



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](#)).

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COMPETITION & STATE AID

Competition

European Commission adopts revised Market Definition Notice for competition cases (see [here](#))

On 8 February 2024, the Commission adopted the revised Market Definition Notice (*Communication from the Commission – Commission Notice on the definition of the relevant market for the purposes of Union competition law*).

This is the first revision of the 1997 Market Definition Notice, which provides guidance on the principles and best practices on how the Commission applies the concept of relevant product and geographic market in enforcing EU competition law.

The revised Notice is also published, in part, in response to some stakeholders' views that mergers between European companies in certain sectors have been challenged as leading to allegedly too-high concentration levels within Europe, whereas the merging parties have argued that scale and size are necessary to compete globally.

The revision sought to take into account, in particular,:

- Significant market developments over the years (e.g., digitalization, globalization, and new ways of offering goods and services); and
- Competition policy's role in contributing to the EU's green and digital transitions and resilience of the single market by safeguarding well-functioning markets and addressing market failures, e.g., by:
 - Contributing to increasing the resilience of the EU economy and preventing excessive dependency by enabling strong and diversified supply chains, and
 - Complementing the EU's regulatory framework on environmental sustainability by taking into account sustainability factors to the extent relevant to the competition assessment, including as part of market definition.

The revised Notice seeks to boost guidance, transparency and legal certainty for businesses to facilitate compliance, including key features such as:

- More accessible guidance, providing detailed structure and concrete illustrations of practical applications of market definition concepts.
- Recognition of the importance of non-price parameters for market definition, including product innovation, quality, reliable supply and sustainability, e.g.:
 - Resource efficiency and durability;
 - Security and privacy protection;
 - Availability, including in terms of lead-time, resilience of supply chains, reliability of supply, and transport costs.
- Specific guidance on applying market definition concepts in particular circumstances, e.g.:

- Digital markets, such as with respect to digital “ecosystems”, for instance, concerning products built around a mobile operating system.
- Innovation-intensive industries, where companies compete on innovation, including through developing new products.
- Clarifications on dynamic and forward-looking assessments especially in markets undergoing structural transitions, such as regulatory or technological changes.
- Expanded guidance on geographic market definition focusing on factors that can justify defining markets as global, EEA-wide, national, or local, and on the role of imports when defining the relevant geographic market.

The revised Notice states that the Commission will continue to develop the concept of relevant product and geographic market in light of its case practice, market developments and competition dynamics, evolutions in best practices in market definition, and case law of the EU courts.

The Commission’s Q&A on the revised Notice provides further details (see [here](#)).

European Commission publishes Update on Competition Enforcement in Pharmaceutical Sector (2018-2022) (see [here](#))

On 26 January 2024, the Commission published its Update on Competition Enforcement in the Pharmaceutical Sector (2018-2022). The report provides an overview of the enforcement of EU antitrust and merger rules by the Commission and the national competition authorities (NCAs) in the pharmaceutical sector and asserts its view that such active enforcement continues to play a key role in affording European patients with access to a broader choice of affordable and innovative medicines.

The Update responds to concerns previously raised by the Council of the European Union and the European Parliament, expressing their views that patients’ access to affordable and innovative essential medicines may be jeopardized by a combination of allegedly very high and unsustainable price levels, certain business strategies by pharmaceutical companies, and limited bargaining power of national governments against these companies.

Among its main findings, the Update sets out its views on the following:

Antitrust enforcement. Concerning alleged anti-competitive agreements and cases of abuse of dominance in the pharmaceutical sector, the Update states that since 2018, the Commission and NCAs have:

- adopted 26 decisions against practices deemed as anti-competitive and as harming innovation and prices in the supply of medicines (e.g., disparagement of a competitor’s products to protect the dominant company’s sales; excessive prices charged for off-patent medicines), resulting in fines totalling over €780 million and legally binding commitments offered by companies to remedy their anti-competitive behavior; and
- investigated over 70 other cases, ultimately closing 40 of these and with 30 cases still ongoing.

Merger control. The Commission reviewed over 30 mergers in the pharmaceutical sector and raised its concerns in five cases (e.g., where mergers allegedly could have led to price increases or diminished

innovative efforts to develop new medicines). The Commission cleared four of these mergers following the companies' remedies to address the Commission's concerns. One case was abandoned after the Commission raised initial competition concerns.

The Update also reports on the Commission's [guidance and coordination initiatives](#), such as the Temporary Framework Communication adopted on 8 April 2020, setting out the main criteria for assessing cooperation projects aimed at addressing a shortage of supply of essential products and services during the COVID-19 outbreak (see [here](#)). The Communication also set out the possibility of providing companies with written comfort (via ad hoc "comfort letters") on specific cooperation projects falling within the scope of the Temporary Framework (see also [Jones Day COVID-19 Update No. 3 of 10 April 2020](#)).

The Update concludes by stating the Commission's view that competition law enforcement, while significantly contributing to improving competition in pricing and innovation by guidance and deterrence, nonetheless remains complementary to legislative and regulatory action, such as the [EU Pharmaceutical Strategy](#) of November 2020 and the major [reform of EU pharmaceutical legislation](#) (see also [Jones Day EU Emergency Response Update No. 102 of 3 May 2023](#)).

For further details on the Update, see below Section on Medicines and Medical Devices.

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 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 February 2024):

- €240 million (DKK 1.8 billion) Danish scheme to support the production of investments in specific strategic goods to foster the transition towards a net-zero economy.
- €37.6 million (RON 187 million) Romanian scheme to support tomato and garlic producers in the context of Russia's war against Ukraine.
- €40 million aimed at supporting mid-sized companies, in the context of Russia's war against Ukraine.
- €50 million Dutch scheme to support the agricultural primary plant production sector in the context of Russia's war against Ukraine.
- €56 million (RON 278.6 million) Romanian scheme to support the pig and poultry sectors in the context of Russia's war against Ukraine.
- €241 million (RON 1.2 billion) Romanian scheme to support the agricultural primary plant production sector in the context of Russia's war against Ukraine.

- €550 million Italian State aid scheme to support investments for the use of hydrogen in industrial processes to foster the transition to a net-zero economy.
- €230 million (PLN 1 billion) Polish scheme to support the corn production sector in the context of Russia's war against Ukraine.
- €2.9 billion French scheme supporting the production of batteries, solar panels, wind turbines and heat-pumps, related key components and critical raw materials.
- €902 million German State aid measure to support Northvolt in the construction of an electric vehicle battery production plant to foster the transition to a net-zero economy.

TRADE / EXPORT CONTROLS

Second year of Russia's war against Ukraine – Remarks from G7 (see [here](#))

The second year of Russia's war against Ukraine, launched on 24 February 2022, drew remarks from Leaders of the Group of Seven (G7),* who issued a Statement following their meeting with Ukraine's President Volodymyr Zelensky to express their sustained support for Ukraine, and in particular:

- Reaffirmed commitment to fully implementing and enforcing sanctions on Russia and adopting new measures as necessary, e.g., by imposing additional sanctions on companies and individuals in third countries who aid Russia in acquiring weapons or key inputs for weapons; and by countering attempts to circumvent sanctions and export control measures, in close cooperation with third countries;
- Sustained significant pressure on Russian revenues from energy and other commodities, e.g., by continuing to tighten compliance and enforcement of the oil price cap and responding to price cap violations (*for details on the G7 Oil Price Cap Coalition, see [here](#)*); and continuing to impede Russia's development of future energy projects and disrupt its development of alternatives for energy shipping and other services;
- Appropriate steps to deter financial institutions from supporting Russia's war machine; and
- Pursuit of ongoing efforts to ensure that Russia pays for Ukraine's long-term reconstruction, including reaffirming that Russia's sovereign assets in G7 jurisdictions will remain immobilized until Russia pays for the damage it caused to Ukraine. The G7 notably welcomed the EU's adoption of legal acts concerning extraordinary revenues of central securities depositories gained from Russia's immobilized sovereign assets (see below item), and encouraged further steps to enable their use, consistent with applicable contractual obligations and in accordance with applicable laws.

* *The G7 forum brings together the leaders of the world's leading industrial nations (Canada, France, Germany, Italy, Japan, UK, and U.S., in addition to the EU). The annual G7 Summits have developed into a platform for determining the course of*

multilateral discourse and shaping political responses to global challenges. Decisions by the G7 are non-binding, but exert strong political influence.

Council of the European Union adopts a Decision and a Regulation on immobilized Russian assets (see [here](#))

On 12 February 2024, the Council of the European Union adopted a Decision* and a Regulation** clarifying the obligations of Central Securities Depositories (CSDs)*** holding assets and reserves of the Central Bank of Russia (CBR) that are immobilized under the EU's restrictive measures (i.e., prohibition on any transactions related to the management of CBR reserves and assets).

The Council, in line with the G7 position, clarified the prohibition on such transactions and the legal status of revenues generated by CSDs in connection with holding of immobilized CBR assets and set out clear rules for entities holding these. In particular:

- CSDs holding over €1 million of CBR assets must set aside extraordinary revenues stemming from these assets, which are accumulating due to EU restrictive measures. CSDs are also prohibited from disposing of such net profits.
- A CSD may request its supervisory authority to authorize a release of a share of such net profits in view of complying with statutory capital and risk management requirements, given the risks and costs related to holding CBR assets and reserves.

The Council has thus opened the way to potentially establishing a financial contribution to the EU budget raised on these net profits to support Ukraine and its recovery and reconstruction. Such financial contribution could be channeled through the EU budget to the Ukraine Facility on which the Council and the European Parliament reached a [provisional agreement](#) on 6 February 2024.

The Council reports that some €260 billion in CBR assets are immobilized in the form of securities and cash in the jurisdictions of the G7 partners, the EU and Australia, with over two-thirds of these immobilized in the EU.

* [Council Decision \(CFSP\) 2024/577](#) of 12 February 2024 amending Decision 2014/512/CFSP concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

** [Council Regulation \(EU\) 2024/576](#) of 12 February 2024 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine (see).

*** CSDs within the meaning of [Regulation \(EU\) No 909/2014](#).

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:

Russia: On 23 February 2024, marking the second year of Russia's war against Ukraine, the Council adopted a 13th package of sanctions,* focusing in particular on:

- Import restrictions, e.g.:
 - Adding the United Kingdom to a list of partner countries that apply restrictive measures on imports of iron and steel from Russia, and a set of import control measures substantially equivalent to the EU's.
- Export restrictions, e.g.:
 - Further restrictions on exports of goods that could contribute to the technological enhancement of Russia's defence and security sector, such as components for the development and production of unmanned aerial vehicles (UAV) and aluminium capacitors, which have military applications, such as in missiles, drones, and communication systems for aircrafts and vessels.
 - Adding 27 new entities to the list of those directly supporting Russia's military and industrial complex in its war against Ukraine. They will be subject to tighter export restrictions concerning dual use goods and technologies, as well as goods and technology that may contribute to the technological enhancement of Russia's defence and security sector (including entities located in India, Sri Lanka, China, Serbia, Kazakhstan, Thailand, and Turkey trading in electronic components and involved in circumventing trade restrictions).

The Council also added an unprecedented 194 individual designations (106 individuals and 88 entities) responsible for actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine, targeting primarily the military and defence sectors and associated individuals, including 10 Russian companies and individuals involved in DPRK (Democratic People's Republic of Korea) armament supply to Russia.

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 2,000 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 in February 2022 with the so-called first package of sanctions (see [here](#)). The 12th package of sanctions was adopted by the Council on 18 December 2023 (see also [Jones Day EU Emergency Response Update No. 111 of 29 December 2023](#)).

* *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)).*

European Commission proposes new initiatives to strengthen economic security (see [here](#))

On 24 January 2024, the European Commission adopted a comprehensive package of five initiatives on trade, investment, and research to strengthen the EU's economic security in the face of rising geopolitical tensions and significant technological change, as set out in a [Communication on Advancing European economic security: an introduction to five new initiatives](#).

These new initiatives are in furtherance of the goals of the [European Economic Security Strategy](#) of 20 June 2023 (Strategy), a broad three-pillar approach to EU economic security based on promoting the EU's competitiveness, protecting against risks, and partnering with the widest possible range of countries to promote shared economic security interests.

The Strategy additionally aims at undertaking a thorough assessment of risks to economic security in four areas: (i) resilience of supply chains, including energy security; (ii) physical and cybersecurity of critical infrastructure; (iii) technology security and technology leakage; and (iv) weaponization of economic dependencies or economic coercion (see also [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)).

The five initiatives of the new package comprise:

- A proposal for a new regulation to [revise the EU Foreign Direct Investment Screening Regulation](#) to enhance its effectiveness and efficiency (see [here](#)), e.g., by ensuring that all Member States have a screening mechanism, with better-harmonized national rules;
- A White Paper launching a process to identify potential [security risks linked to EU investment in third countries \(outbound investment\)](#) (see [here](#)), e.g., by proposing a step-by-step analysis of outbound investments to understand potential risks linked to them, including consulting stakeholders and monitoring/assessing outbound investments at national level;
- A White Paper on increasing the [effectiveness of EU controls on the export of goods with civilian and military use \(dual-use goods\)](#), in light of safeguarding EU and international security due to widening geopolitical tensions (see [here](#)), e.g., by introducing uniform EU controls on items not adopted by the multilateral export control regimes following opposition by certain members, in view of avoiding varied national approaches
- A White Paper on enhancing support for [research and development involving technologies with dual-use potential](#) (see [here](#)); e.g., by creating a dedicated instrument with a specific focus on R&D with dual-use potential; and
- A proposed Council Recommendation on [enhancing research security](#) to address risks arising from sharing sensitive knowledge and technology, which can endanger European and national security if used for military purposes by a foreign research partner (see [here](#)), e.g., by setting out principles for responsible internationalization that should underpin all research security

policies in the Member States and the research and innovation sector.

The Commission invites the Member States, the European Parliament and the Council, in line with their respective competences, to consider these five initiatives, and to give them appropriate follow up, in close cooperation with the Commission. Given the current geopolitical environment, and the opportunities and risks that it entails, progress on these initiatives must proceed at a “*steady pace*.”

MEDICINES AND MEDICAL DEVICES

European Commission proposes Council Recommendation on Vaccine-Preventable Cancers ([here](#))

On 31 January 2024, the European Commission issued a Proposal for a Council Recommendation on Vaccine-Preventable Cancers.

The Commission indicates that an estimated 40% of cancer cases in the European Union (“EU”) are preventable. Notably, cancers caused by Human papillomaviruses (“HPV”) and Hepatitis B virus (“HBV”), can be prevented by vaccination. However, according to a 2024 OECD report, only some 5% of total health spending was dedicated to cancer prevention in the EU Member States in 2021 (see [here](#)).

The Proposal is one aspect of Europe's Beating Cancer Plan, a key component of the European Health Union and the Commission's response to the increasing number of cancer cases and cancer-related deaths across the EU. Among the Cancer Plan's goals is for EU Member States to attain HPV vaccination rates of at least 90 % of girls and to significantly increase the vaccination of boys by 2030. The Cancer Plan also seeks to ensure access and increased uptake of the HBV vaccination, particularly towards preventing liver cancer.

To reach these vaccination goals, the Proposal recommends that Member States take measures such as the following:

- Introduce or strengthen the implementation of HPV and HBV vaccination programs as part of national immunization programs, including by providing vaccination free of charge and/or fully reimbursing related costs for those for whom vaccination is recommended;
- Improve the monitoring of vaccination coverage rates, in compliance with the General Data Protection Regulation, by building or upgrading population-based electronic vaccination registries that enable the availability of data at national level and subnational level and to which data recorded by different vaccine providers can be seamlessly transferred, to inform efficient, data-driven public health action;
- Streamline national procedures for obtaining parental consent to vaccinate minors in respect of national legislation, including by sharing and discussing national approaches to facilitate vaccination uptake; and
- Actively participate in efforts to further facilitate EU citizens' access to their vaccination data, empowering them to follow their vaccination history and make decisions on vaccination, as well as to further facilitate the exchange of such data for continuity of care purposes across the EU.

The Commission would also support Member States in implementing the proposed Recommendation. In particular, it would provide a model for communication campaigns, adaptable to national needs, to help raise awareness of the importance of these vaccinations. The Commission would also support work to improve monitoring across the EU, while the European Centre for Disease Prevention and Control (ECDC) would develop a new dashboard of national vaccination rates for HPV and HBV by end-2024, towards providing a better overview of the situation.

European Parliament and Council reach provisional political agreement on proposed revised Urban Wastewater Treatment Directive ([here](#))

On 29 January 2024, the European Parliament and the Council of the European Union reached a provisional political agreement regarding the Proposal for a revised Urban Wastewater Treatment Directive, issued by the European Commission on 26 October 2022 (see [here](#)).

The Proposal, which is a key element of the European Green Deal (see [here](#)), aims to substantially strengthen the protection of human health and the environment from harmful discharges of urban wastewater.

According to the Commission, the cosmetic and pharmaceutical industries are jointly responsible for 92% of the toxic load in wastewater. Therefore, the Proposal introduces an “Extended Producer Responsibility” (EPR) scheme, such that:

- Producers (including importers) must bear the cost of removing micro-pollutants from urban wastewater;
- The financial contribution of producers will be determined on the basis of the quantities and toxicity of products placed on the market;

This new EPR obligation is in line with the “polluter pays” principle. It aims to incentivize research and innovation into toxic-free products, while also promoting fairness in the financing of wastewater treatment.

In addition, once adopted, the revised Directive will:

- Apply to a broader number of areas by also covering smaller agglomerations starting at 1,000 inhabitants;
- Impose new monitoring obligations on Member States, such as monitoring key health-related parameters in urban wastewaters, including anti-microbial resistance or SARS Covid in case of a pandemic. Furthermore, it introduces systematic monitoring of microplastics in the inlets and outlets of urban wastewater treatment plants as well as in sludge and imposes additional monitoring of “forever chemicals” such as PFAS (per- and polyfluoroalkyl substances);
- Require the removal of more nutrients and micropollutants from urban wastewater, particularly those coming from toxic pharmaceuticals and cosmetics; and
- Allow for the public to pursue compensation for damage to health occurring as a result of a breach of (national implementing) rules.

The European Parliament and the Council must now formally adopt the revised Directive before it can enter into force. It would then enter into force 20 days after its publication in the Official Journal of the EU. Member States

would then need to start working on implementing its requirements and send the Commission the first updated national implementation programs in 2026.

European Commission publishes Update on Competition Enforcement in Pharmaceutical Sector (2018-2022) (see [here](#))

On 26 January 2024, the Commission released its Update on Competition Enforcement in the Pharmaceutical Sector (2018-2022). The report provides an overview of the enforcement of EU antitrust and merger rules by the Commission and the national competition authorities (NCAs) in the pharmaceutical sector and asserts its view that such active enforcement continues to play a key role in affording European patients with access to a broader choice of affordable and innovative medicines.

The Update highlights the societal and economic importance of the pharmaceutical sector and the healthcare sector in general, which became even more evident during the COVID-19 crisis. For instance, spending on preventive care (e.g. testing, tracing, information campaigns related to the pandemic) increased by nearly one-third, and spending growth on inpatient care reached nearly 9% in 2020 (compared to 2019).

The Update, in particular:

- Describes the main characteristics of the pharmaceutical sector that shape the competition assessment, as the effectiveness of competition policy and its enforcement activities in the pharma sector depends on taking account of its particularities and resulting competitive dynamics, e.g.:
 - Relatively long life-cycles of medicines, with development cycles for innovative drugs that are typically risky, lengthy, and entail high development costs;
 - Market exclusivity for new medicines that is limited in time; and
 - Companies that may attempt to misuse the regulatory system which grants patent or exclusivity protection, in order to gain additional time before competing products can enter the market.
- Explains how competition law protected undertakings and consumers during the COVID-19 crisis, e.g., during the pandemic, the Commission issued two comfort letters under the Temporary Framework (see [here](#)) for cooperation projects aimed at addressing a shortage of supply of essential products and services during the COVID-19 outbreak:
 - (i) a comfort letter sent on 8 April 2020 to “Medicines for Europe”, an association of pharmaceutical manufacturers, concerning a temporary voluntary cooperation to address the risk of shortages of critical intensive care medicines for the treatment of COVID-19 patients by significantly increasing the production capacity of COVID-19 medicines (see [here](#) and [here](#)); and
 - (ii) a comfort letter on 25 March 2021, addressed to co-organizers of a pan-European “matchmaking” event, which aimed at addressing bottlenecks in producing COVID-19 vaccines and accelerating the use of additional available capacities across Europe (see [here](#)). The comfort letter

identified the conditions under which exchanges of information between the companies, including direct competitors, could take place in compliance with the EU competition rules.

The Update concludes by stating the Commission's view that competition law enforcement, while significantly contributing to improving competition in pricing and innovation by guidance and deterrence, nonetheless remains complementary to legislative and regulatory action, such as the [EU Pharmaceutical Strategy](#) of November 2020 and the major [reform of EU pharmaceutical legislation](#) (see also [Jones Day EU Emergency Response Update No. 102 of 3 May 2023](#)).

For further details on the Update, see above Section on Competition.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts first European cybersecurity certification scheme (see [here](#))

On 31 January 2024, the European Commission adopted the first-ever European cybersecurity scheme ([Commission Implementing Regulation \(EU\) 2024/482 of 31 January 2024 on rules for applying Regulation \(EU\) 2019/881 on the EU Cybersecurity Act * as regards the adoption of the European Common Criteria-based cybersecurity certification scheme \(EUCC\)](#)).

The voluntary cybersecurity scheme establishes harmonized rules and procedures for certifying Information and Communications Technology ("ICT") products throughout their life-cycle, aiming to enhance trustworthiness for users.

Furthermore, the scheme is intended, in particular, to:

- Complement the forthcoming [EU Cyber Resilience Act](#) (*proposed Regulation on horizontal cybersecurity requirements for products with digital elements – expected to enter into force in 2024 once formally adopted, following the [political agreement](#) reached between the European Parliament and Council on 30 November 2023*), which imposes cybersecurity requirements on hardware and software available in the EU (see also [Jones Day COVID-19 Update No. 87 of 23 September 2022](#)).
- Reinforce implementation of the [NIS 2 Directive](#) (*Directive (EU) 2022/2555 of 14 December 2022 on measures for a high common level of cybersecurity across the Union, see also [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)*).

The cybersecurity certification scheme was published in the Official Journal of the EU on 7 February 2024 and entered into force 20 days after publication.

On 7 February 2024, the Commission also released the first [Union Rolling Work Programme for European cybersecurity certification](#). This document outlines a strategic vision and potential areas for future cybersecurity certification schemes, taking into account legislative and market developments that may eventually lead to requests for new schemes as needed.

* *Regulation (EU) 2019/881 of 17 April 2019 on the European Union Agency for Cybersecurity (“ENISA”) and on information and communications technology cybersecurity certification (see [here](#)).*

European Commission adopts Communication on Artificial Intelligence in the European Commission (AI@EC) (see [here](#))

On 24 January 2024, the European Commission adopted a Communication on Artificial Intelligence in the European Commission (AI@EC) – A strategic vision to foster the development and use of lawful, safe and trustworthy Artificial Intelligence systems in the European Commission.

The Communication, aimed at preparing for implementation of the forthcoming [AI Act](#) (*proposed Regulation laying down harmonized rules on Artificial Intelligence – now subject to formal adoption, following the [political agreement](#) reached between the European Parliament and Council on 9 December 2023*), details the Commission’s specific actions for bolstering its institutional and operational capabilities to ensure the safe, transparent, and human-centered deployment of AI within its operations. These include, for instance:

- Actions aimed at preparing for the AI Act, such as developing internal operational guidelines that give staff clear guidance on how to put AI systems in operation; and refraining from using any AI systems that are considered incompatible with European values or that represent a threat to the security, health, and fundamental rights of people.
- Organizational actions, such as creating a dedicated AI governance structure tasked with evaluating AI aspects in the Commission’s IT investments (e.g. initiatives that support the legislative process, the financial processes, and engagement with public and stakeholders); monitoring compliance with the Commission’s guidelines; and supporting a broad “bottom up” network of interested colleagues.
- Operational actions, such as establishing and maintaining a register of AI systems used at the Commission; and developing a policy to build and maintain an AI-skilled workforce.

Furthermore, the Communication outlines existing and forthcoming AI use cases in the Commission, such as AI-powered language services that provide automated translation and summaries, or AI-powered services that provide research services in EU law.

The Commission is also preparing to work with EU public administrations in their adoption and use of AI, as well as with innovative startups and GovTech companies.

The Communication indicates that implementation of this AI initiative and early adoption of the principles of the forthcoming AI Act will start without delay.

EDPB publishes latest One-Stop-Shop case digest of decisions from EDPB’s public register (see [here](#))

On 18 January 2024, the European Data Protection Board (“EDPB”) published the second One-Stop-Shop case digest of decisions from EDPB’s [public register](#). This digest covers Security of Processing and Data Breach Notification (see [here](#)).*

This latest digest, which specifically focuses on matters related to the security of personal data processing and personal data breaches, provides

insights into the decisions of Data Protection Authorities (“DPAs”) concerning the One-Stop-Shop mechanism. This mechanism is a procedure that allows organizations engaged in cross-border EU data processing to deal with a single lead supervisory authority for their data protection compliance obligations.

In the digest, the EDPB underlines that:

- Regarding the security of processing (Article 32 GDPR), DPAs conducted individualized assessments of the technical and organizational measures implemented by companies impacted by data breaches. Additionally, in many instances, DPAs reviewed the post-breach actions taken by these companies and provided recommendations for appropriate measures.
- With regard to the notification and communication of personal data breaches (Articles 33 and 34 GDPR), DPAs have mostly focused on examining whether data controllers complied with their obligations under GDPR. Although notification of a data breach is not required when the latter is unlikely to result in a risk to the rights and freedoms of natural persons, DPAs have found that data controllers tend to notify data breaches in most cases.

* *The first One-Stop-Shop case digest, dated 9 December 2022, covers the right to object and right to erasure (see [here](#)).*

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