Heads of Medicines Agencies (HMA) are phasing out the extraordinary regulatory flexibilities for medicines put in place during the COVID-19 pandemic. Such flexibilities were first set out on 10 April 2020 in the "*Notice to stakeholders: Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic*" (see also [Jones Day COVID-19 EU Update No. 4 of 17 April 2020](#)).

The phasing out follows the WHO's declaration of the end of the COVID-19 public health emergency in May 2023 (see also [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)).

To recall, the extraordinary flexibilities helped to address regulatory and supply challenges arising from the crisis to ensure the continued availability of medicines during the COVID-19 pandemic, while safeguarding good manufacturing (GMP) and distribution practice (GDP) standards. These flexibilities covered areas such as:

- marketing authorization,
- manufacturing and importation of active pharmaceutical ingredients and finished products,
- quality variations,
- labelling and packaging requirements, and
- compliance and inspections of manufacturing facilities

As from 7 July 2023, in particular, regulatory flexibilities introduced jointly by the EMA, Commission, and HMA specifically during the COVID-19 pandemic should no longer be granted. In this respect, for already approved labelling flexibilities (e.g. English-only labelling for COVID-19 vaccines), the EMA indicated that their application will be extended until end-2023 in view of ensuring a smooth phase-out and avoiding supply difficulties or other disruptions due to a sudden change in applicable requirements. After 2023, the regular mechanisms foreseen in legislation on labelling exemptions should be applied.

ICMRA publishes statement on safety of COVID-19 vaccines (see [here](#))

On 5 July 2023, the International Coalition of Medicines Regulatory Authorities (ICMRA)* published a statement to provide the general public with vital information on COVID-19 vaccine safety, including addressing some of the most common types of misinformation.

In particular, the statement provides:

- Key messages (e.g., SARS-CoV-2 keeps changing and revaccination may be required to protect against new variants);
- Benefits of COVID-19 vaccinations (e.g., avoiding further overload of healthcare systems, and emerging scientific evidence shows that vaccines reduce the impact of long COVID);
- Evidence of COVID-19 vaccine safety after use of billions of doses (e.g., very rare reports of deaths following vaccination);
- COVID-19 vaccine safety in special populations (e.g., COVID-19 vaccines are as safe for children as for adults);
- Long COVID and vaccines (e.g., the very large body of data held by international regulators provides no suggestion that long COVID is a possible side effect of COVID-19 vaccination);
- False information on COVID-19 vaccine safety (e.g., no evidence that COVID-19 vaccination causes immune impairment. In fact, SARS-CoV-2 infection is known to cause immune impairment).

** ICMRA gathers 38 medicines regulatory authorities, including those in the European Union (EMA and European Commission Directorate-General for Health and Food Safety (DG SANTE)). The World Health Organization (WHO) acts as an observer (see [here](#)).*

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission welcomes political agreement on proposed Cybersecurity Regulation (see [here](#))

On 26 June 2023, the Commission welcomed the political agreement between the European Parliament and the Council of the European Union on the proposed Regulation on measures for a high common level of cybersecurity at the institutions, bodies, offices and agencies of the Union.

The proposed Regulation will create a common framework in the field of cybersecurity for all EU entities in view of strengthening their resilience and incident response capacities.

The Commission, to recall, had set forth the proposed Regulation against the backdrop of the growing digitization of the EU institutions, bodies and

agencies in recent years, as well as the evolving cybersecurity threat landscape. The Commission noted that the onset of the COVID-19 crisis had amplified both such developments, and the number of cyber incidents continues to rise, with increasingly sophisticated attacks coming from a wide range of sources.

In particular, the proposed Regulation sets out the following:

- Requires all EU entities to undertake measures for a high common level of cybersecurity by:
 - establishing a governance, risk management and control framework in the area of cybersecurity;
 - implementing cybersecurity measures addressing identified risks, undertaking regular cybersecurity maturity assessments, and putting in place a cybersecurity plan.
- Strengthens rules on sharing incident-related information with the Computer Emergency Response Team for the EU institutions, bodies, offices and agencies (CERT-EU), such that all EU entities will be required to share non-classified incident-related information with CERT-EU without undue delay; and
- Establishes a new inter-institutional Cybersecurity Board that will monitor the Regulation's implementation, as well as supervise CERT-EU's implementation of general priorities and objectives and provide it with strategic direction.

In announcing the political agreement, Johannes Hahn, Commissioner for Budget and Administration, emphasized: *“Cybersecurity is a political and operational priority for the EU, and this Regulation is a milestone in this respect. More cooperation, certainty and efficiency will create a climate of collaboration and trust where people, data and networks can operate and interact safely.”*

Next steps. Once the text is finalized, the European Parliament and the Council will adopt the new Regulation.

European Court of Human Rights rules that Russia illegally used facial recognition technology to arrest protestor (see [here](#))

On 4 July 2023, the European Court of Human Rights ruled on a case (*Glukhin vs. Russia*, Application no. 11519/20) concerning a Russian protestor's (Applicant) administrative conviction for his failure to notify the authorities of his intention to hold a solo demonstration in Moscow. The police used facial recognition technology in the framework of administrative offence proceedings to identify, locate and arrest him.

The Applicant contended that the administrative offence proceedings violated his rights, in particular, under the European Convention on Human Rights' (ECHR) Article 8 (right to respect for private life).

In examining the case, the Court reviewed relevant law and guidance, including:

- The EU Law Enforcement Directive,* which addresses the processing of personal data by data controllers for “law enforcement purposes” and which falls outside of the GDPR's scope; and

- European Data Protection Board Guidelines 05/2022 on the use of facial recognition technology in the area of law enforcement of 26 April 2023.

With respect to Russia’s processing of personal biometric data by using “*highly intrusive*” facial recognition technology against the Applicant, the Court found this unjustified and notably in violation of ECHR Article 8 on respect for private life. The Court found, in particular, that the Applicant was never accused of committing any reprehensible acts during his demonstration, such that processing of the Applicant’s personal data using facial recognition technology did not correspond to a “*pressing social need*” and could not be seen as “*necessary in a democratic society*”).

The Court awarded the Applicant €9,800 in respect of non-pecuniary damage, in addition to €6,400 for legal fees incurred before the domestic courts and before the Court.

* *Directive (EU) 2016/680 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data states, among others*

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