



EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

No. 100 | 3 April 2023

This 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).

LATEST KEY DEVELOPMENTS

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- 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

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- European Commission welcomes provisional political agreement on Anti-Coercion Instrument
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Cybersecurity, Privacy & Data Protection

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COMPETITION & STATE AID

Competition

EU-US hold third Joint Technology Competition Policy Dialogue (see [here](#))

On 30 March 2023, the third meeting of the EU-US Joint Technology Competition Policy Dialogue (TCPD) took place in Washington, D.C. with European Commission Executive Vice-President and Competition Commissioner Margrethe Vestager, US Federal Trade Commission (FTC) Chair Lina Khan, and the Assistant Attorney General for Antitrust of the US Department of Justice (DOJ) Jonathan Kanter.

To recall, the TCPD was launched on 7 December 2021 to further consolidate cooperation efforts to ensure and promote fair competition in the digital sector (see also [Jones Day COVID-19 Update No. 91 of 9 November 2022](#)).

On the occasion of this third TCPD meeting, FTC Chair Khan stated that the TCPD “*continues to provide an invaluable forum for the U.S. agencies to engage with the European Commission on challenges in digital markets. At this moment of unique risk and opportunity, it is especially critical that we deepen our cooperation with key enforcement partners.*”

The third meeting’s discussions centered on:

- crucial issues facing the agencies, including why mergers between digital players may raise competition concerns.
- abuse of dominance and monopolization in the digital sector and recent related policy initiatives.
- evolving business strategies of big tech companies and the implications for enforcement.

Furthermore, in view of continuing close collaboration under the TCPD, agency experts from the DOJ and FTC will be sent to Brussels to support [implementation of the Digital Markets Act \(DMA\)](#), which entered into force on 1 November 2022 and is applicable as of 2 May 2023 (see also [Jones Day COVID-19 Update No. 92 of 18 November 2022](#)).

The TCPD will continue with high-level meetings, as well as ongoing discussions at technical level.

State Aid

Recovery and Resilience Facility developments: European Commission disburses over €150 billion and launches interactive map (see [here](#) and [here](#))

On 31 March 2023, the Commission announced two notable developments concerning the Recovery and Resilience Facility (RRF), the key instrument at the core of the €800 billion NextGenerationEU recovery plan for Europe. To recall, the RRF was established in February 2021 by [RRF Regulation \(EU\) 2021/241](#) (running until end-2026) in response to the COVID-19 pandemic to support faster and more resilient Member State recovery. The two developments concern the following:

- (i) In just over two years of the RRF’s existence, the [Commission surpassed €150 billion in disbursements to Member States under the RRF](#), following its €6 billion payment to Spain on 31 March 2023.

The payment was made possible on the basis of the Commission's opinion that Spain complies with the 24 milestones and 5 targets linked to the third tranche of its national recovery plan. The payment request covers, in particular, various reforms and investments in the areas of green and digital transitions; research, development and innovation; and education and vocational training.

For each Member State, payments under the RRF are performance-based and depend on implementation of the investments and reforms outlined in its national recovery plan. The Commission's [Recovery and Resilience Scoreboard](#), in particular, regularly provides updates on disbursements and progress made by Member States.

(ii) To further increase transparency on the RRF's functioning and its actual impact on EU citizens and businesses, the Commission also launched an [online, interactive map showing Member State projects supported by the RRF](#). The map seeks to provide a "virtual tour" of Member State implementation of their national recovery plans.

The [Commission cautions, however, the following with respect to the map](#):

- Inclusion of a specific reform or investment on the map does not necessarily imply that the Member State has already received RRF funding related to that project (e.g., a Member State may have already commenced implementing a project with national funding).
- The map is not intended to provide an exhaustive overview of RRF-funded projects, particularly since the RRF's implementation remains ongoing, and some projects that will receive RRF funding are not yet defined.

The interactive map will be regularly updated as implementation of national recovery plans progresses, and as the Commission acquires new information on the advancement of projects linked to Member State reforms and investments.

The map will also incorporate, in particular, information (when available later in 2023) on the [100 largest final recipients of RRF funding](#) for each national recovery plan.

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

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

Among the most recently approved State aid schemes under the new TCTF (until 3 April 2023):

- €450 million Italian scheme to support the production of renewable hydrogen with the aim to foster the transition to a net-zero economy, in line with the Green Deal Industrial Plan.
- €30 million Italian scheme to support commercial bus transport operators in the context of Russia's war against Ukraine.

dependencies (see [here](#))

- €25 million Greek scheme to support apple and chestnut producers in the context of Russia's war against Ukraine.
- €126 million (PLN 600 million) Polish scheme to support the wheat and maize production sector in the context of Russia's war against Ukraine.
- €109 million (BGN 213 million) Bulgarian scheme to support farmers in the context of Russia's war against Ukraine.
- €100 million Lithuanian scheme to support companies in the context of Russia's war against Ukraine.
- €1 billion Finnish scheme to support companies in the context of Russia's war against Ukraine.
- €100 million Irish scheme to support the microelectronics-manufacturing sector in the context of Russia's war against Ukraine.

TRADE / EXPORT CONTROLS

European Commission welcomes provisional political agreement on Anti-Coercion Instrument (see [here](#))

On 28 March 2023, the European Commission welcomed the provisional political agreement reached by the Council of the European Union and the European Parliament on the proposed Regulation on the protection of the Union and its Member States from economic coercion by third countries, published on 8 December 2021 (so-called Anti-Coercion Instrument (ACI), see [here](#)).

The proposed ACI is a new tool aimed at counteracting third-country economic coercion against the EU or any of its Member States. Such coercion restricts trade or investment (or threatens to), with the aim of pressuring the EU or Member States into making certain policy choices in areas such as climate change, taxation or consumer security. As the EU legislative framework currently lacks an instrument specifically addressing coercion, the proposed ACI seeks to fill this gap, which is viewed as particularly important in view of current global adversities:

- The European Parliament's [Report on the proposed ACI](#) of 13 October 2022 noted the urgent need for an anti-coercion instrument, particularly in the context of "*global trade tensions and the impact of COVID-19 pandemic on global supply chains, whose vulnerabilities were further exposed following Russia's military invasion of Ukraine in February 2022. ... [T]he EU cannot be a credible interlocutor on the global arena without a powerful trade instrument preserving its interests, rights and sovereign political choices.*"
- The European Commission's [Impact Statement](#) accompanying the proposed ACI also noted the specific need for an anti-coercion instrument to aid in navigating rising global tensions, aggravated by the COVID-19 crisis, with trade increasingly "weaponized" in a geo-economic context (e.g., cases of "vaccine diplomacy", where certain countries reportedly accompanied COVID-19 vaccine supplies with soft power messages to support their standing or positions, or withheld such vaccines subject to changing a policy position).

The proposed ACI would empower the Commission to apply a wide range of potential trade, investment or other restrictions towards any non-EU country deemed as unduly interfering in the policy choices of the EU or its Member States. Trade restrictions, for example, would be available in the form of

increased customs duties, import or export licenses, or restrictions in the field of services or public procurement.

The provisional political agreement agreed to the following, in particular:

- The Council will have an important role in the decision-making process by determining what constitutes economic coercion.
- The Commission will be given implementing powers in decisions on the EU's response measures, while ensuring closer Member State involvement in those decisions.
- The Parliament obtained an extension to the scope of the proposed ACI to include measures to repair the injury where deemed appropriate.
- The Parliament also introduced deadlines for determining whether coercion has occurred and for adopting a response to such coercion, with the aim of avoiding administrative delays.

As the anti-coercion instrument is designed with deterrence as its primary goal, any countermeasures taken by the EU would be applied only as a last resort.

Next steps. The final negotiated text still requires endorsement at a final meeting, followed by formal approval by the Parliament and Council. Once officially adopted by both institutions, the Regulation will enter into force 20 days after its publication in the Official Journal of the European Union.

Council of the European Union expands sanctions against Iran (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:

Iran: On 20 March 2023, the Council decided to impose restrictive measures on additional 8 individuals and one entity responsible for serious human rights violations in the context of the existing Iran human rights sanctions regime (see [here](#)). The Council is sanctioning, among others:

- members of the judiciary responsible for issuing death sentences in unfair trials and for the torturing of convicts;
- conservative clerics undermining the freedom of girls and women or propagating hate against women;
- a member of the Iranian Parliament (Madjles) and its spokesman for the cultural commission; and

- the chief for cultural affairs and policy evolution at EU-listed Islamic Republic of Iran Broadcasting (IRIB), which broadcasted forced confessions from foreign hostages during the 2022/2023 protests.

Restrictive measures against Iran now apply to a total of 204 individuals and 34 entities. They consist of an asset freeze, a travel ban to the EU and a prohibition to make funds or economic resources available to those listed. A ban on exports to Iran of equipment which might be used for internal repression and of equipment for monitoring telecommunications is also in place.

Additionally, in particular, in light of Iran's military cooperation with Russia, the Council had earlier added 4 individuals and 4 entities on 12 December 2022 to the list of those subject to restrictive measures for undermining or threatening the territorial integrity, sovereignty and independence of Ukraine, in view of their role in developing and delivering Unmanned Aerial Vehicles (UAVs) used by Russia in its war against Ukraine (see [here](#)).

MEDICINES AND MEDICAL DEVICES

EMA publishes Regulatory Science Strategy to 2025 Mid-point achievements to end 2022 (see [here](#))

On 22 March 2023, the European Medicines Agency (EMA) published its Report on Regulatory Science Strategy to 2025 – Mid-point achievements to end 2022.

The Report sets out progress made across the human and veterinary areas (between March 2020 and December 2022) under the Regulatory Science Strategy to 2025 published on 31 March 2020 (see [here](#)). The Strategy aims at building a more agile regulatory system that will encourage innovation in human and veterinary medicine, given the significantly increased pace of innovation in recent years and the need for regulators to support the development of increasingly complex medicines.

The Report notes that in parallel to implementing the Strategy, the EMA prioritized responding to the COVID-19 pandemic over the past two years. The pandemic also demonstrated the urgent need to address the dramatic acceleration of innovation, given the interplay of vaccines, therapeutics, diagnostics and medical technology developments.

In particular, the Report highlights five core recommendations in the area of human medicine and accompanying achievements viewed as delivering the most significant change under the Strategy's lifetime. These core recommendations include:

(1) Fostering innovation in clinical trials. Achievements include:

- Launch of the Clinical Trial Information System ("CTIS") (see [Jones Day COVID-19 Update No. 96 of 27 January 2023](#)). Among other things, EMA has provided an online training programme dedicated to sponsors and Member State users to support the onboarding of the user community on the use of CTIS and user activity in CTIS.
- Establishment of Accelerating Clinical Trials in the EU (ACT EU) (see also [Jones Day COVID-19 Update No. 73 of 17 January 2022](#)) and associated work plan to 2026 (see [here](#)). EMA, in particular, established

the ACT EU Steering Group and published a Q&A on Complex Clinical Trials (see [here](#)).

(2) Promoting use of high-quality real-world data (RWD) in decision making. Achievements include:

- Establishment of DARWIN EU (Data Analysis and Real-World Interrogation Network), starting in February 2022 with the DARWIN EU contract awarded to Erasmus University Medical Centre Rotterdam with a number of subcontractors. DARWIN EU provides real-time evidence on the use, safety and effectiveness of medicines for human use, including vaccines from databases across the EU (see [here](#)).
- Establishment and expansion of a catalogue of observational data sources for use in medicines regulation. In particular, the updated meta data list, which defines the structure of the catalogue, was adopted and published.

(3) Reinforcing patient relevance in evidence generation. Achievements include:

- Mapping and analyzing existing methodologies for the collection and use of patient experience data, including a report from the University of Lisbon prepared with EMA (see [here](#)).
- Holding a multi-stakeholder workshop on Patient Experience Data (PED). The executive summary describing the key workshop outputs was published (see [here](#)).

(4) Contributing to Health Technology Assessment's (HTA) preparedness and downstream decision making for innovative medicines. Achievements include:

- Delivering on agreed priorities under the joint work plan to 2021 (e.g., provided over 60 parallel consultations to medicine developers to allow them to obtain feedback from regulators and HTA bodies on their evidence-generation plans to support decision-making on marketing authorization and reimbursement of new medicines).
- Initiating preparation, from a methodological and operational perspective, for the coming into application of the Regulation on Health Technology Assessment (EU) 2021/228 (see [Jones Day COVID-19 Update No. 95 of 9 January 2023](#)).

(5) Supporting developments in precision medicine, biomarkers and 'omics*. Achievements include:

- An R&D platform industry stakeholders focus group was established on process improvement for qualification of opinions. The focus group discussed horizon scanning activities as well as case studies related to common or emerging qualification objects (digital endpoints, biomarkers, modelling and simulation approaches to bioequivalence).
- Support to developers via the Innovation Task Force (ITF) and Business Pipeline Meetings (BPM), expanding early points of contacts to technologies and methods related to drug development (e.g., increased number of support meetings).
- Publications on the development of biomarkers from discovery to regulatory qualification for drug development (see [here](#) and [here](#)).

Following the Strategy's completion, a final report will be published in 2026.

* *'omics is a rapidly evolving, multi-disciplinary, and emerging field in biological sciences that ends with "-omics" (e.g. genomics, epigenomics, etc.).*

European Commission announces political agreement on proposed Regulation to establish a new EU Drug Agency (see [here](#))

On 28 March 2023, the European Commission welcomed the political agreement between the Council of the European Union and European Parliament on a proposed Regulation that strengthens the mandate of the European Monitoring Centre for Drugs and Drug Addiction by transforming it into a full-fledged agency, the new European Union Drugs Agency (see [here](#) and [here](#)).

According to the proposed Regulation, the new Agency should provide the EU and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at EU level concerning drugs, drug addiction, drug markets and their consequences, and to recommend appropriate evidence-based actions on how to timely address the related challenges.

In highlighting currently insufficient responses to new drug market challenges, the Commission notes in particular that the COVID-19 pandemic led to a greater adoption of new technologies to facilitate drug distribution. Drug trading is using different platforms, including social media networks and mobile applications. An estimated two-thirds of the offers on darknet markets are drug-related. These recent developments are expected to have long-term impacts on drug markets. This new challenge emphasizes the urgency for a new EU Drugs Agency to address the need for clear, up-to-date and reliable evidence and analysis capabilities on illicit drugs in the EU.

The new Agency's main task would continue to be the collection, analysis, and dissemination of information and data. Its new role will further include, in particular:

- Monitoring and addressing the simultaneous consumption of different drugs;
- For new psychoactive substances, conducting risk assessment procedures and reporting on potential risks, in addition to related information exchanges and an early warning system;
- Establishing a network of forensic and toxicological laboratories particularly active in the forensic and toxicological investigations of drugs and drug-related harms;
- Supporting the Member States in implementing their national drug strategies, quality standards and innovative best practices and facilitating exchanges of information between national decision-makers;
- Supporting the exchange and dissemination of EU best practices and implementable research results at international level;
- Providing research and support on health-related issues such as drug markets and drug supply; and
- Designing, developing and promoting EU-wide programmes and campaigns for the prevention of drug-related problems and raising awareness of the adverse effects of drugs.

The proposed Regulation must now be formally adopted by the European Parliament and the Council.

CYBERSECURITY, PRIVACY & DATA PROTECTION

ENISA publishes first Transport Threat Landscape (see [here](#))

On 21 March 2023, the European Union Agency for Cybersecurity (ENISA) published the first ENISA Transport Threat Landscape Report, covering the period of January 2021 to October 2022. The Report's objective is to shed light on cybersecurity threats facing the transport sector by identifying major threats, threat actors and trends based on the analysis of cyberattacks targeting aviation, maritime, railway and road transport.

The Report focuses on cyber incidents observed in EU Member States and identifies their core elements, seeking to respond to important questions such as how the attacks occurred, the systems being targeted, and the transport subsectors most affected.

Prime threats. During the reporting period, ransomware attacks became the most significant threat against the sector during 2022, overtaking data-related threats, which were the greatest threat in 2021. Other threats included malware, denial-of-service (DoS), distributed denial-of-service (DDoS) and ransom denial-of-service (RDoS) attacks, phishing, spear phishing and supply-chain attacks.

On trends in each transport sector, the Report highlighted, in particular, the impact of Russia's invasion of Ukraine on cyberattacks. Hacktivist elements with pro-Russian/anti-NATO sentiments have been carrying out DDoS attacks, targeting several European nations perceived by these groups as supporting Ukraine's war effort.

The Report noted the following trends:

- The aviation sector's most prominent threats were data-related, coupled by ransomware and malware attacks. In March 2021, for example, the passenger service system provider SITA was hacked, and hundreds of thousands of Star Alliance passengers' details were stolen;
- The maritime sector faces ransomware, malware, and phishing attacks aimed at port authorities, port operators, and manufacturers. In October 2021, for example, Microsoft reported that "Iran-linked" hackers targeted US, EU and Israeli defence and maritime sectors with password spray attacks;
- The railway sector is confronted by ransomware and data-related threats primarily targeting IT systems (e.g., passenger services, ticketing systems, and mobile applications) and causing service disruptions. Hacktivist groups have been conducting DDoS attacks against railway companies with an increasing rate, primarily due to Russia's invasion of Ukraine. In June 2022, for example, Latvian passenger train company SJSC was targeted with DDoS attacks, likely by pro-Russian hacktivists;
- The road transport sector faces ransomware attacks most significantly, followed by data-related and malware threats. In May 2022, for example, Czechia's Directorate of Roads and Highways was

targeted with DDoS attacks by Russian hacker group Killnet, resulting in disruption to web-based services.

The Report further highlights that a limited number of cyber incidents cannot be attributed to one specific subsector. These include general campaigns targeting an entire country's transportation sector. These campaigns are often attributed to hacktivists and state-sponsored actors and are linked to geopolitical tensions.

The Report also draws attention to issues in the reporting of cyber incidents and that ENISA still has limited knowledge and information on these incidents. The Report's analysis indicates that publicly disclosed incidents only represent the "*tip of the iceberg*."

European Commission publishes 2022 General Report on Activities of the European Union (see [here](#))

On 15 March 2023, the Commission published "The EU in 2022 – General Report on the Activities of the European Union."

The Report presents the EU's key activities of the EU in 2022, highlighting in particular the EU's actions to update cybersecurity rules, recognize digital rights and increase the accountability of digital service providers, while putting in place needed digital infrastructure and supporting the development of digital skills. The EU also proposed new rules for fairer data access and made progress in regulating the digitalization of different sectors. Among its specific actions in 2022, the EU:

- Updated legislation on measures to achieve a high level of common cybersecurity in all Member States. The new rules, known as the NIS 2 Directive (see [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)), replace the previous NIS 1 Directive and expand the list of critical entities and sectors that must take risk-management measures.
- Reached an agreement on the Proposal for a Directive on the resilience of critical entities (see [here](#)), which will provide the EU with an updated and comprehensive legal framework to reinforce both the physical and cyber resilience of critical infrastructure.
- Presented a proposal for a new Cyber Resilience Act (see [Jones Day COVID-19 Update No. 87 of 4 October 2022](#)) which will aim at ensuring that manufacturers improve the security of their products and the transparency of security properties.

The Report also highlighted that, in the framework of the Digital Europe Programme (i.e., the first EU funding programme focused on bringing digital technology to public administrations, businesses and citizens), several calls for proposals were launched, including funding opportunities for initiatives to improve cybersecurity cooperation between Member States and the Commission.

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