

EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

No. 115 | 24 June 2024

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 adopts updated guidance on Recovery and Resilience Plans
- Executive Vice-President and Commissioner for Competition Margrethe Vestager comments on State aid approval of two IPCEIs in hydrogen and healthcare sectors
- 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 expands sanctions against Russia
- Council of the European Union approves use of proceeds from immobilized Russian assets to support Ukraine's self-defence and reconstruction
- New EU Directive criminalizing the violation of EU sanctions enters into force
- · Critical Raw Materials Act enters info force

Medicines and Medical Devices

- European Commission welcomes agreement on revised International Health Regulations
- European Commission publishes Communication on European Health Union

Cybersecurity, Privacy & Data Protection

- European Commission establishes Artificial Intelligence Office
- ENISA holds 7th Cyber Europe Exercise

COMPETITION & STATE AID

European
Commission
announces adoption
of updated guidance
on Recovery and
Resilience Plans
(see here)

On 3 June 2024, the Commission announced the adoption of a Commission Notice on Updated Guidance on Recovery and Resilience Plans (RRPs), which provides new practical measures regarding implementation of the Recovery and Resilience Facility (RRF).*

<u>Background</u>. To recall, the RRF is the key component of <u>NextGenerationEU</u>, the EU's €806.9 billion plan for rebounding from the COVID-19 pandemic and setting out a blueprint for a greener, more digital, and more resilient future. In particular, the RRF supports reforms and public investment projects foreseen for implementation under Member State RRPs. As of end-April 2024, some €232 billion had been disbursed to Member States.

The RRF is also key to implementing <u>REPowerEU</u>, launched in May 2022 in response to the energy market disruption caused by Russia's war against Ukraine. REPowerEU aims at enhancing the EU's strategic autonomy through diversified energy supplies, ceasing dependency on Russian fossil fuel, and accelerating the clean energy transition (see also <u>Jones Day COVID-19 Update No. 98 of 1 March 2023</u>).

Improving RRF implementation. The Commission's Updated Guidance seeks to address, in particular, the conclusions of the Council of the European Union of April 2024 (see here), which indicated a higher-than-expected administrative burden related to the RRF's implementation, both for the Commission and Member States. The Council thereby requested them to identify concrete ways to streamline and improve implementation of the RRPs, while adequately protecting the EU's financial interests (see also European Court of Auditors Special Report on Recovery and Resilience Facility's performance monitoring framework, Jones Day EU Emergency Update No. 109 of 3 November 2023).

The Updated Guidance thereby aims at easing administrative burdens under the RRF, while safeguarding a robust level of transparency and ambitions for the RRF. For instance, the Updated Guidance:

- Clarifies how Member States can request the amendment of a milestone or target if they identify an alternative, simpler implementation solution.
- Simplifies Member State reporting requirements, such as by reducing the information requested in bi-annual reporting on the implementation of RRPs.
- Facilitates synergies between the RRF and other EU funds by clarifying the conditions allowing a pro-rata combination of support from the RRF and other EU funds, while avoiding double funding.
- Sets out a framework for the potential reduction and recovery of RRF funds in cases impacting the EU's financial interests that a Member State has not remedied.

State aid. The Updated Guidance reminds that State aid rules fully apply to additional or revised reforms and investments under RRPs and that Member States are responsible for ensuring that all reforms and investments in their RRPs comply with EU State aid rules and follow the applicable State aid procedures (see also Jones Day Commentary, "EU

Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, here).

<u>Looking ahead</u>. The Update Guidance emphasizes that at present, all collective efforts should be focused on the full and timely implementation of RRPs by 2026, and as necessary by addressing implementation bottlenecks when they arise in a flexible manner. The RRPs' envisaged milestones, targets and indicative timetable for implementing reforms, and investments are to be completed by 31 August 2026.

* This Updated Guidance complements earlier Commission guidance of <u>January 2021</u> and replaces the guidance of <u>March 2023</u>, except for information on the REPowerEU chapters, which remains relevant for those Member States intending to submit or revise REPowerEU chapters.

Executive Vice-President and Commissioner for Competition Margrethe Vestager comments on State aid approval of two IPCEIs in hydrogen and healthcare sectors (see here) On 28 May 2024, Margrethe Vestager, Executive Vice-President and Commissioner for Competition, commented on the State aid approval on that day of two Important Projects of Common European Interest ("IPCEIs")*:

(1) <u>Hy2Move</u> is the <u>first industrial deployment of breakthrough</u> <u>hydrogen technologies</u> to help decarbonize the mobility and transport sectors and is the fourth IPCEI in the hydrogen value chain. The project focuses exclusively on specific challenges and objectives for hydrogen technology in mobility and transport applications (road, rail, maritime and aviation) using hydrogen as a fuel.

The Hy2Move project was jointly notified by seven Member States (Estonia, France, Germany, Italy, Netherlands, Slovakia, Spain), which will provide up to €1.4 billion in public funding and which in turn is expected to unlock a further €3.3 billion in private investments. Under Hy2Move, 11 companies with activities in one or more Member States will undertake 13 innovative projects.

The completion of the overall IPCEI is expected by 2031. Some 3,600 direct jobs are anticipated to be created, and many more indirect ones.

(2) <u>Med4Cure</u> is the <u>first IPCEI in healthcare</u>. The project will support research, innovation, and the first industrial deployment of healthcare products and innovative production processes of pharmaceuticals.

The Med4Cure project was jointly notified by six Member States (Belgium, France, Hungary, Italy, Slovakia, Spain), which will provide up to €1 billion in public funding and which in turn is expected to unlock a further €5.9 billion in private investments. Under Med4Cure, 13 companies with activities in one or more Member States will undertake 14 highly innovative projects.

The completion of the overall IPCEI is expected by 2036. Some 6,000 direct and indirect jobs are anticipated to be created.

Commissioner Vestager's comments referred to IPCEIs as a "powerful instrument in our industrial policy toolbox," highlighting the following in particular:

 Ten IPCEIs. With the two new projects Hy2Move and Med4Cure, the Commission has now approved ten IPCEIs since 2018. These include one on Next Generation Cloud Infrastructure and Services, two in batteries, two in microelectronics, and now four in the hydrogen value chain, and one in health.

These ten IPCEIs have involved 22 Member States, with the Commission assessing over 330 projects from nearly 250 companies and approving a total of aid of over €37 billion. According to the Commission, these public investments have attracted €66 billion in additional private investment.

- Successes. While most IPCEIs remain ongoing, and with most to be completed between 2030 and 2036, Commissioner Vestager flagged achievements such as:
 - In the area of <u>power semiconductors</u>, the IPCEI enabled STMicroelectronic's project in Italy and France to improve the overall efficiency of power components and conversion modules. The IPCEI's research & development is already helping to lower dependency on non-EU sources for producing silicon carbide power devices (see also <u>Jones Day EU Emergency Update No. 102 of 3 May 2023</u>).
 - In <u>battery technology</u>, the first IPCEI for batteries allowed BASF to launch its production facility for active cathode materials, which is the first in Germany to produce such highperformance materials. It will supply products tailored to the needs of cell manufacturers and automotive producers in Europe.

Commission Vestager stated that "these successes are evidence that IPCEI innovations actually do "get to market". The IPCEIs and the 100 billion euro of investments that they enable are industrial policy in practice."

* The EU's IPCEI rules (<u>Communication on Important Projects of Common European Interest</u>) seek to enable Member States and industry to jointly invest in ambitious pan-European projects in a transparent and inclusive manner, where the market alone appears unable to deliver and particularly where the risks are deemed as too large for a single Member State or company to assume (see also Jones Day EU Emergency Update No. 107 of 29 September 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 (see
here)

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 24 June 2024):

- €486 million (PLN 2.1 billion) Polish scheme to support producers of cereals in the context of Russia's war against Ukraine.
- — €4 billion French State aid scheme to support decarbonization measures in the manufacturing sector.
- €120 million Spanish scheme to support investments in strategic sectors in the region of Asturias to foster the transition towards a net-zero economy.

 French aid scheme worth €80 million aimed at supporting wine growers in the south of France in the context of Russia's war against Ukraine.

TRADE / EXPORT CONTROLS

Council of the European Union expands sanctions against Russia (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'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:

<u>Russia</u>: On 24 June 2024, the Council adopted a <u>14th package of</u> sanctions,* focusing on measures such as:

- Energy-related measures concerning Liquified Natural Gas (LNG), e.g.:
 - Prohibiting all future investments in, and exports to, LNG projects under construction in Russia.
 - Prohibiting reloading services of Russian LNG in EU territory for the purpose of transshipment operations to third countries.

Anti-circumvention, e.g.:

Requiring EU parent companies to undertake their best efforts to
ensure that their third-country subsidiaries do not take part in any
activities resulting in an outcome that the sanctions seek to prevent.
EU parent companies must ensure that their subsidiaries are
particularly cautious when, for example, trading in specific types of
sensitive goods and in conducting appropriate due diligence.

Import restrictions, e.g.:

Finetuning the ban already agreed in the 12th sanctions package through a "grandfathering" clause for <u>diamonds</u> that were physically located in the EU or a third country (other than Russia) or were polished or manufactured in such third country, before the import ban on Russian diamonds entered into force. Such diamonds are not subject to the ban, particularly as these stocks no longer provide revenue to Russia.

Export restrictions, e.g.:

- Adding further restrictions on exports of goods that contribute in particular to enhancing Russian industrial capabilities (e.g. chemicals (including manganese ores and compounds of rareearths), plastics, excavating machinery, electrical equipment).
- Adding <u>61 new entities</u> to the list of those directly supporting Russia's military and industrial complex in its war against Ukraine,

which will be subject to tighter export restrictions concerning dual use goods and technologies, as well as goods and technology which may contribute to the technological enhancement of Russia's defence and security sector. Certain of these entities are located in third countries (such as China, Kazakhstan, Turkey, and United Arab Emirates) and have been involved in circumventing trade restrictions and procuring sensitive items (e.g., for producing drones), or providing material support for Russian military operations.

The Council also added a total of <u>116 additional listings</u> (69 individuals and <u>47 entities</u>) responsible for actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine, targeting various sectors of the Russian state, including military companies, companies active in space engineering, in the chemical sector or in the explosives sector, and leading Russian energy companies.

Such individuals and entities are 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 2,200 individuals and entities.

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 on 23 February 2022 in adopting the so-called first package of sanctions. 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).

* An in-depth analysis of the 14th 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)).

Council of the
European Union
approves use of
proceeds from
immobilized Russian
assets to support
Ukraine's selfdefence and
reconstruction (see
here)

On 21 May 2024, in light of Russia's continued war against Ukraine, the Council of the European Union adopted a set of legal acts* in view of ensuring that net profits arising from unexpected and extraordinary revenues accruing to central securities depositories (CSDs) in the EU, as a result of implementing EU restrictive measures,** will be used for further military support to Ukraine, as well as Ukraine's defense industry capacities and reconstruction.

In announcing these measures, Valdis Dombrovskis, European Commission Executive Vice-President for an Economy that Works for People, stated: "I welcome the formal decision taken today in the Council which will allow the extraordinary revenues from assets of the Russian Central Bank immobilised under sanctions following Russia's war of aggression against Ukraine, to be used to the benefit of Ukraine. The EU has chosen a way forward that is legally sound, and flexible so that support can adjust to Ukraine's most pressing needs...."

Thus, CSDs holding Russian sovereign assets and reserves of over €1 million will make a financial contribution from their corresponding net profits, accumulating since 15 February 2024. The Commission estimates that revenues generated from immobilized assets, depending on interest rates, are likely to annually yield some €2.5 billion to €3 billion for Ukraine's benefit.

Resources will be available in bi-annual payments, with such distribution of resources to be reviewed annually. The first review is foreseen by 1 January 2025, which will allow for the prioritization of needs that is likely to evolve over time.

- * Council Regulation (EU) 2024/1469 of 21 May 2024 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine; and Council Decision (CFSP) 2024/1470 of 21 May 2024 amending Decision 2014/512/CFSP concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.
- ** To recall, on 12 February 2024, the Council decided that CSDs holding over €1 million of assets and reserves of the Central Bank of Russia that were immobilized as consequence of EU's restrictive measures, must set aside extraordinary cash balances accumulating due to EU restrictive measures, and may not dispose of the ensuing net profits (see also <u>Jones Day EU Emergency</u> Response Update No. 112 of 24 February 2024).

New EU Directive criminalizing the violation of EU sanctions enters into force (see here) On 17 May 2024, the new EU Directive on criminalizing the violation of EU sanctions entered into force.* The Directive establishes EU-wide minimum rules for prosecuting the violation or circumvention of EU sanctions in the Member States (see also <u>Jones Day EU Emergency Response Update No. 105 of 31 August 2023</u>).

In announcing the Directive's entry into force, Věra Jourová, European Commission Vice-President for Values and Transparency, stated: "With Putin continuing his illegal aggression against Ukraine, it is paramount that EU sanctions are fully implemented and the violation of those measures is punished. In addition, the new rules will also make it easier for Member States to confiscate some of the frozen assets of people and companies that support the war. Member States should now swiftly transpose the new rules and make them work in practice."

Key features of the Directive include:

- A <u>list of criminal offences</u> that violate EU sanctions, e.g.:
 - making funds or economic resources available (directly or indirectly) to a natural or legal person subject to restrictive measures; failing to freeze such funds/economic resources;
 - engaging in trade or financial activities that are prohibited or restricted; and
 - providing other services that are prohibited or restricted, such as legal advisory services, business and management consulting, and tax consulting services.
- Offences also notably include <u>circumventing EU restrictive</u> <u>measures</u>, i.e., by bypassing or attempting to bypass such measures by concealing funds or concealing the fact that a person is the ultimate owner of funds.

- Common basic standards for penalties, such that for the most serious offences:
 - individuals could be subject to a maximum penalty of at least five years in prison; and
 - <u>companies</u> could be subject to penalties of 5% of the total worldwide turnover of the company (either in the business year preceding that in which the offence was committed, or in the business year preceding the decision to impose the fine); or an amount corresponding to €40 million.
- Whistleblower protection: The Directive applies the protections of <u>Directive (EU) 2019/1937</u> to persons reporting violations of EU sanctions, safeguarding them from retaliation.

<u>Looking ahead</u>. Member States must transpose the Directive into national law by 20 May 2025. The Commission shall submit a report to the European Parliament and to the Council, on Member State compliance with the Directive by 20 May 2027.

* Directive (EU) 2024/1226 of 24 April 2024 on the definition of criminal offences and penalties for the violation of Union restrictive measures and amending <u>Directive (EU) 2018/1673</u> (on combating money laundering by criminal law).

Critical Raw Materials Act enters info force (see here)

On 23 May 2024, the Critical Raw Materials Act entered into force,* 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. 113 of 2 April 2024).

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 war on Ukraine.

The Act notably 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:

- 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 <u>benchmarks for domestic capacities</u> along the strategic raw material supply chain to significantly increase EU capacities for each SRM by 2030, notably in terms of the EU's extraction, processing, and recycling capabilities.

- Sets clear <u>benchmarks for diversifying EU supply</u>, 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.
- Establishes a <u>new framework to select and implement "Strategic Projects"</u> (i.e., projects contributing to building strategic raw materials capacities across all value chain stages, both within and outside of the EU), which can benefit from streamlined permitting and from enabling conditions for access to finance. The Commission's first Call for Strategic Projects Applications is due on 22 August 2024 (see here).
- Establishes a <u>European Critical Raw Materials Board</u>, composed of EU countries and the Commission, to advise on and coordinate the implementation of measures under the Act and discuss the EU's strategic partnerships with third countries. The Board's first meeting took place on 23 May 2023 (see here).

<u>Next steps</u>. Among other reporting requirements, by 24 November 2026, the Commission shall submit a report, including indicative projections of the annual consumption of each critical raw material in 2030, 2040 and 2050, as well as indicative benchmarks for extraction and processing per strategic raw material.

* Regulation (EU) 2024/1252 of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020

MEDICINES AND MEDICAL DEVICES

European
Commission
welcomes
agreement on
revised International
Health Regulations
(see here)

On 1 June 2024, the European Commission welcomed the agreement on the revised International Health Regulations ("IHR") reached on the same day at the World Health Assembly, composed of 194 member countries. The package of amendments to the IHR will reinforce global preparedness, surveillance and responses to public health emergencies, including pandemics.

The IHR is a legally binding framework developed by the World Health Organization ("WHO") to ensure security against the international spread of diseases. This framework requires countries to build capacities to detect, report, and respond to public health risks and emergencies of international concern. The IHR entered into force in June 2007 and is binding for all EU Member States.

Since January 2022, following the COVID-19 pandemic, countries negotiated potential IHR amendments to further build global preparedness and response capacity to public health emergencies.

Among other things, the revised IHR:

Introduced the <u>definition of a "pandemic emergency</u>", to trigger more
effective international collaboration in response to events that are at
risk of becoming, or have become, a pandemic. It is the highest level
of global alert that the WHO Director General can issue;

- Established a <u>Coordinating Financial Mechanism</u>, which would allow WHO to rapidly mobilize resources; and
- Established a <u>States Parties Committee</u> and <u>National IHR Authorities</u> as bodies to promote and support the agreement's provisions within and between member states.

The IHR amendments will come into force 12 months after their notification by the WHO Director General to all States Parties.

The WHO Q&As provide further details on the IHR and the amendment process (see here).

European
Commission
publishes
Communication on
European Health
Union (see here)

On 22 May 2024, the European Commission published the Communication on the European Health Union: acting together for people's health ("Communication").

The European Health Union was set out in November 2020, with a vision to ensure that Member States are better prepared for future health crises and to support modern and innovative health policies for all EU citizens.

The Communication highlights the achievements made in EU health policy over the past four years. In particular:

- The proposed reform of the EU's pharmaceutical legislation, which seeks a redesigned system of incentives to encourage companies to deliver on public health objectives (i.e., timely and equal access to medicines and unmet medical needs), measures to ensure the availability of critical medicines and medical devices (i.e., to manage shortages), and measures to fight antimicrobial resistance (see also Jones Day EU Emergency Response Update No. 102 of 3 May 2023);
- The proposed European Health Data Space ("EHDS"), which will introduce clear rules for the use of electronic health data and a common European format to exchange healthcare documents. Under the EHDS, patients will have immediate, free and easy access to their electronic data which they can share. The EHDS will also empower the use of health data for research, innovation, policy making and regulatory activities (see also <u>Jones Day EU Emergency Response Update No. 113 of 2 April 2024</u>);
- The <u>creation of the Health Emergency Preparedness and Response Authority</u> ("HERA"), in view of strengthening the development, manufacturing, procurement and equitable distribution of critical medical countermeasures in case of public emergencies (see also Jones Day COVID-19 Update No. 77 of 23 February 2022)</u>; and
- The amendments to the Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation to extend their transition periods and to ensure continuity of the supply of critical devices (see also Jones Day Commentary of February 2023: EU Commission Proposes Extended Deadlines to Comply with the Medical Device Regulation and In Vitro Diagnostic Regulation).

In addition, the Communication emphasizes where <u>further actions are</u> needed. In particular:

 Further exploring instruments such as <u>joint procurement</u> to support Member States in accessing medicines in the area of rare diseases and orphan medicines;

- Making clinical trials in the EU attractive and efficient to accelerate research and development for antimicrobials and medical countermeasures for future pandemics;
- Integrating <u>artificial intelligence into healthcare and digital upskilling</u> of healthcare professionals for improved efficiency, accessibility and sustainability; and
- Further <u>maximizing the potential of digital health</u> to revolutionize healthcare.

The Commission also published accompanying factsheets such as on the European Health Union (see here), Pharma – Putting patients in the centre (see here), European Health Data Space (see here), and on HERA (see here).

CYBERSECURITY, PRIVACY & DATA PROTECTION

European
Commission
establishes Artificial
Intelligence Office
(see here)

On 29 May 2024, the European Commission announced the establishment of the Artificial Intelligence (AI) Office within the Commission, as provided in its earlier Decision establishing the European AI Office (see here). The AI Office will play a crucial role in the coherent implementation of the AI Act,* particularly regarding so-called "general-purpose" AI models.**

The AI Office will, in particular, (i) support governance bodies in Member States; (ii) direct enforce the rules for general-purpose AI models; (ii) coordinate the drawing up of state-of-the-art codes of practice and conducting testing and evaluating general-purpose AI models, in cooperation with AI developers, the scientific community, and other stakeholders; (iii) as well as apply sanctions, when necessary.

On <u>risks raised by AI</u> (e.g., cyberattacks against AI systems can leverage AI specific assets, such as training data sets (e.g. data poisoning), the AI Office will also pursue measures such as monitoring the emergence of unforeseen risks stemming from general-purpose AI models, including by responding to alerts from its scientific panel of independent experts.

The Al Office is composed of the following:

- Regulation and Compliance Unit, coordinating the regulatory approach to facilitate the AI Act's uniform application and enforcement across the EU, working closely with EU Member States. The Unit will contribute to investigations on possible infringements, administering sanctions;
- <u>Unit on Al Safety</u>, focusing on identifying systemic risks of very capable general-purpose models, possible mitigation measures, as well as evaluation and testing approaches;
- Excellence in AI and Robotics Unit, supporting and funding research and development to foster an ecosystem of excellence;
- Al for Societal Good Unit, overseeing the design and implementation of the Al Office's international engagement for worthy causes, such as weather modelling and cancer diagnoses;
- Al Innovation and Policy Coordination Unit, overseeing the execution of the EU Al strategy by monitoring trends and investment.

The AI Office will gather over 140 staff members to undertake its responsibilities, including technology specialists, policy specialists, and economists.

Next steps. The above-mentioned organizational changes took effect on 16 June 2024. The AI Office is preparing guidelines on the AI system definition and on prohibited AI systems, both due six months after the entry into force of the AI Act. The AI Office will also coordinate the preparation of codes of practice for obligations for general-purpose AI models, due 9 months after entry into force.

- * Regulation (EU) 2024/1689 of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence (AI) Act)(see here)
- ** The definition of a general-purpose AI model is based on its key functional characteristics, in particular the generality and the capability to competently perform a wide range of distinct tasks. These models are typically trained on large amounts of data, through various methods, such as self-supervised, unsupervised or reinforcement learning (see Recital 97 and Article 3.63 of AI Act).

ENISA holds 7th Cyber Europe Exercise (see here)

On 20 June 2024, the European Union Agency for Cybersecurity ("ENISA"), held the 7th edition of Cyber Europe, a biennial cybersecurity exercise and one of the largest in Europe. This edition's exercise focused on challenging the resilience of the EU energy sector, following the 6th edition's focus on the healthcare sector in 2022 (see here).

Cybersecurity has increasingly become a <u>significant threat to EU critical</u> <u>infrastructure sectors</u>, with the number of cyberattacks rising substantially in recent years. In 2023, over 200 reported cyber incidents targeted the energy sector, with more than half directed specifically at Europe. The pivotal role of the energy sector in the European economy makes it particularly vulnerable to cyber threats and attacks.

The two-day pan-European event brought together 30 national cybersecurity agencies, several EU agencies, bodies and networks, and over 1000 experts dealing with various areas from incident response to decision-making. The exercise simulated a series of large-scale cyber incidents. Working together, participants honed their coordination and crisis management skills to tackle the challenges posed by the advanced scenarios and ensure business continuity in the face of a crisis.

<u>Next steps</u>. Following the exercise, an analysis of the processes and outcomes will be conducted to gain insights into the identified weaknesses. These findings will be included in the after-action report, which aims to provide guidance for further improvement both for the exercise itself and for strengthening the resilience of the EU energy sector.

LAWYER CONTACTS

Kaarli H. Eichhorn

Partner, Antitrust & Competition Law; Government Regulation; Technology Brussels

keichhorn@jonesday.com

+32.2.645.14.41

Dr. Jörg Hladjk

Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology Brussels jhladjk@jonesday.com

+32.2.645.15.30

Nadiya Nychay

Partner, Government Regulation; Antitrust & Competition Law Brussels
nnychay@jonesday.com
+32.2.645.14.46

Cristiana Spontoni

Partner, Health Care & Life Sciences; Government Regulation Brussels cspontoni@jonesday.com

+32.2.645.14.48

Rick van 't Hullenaar

Partner, Government Regulation; Investigations & White Collar Defense Amsterdam rvanthullenaar@jonesday.com +31.20.305.4223

Dimitri Arsov (Associate), **Lucie Fournier** (Associate), **Mihai loachimescu-Voinea** (Associate), **Cecelia Kye** (Consultant), and **Justine Naessens** (Associate) in the Brussels Office contributed to this Update.