

COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 96 | 27 January 2023

This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

This COVID-19 Update will soon be transitioning to the new EU Emergency Response Update – Key Policy & Regulatory Developments, which will continue to cover key regulatory developments related to EU emergency responses, including in particular, to the COVID-19 and Ukraine-Russia situations.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- Foreign Subsidies Regulation enters into force
- European Commission approves further schemes under COVID Temporary Crisis Framework
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

Trade / Export Controls

- Foreign Subsidies Regulation enters into force
- Council of the European Union prolongs and expands sanctions against Russia and Iran

Medicines and Medical Devices

- European Commission publishes conference report on Health Security in the EU: COVID-19 lessons learned
- European Commission publishes report on survey on implementation of Clinical Trials Regulation

Cybersecurity, Privacy & Data Protection

- ENISA publishes report on Engineering Personal Data Sharing
- EDPB adopts 2022 report on first Coordinated Enforcement Action Use of cloud-based services by the public sector

COMPETITION & STATE AID

Competition	
Foreign Subsidies Regulation enters into force (see <u>here</u>)	On 12 January 2023, the Foreign Subsidies Regulation (FSR) entered into force (<i>Regulation 2022/2560 of 14 December 2022 on foreign subsidies distorting the internal market</i>).
	The FSR affords the European Commission with extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market, which have fallen outside of the existing EU State aid, merger control and antitrust framework (<i>see also Jones Day Alert, "EU Foreign Subsidies Regulation Filings Mandatory Starting in October 2023" of December 2022</i> , <u>here</u>).
	In presenting the proposed FSR, to recall, the Commission argued that the COVID economic crisis had led to higher levels of subsidization worldwide. The Commission's Impact Assessment on the proposed FSR (see <u>here</u>) further contended that the problem of distortive foreign subsidies is becoming more pressing in the context of acquisitions, public procurement and other market situations.
	Combining elements from EU rules on merger control, State aid, trade defense, and public procurement, the FSR introduces three tools applicable to all sectors of the economy and all companies active in the EU, i.e.:
	• <u>Mandatory merger notification</u> . In mergers and acquisitions facilitated by foreign subsidies, the acquirer must submit a prior notification to the Commission when:
	 An EU turnover at least €500 million is generated by the company to be acquired, one of the merging parties, or the joint venture; <u>and</u>
	 the involved aggregate foreign financial contribution amounts to at least €50 million.
	 <u>Mandatory public procurement notification</u>. Bidders in public procurement procedures must disclose any foreign subsidies received by submitting a prior notification to the Commission when:
	 the estimated contract value is at least €250 million; and
	 the bid involves a foreign financial contribution of at least €4 million per non-EU country.
	• <u>Own-initiative review of foreign subsidies</u> . For all other market situations, the Commission can start investigations on its own initiative (ex-officio) when it suspects that a foreign subsidy may be involved, including the possibility to request ad-hoc notifications for smaller concentrations and public procurement procedures.
	In the above-two notification regimes, a <u>standstill obligation</u> will apply pending the Commission's review, i.e., the concentration at issue cannot be completed and the investigated bidder cannot be awarded the public procurement contract. In case of <u>failure to notify</u> , the Commission may impose fines of up to 10% of the company's annual aggregated turnover.
	<u>Timing</u> : The FSR will start to apply on 12 July 2023. As of this date, the Commission may launch ex-officio investigations. The notification obligation

	for companies will apply from 12 October 2023. <u>Next steps</u> : The Commission presented a <u>draft Implementing Regulation</u> on 2 February 2023 in view of clarifying the applicable rules and procedures, including the <u>notification forms</u> for concentrations and public procurement procedures, the calculation of time limits, access to file procedures and confidentiality of information. The Implementing Regulation and notification forms will be finalized and adopted before the start of application of the FSR. Stakeholders are invited to give feedback on the draft Implementing Regulation until 6 March 2023 via the " <u>Have Your Say</u> " portal. The Commission's <u>Q&A</u> provides further details on the FSR (see <u>here</u>).
State Aid	
European Commission approves further schemes under	The Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the State aid COVID Temporary Crisis Framework adopted in March 2020.
COVID Temporary Crisis Framework	With certain exceptions, the Temporary Framework applied until 30 June 2022.* Among the latest schemes (up to 27 January 2023):
(see <u>here</u> and <u>here</u>)	 Approximately €40 million (DKK 300 million) Danish guarantee scheme to support travel operators in the context of the coronavirus pandemic.
	* Exceptions notably include the possibility for Member States to provide <u>solvency</u> <u>support measures</u> (until 31 December 2023) aimed at easing access to equity finance for smaller companies. The exception allowing Member States to create <u>direct</u> <u>incentives for private investments</u> ended on 31 December 2022.
European Commission approves further schemes under Ukraine Temporary Crisis Framework (see <u>here</u>)	The Commission continues to approve additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine.
	To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict has also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine.
	The Commission earlier prolonged (until 31 December 2023 (instead of 31 December 2022)) and expanded the Crisis Framework (<i>see <u>Jones Day</u> <u>COVID-19 Update No. 90 of 28 October 2022</u>).</i>
	Among the latest schemes under the Crisis Framework (up to 27 January 2023):
	 Re-introduction of Romanian scheme to support companies in the context of Russia's war against Ukraine, including (i) an overall budget increase by up to €695 million (RON 3.4 billion); (ii) re- introduction of the scheme until 31 December 2023; and (iii) an

increase of the maximum aid ceilings.

- €50 million Italian scheme to support companies active in the region of Campania in the context of Russia's war against Ukraine.
- €100 million Austrian measure to reduce electricity consumption in the context of Russia's war against Ukraine.
- €44 million (RON 217.7 million) Romanian scheme to support the cattle breeders sector in the context of the Russia's war against Ukraine.
- €200 million scheme to support companies in the context of Russia's war against Ukraine.
- €500,000 Cypriot scheme to support the citrus production sector in the context of the Russia's war against Ukraine.
- €50 million budget increase, to support companies in Lombardy in the context of Russia's war against Ukraine, including (i) a budget increase by €50 million; (ii) an extension of the scheme until 31 December 2023; and (iii) an increase of the maximum aid ceilings.
- €40 million Croatian scheme to support companies processing agricultural products in the context of Russia's war against Ukraine.
- €215 million French aid scheme to support the cessation of glyphosate in the agricultural sector in the context of the war in Ukraine.

Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework, provided that their respective cumulation rules are respected.

The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2023. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.

TRADE / EXPORT CONTROLS

Foreign Subsidies Regulation enters into force (see here) On 12 January 2023, the Foreign Subsidies Regulation (FSR) entered into force (*Regulation 2022/2560 of 14 December 2022 on foreign subsidies distorting the internal market*).

The FSR affords the European Commission with extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market, while seeking to keep the EU open to trade and investment (see also Jones Day Alert, "EU Foreign Subsidies Regulation Filings Mandatory Starting in October 2023" of December 2022, here).

	 The FSR combines elements from EU rules on trade defense, merger control, State aid, and public procurement. For further details on the proposed Regulation, see above Section on Competition & State Aid. As concerns trade, to recall, the Commission's Impact Assessment on the proposed FSR (see here) highlighted that openness to trade and investment is an important building block of the resilience of the economy and would contribute to the recovery from the COVID-19 crisis. However, it also noted that EU rules on trade defence instruments (as well as competition and public procurement) do not apply to foreign subsidies that afford their recipients with an unfair advantage when acquiring EU companies, participating in public procurements in the EU, or engaging in other commercial activities in the EU. For example, the Impact Assessment indicated: Although subsidized steel imports can be addressed in trade defence investigations, subsidized steel companies increasingly seek to circumvent those rules (only applicable to trade in goods) via greenfield investments and acquisitions. Trade in services is not covered by the existing EU trade defence instruments. Services are therefore viewed as more vulnerable to possible distortions caused by subsidies. And despite the pandemic, some estimates continue to support that international trade in services could rise by 31% between 2019 and 2025. The FSR addresses such regulatory gaps, for example, by covering the provision of services in the Single Market, as it covers foreign subsidies to undertaking on processing advantage in an economic ordivity in the EU.
	undertakings engaging in an economic activity in the EU. Furthermore, the FSR indicates that it shall not prevent the EU from exercising its rights or fulfilling its obligations under international agreements.
	The Commission's <u>Q&A</u> on the FSR provides additional details (see <u>here</u>).
Council of the European Union prolongs and expands sanctions against Russia and Iran (see <u>here</u> and <u>here</u>)	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 available to the listed individuals and entities; and bans on certain exports/imports.
	Among the most recent developments to the EU sanctions regimes:
	• <u>Russia</u> : On 27 January 2023, the Council decided to extend restrictive measures by six months (until 31 July 2023) targeting <u>specific sectors of the economy of the Russian Federation</u> , including restrictions on finance, transport, defense, energy, technology, and trade. Such restrictions are subject to renewal every six months.
	These sanctions, 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 <u>first package of sanctions</u> (see <u>here</u>) and

now with the <u>ninth package of sanctions</u> (see <u>here</u>) adopted by the Council on 16 December 2022.*

EU restrictive measures against <u>individuals and entities</u> concerning asset freezes and travel restrictions now apply to a total of 1386 individuals and 171 entities. These are in place until 15 March 2023, subject to renewal every six months.

The EU restrictions also concern <u>economic relations</u> (e.g. certain import/export bans; certain bans on advisory/consultancy services) with the illegally annexed Crimea and the city of Sevastopol, the nongovernment controlled areas of the Donetsk and Luhansk oblasts, as well as Zaporizhzhia and Kherson.

A consolidated latest version of all Commission FAQs on implementation of sanctions adopted following Russia's military aggression against Ukraine is available <u>here</u>.

* An in-depth analysis of the ninth package of sanctions against Russia is available from the authors of the COVID-19 Update (see contact details below for Nadiya Nychay (Brussels) and Rick van 't Hullenaar (Amsterdam)).

Iran: On 23 January 2023, the Council added 18 individuals and 20 entities to the list of those subject to restrictive measures in the context of the existing Iran <u>human rights sanctions</u> regime (see <u>here</u>). This is in view of their role in the widespread and excessive use of force against non-violent protestors following the death of Mahsa Amini. The new designations include, in particular, governmental bodies and private companies providing security services and engaging in activities which prohibit, limit, or penalize the exercise of freedom of expression.

Restrictive measures now apply to a total of 164 individuals and 31 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. An export ban to Iran is also in place for equipment that might be used for internal repression or for monitoring telecommunications.

Earlier, to recall, in light of <u>Iran's military cooperation with Russia</u>, the Council had 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 <u>Unmanned</u> <u>Aerial Vehicles</u> (UAVs) used by Russia in its war against Ukraine (see <u>here</u>).

<u>Provision of humanitarian aid</u>: The Commission, to recall, has also provided guidance on the provision of humanitarian aid in compliance with EU sanctions. The Commission most recently published a Guidance Note in June 2022 (see <u>here</u>), which noted the importance of clarifying humanitarian exceptions to EU sanctions imposed in response to Russia's invasion of Ukraine, although the Guidance Note seeks to provide clarifications for all EU sanctions regimes.

This Guidance Note notably builds on previous guidance of August 2021 on the provision of humanitarian aid to fight the COVID-19 pandemic (clarification on COVID-19 vaccines and therapeutics, EU counter-terrorism sanctions and Iran, Nicaragua, Syria, Venezuela sanctions regimes) (see <u>here</u> and <u>Jones</u> <u>Day COVID-19 Update No. 59 of 21 August 2022</u>).

In particular, the Guidance Note provides a series of hypothetical cases on

the application of sanctions. These include various accompanying references to the August 2021 COVID-19 guidance as a source of clarification (e.g., If a designated (sanctioned) person intervenes in a humanitarian transaction, this does not automatically mean that the transaction must be abandoned. Insofar as no funds or economic resources are made available to a designated person, the Iran Regulations do not prohibit liaising with the former).

MEDICINES AND MEDICAL DEVICES

European Commission publishes conference report on Health Security in the EU: COVID-19 lessons learned (see here) On 25 January 2023, the European Commission published the conference report on Health Security in the EU: COVID-19 lessons learned and looking ahead to ensure a stronger EU Health Security Framework.

The conference, held on 22-23 November 2022, gathered participants from the public health field: government officials, scientists, and others working in organizations at local, national, EU and international level. As the pandemic recedes, the conference sought to examine "*What did we do right? What did we do wrong? And how should we prepare for next time? 'They say that those who do not learn from history are condemned to repeat it,' said Stella Kyriakides, EU Commissioner for Health and Food Safety.*"

The conference report examines the following:

<u>The EU's response to COVID-19</u>: Commissioner Kyriakides sets out four conclusions on the health structures and organizations in the EU:

- Most importantly, <u>EU solidarity and coordination are essential</u>, as no country was single-handedly prepared for COVID-19 pandemic's magnitude. To respond to the crisis, the EU erected a range of unprecedented initiatives. In particular, the EU Health Security Committee, established in 2001, proved to be a vital forum for coordinating measures based on the rapidly evolving pandemic. This is why its mandate is strengthened under the new European health security framework (see also Jones Day COVID-19 Update No. 95 of 9 January 2023);
- The COVID-19 pandemic revealed a lack of adequate structures in the EU to deal with the health crisis and the <u>need for a stronger EU</u> <u>health security framework</u> for building the European Health Union, which aims to fill these gaps. The new framework includes key measures that recently entered into force (i.e., Regulation on serious cross-border health threats; Regulation reinforcing the mandate of the European Centre for Disease Prevention and Control; and Regulation on the Emergency framework regarding medical countermeasures) (see also Jones Day COVID-19 Update No. 95 of 9 January 2023). The new framework, in particular, will strengthen the role of health professionals in information sharing and consultations, as well as the designation of European public health reference laboratories to promote harmonization between countries;
- The COVID-19 showed the need to <u>strengthen the development and</u> <u>distribution of medical countermeasures</u> in the context of a health emergency and in this anticipated age of pandemics. The European Health Emergency Preparedness and Response Authority (HERA) was created to address this need (*see also Jones Day COVID-19 Update No. 61 of 21 September 2021*) and whose mandate was

	reinforced with the Regulation on the Emergency framework regarding medical countermeasures <i>(see also <u>Jones Day COVID-19</u>)</i> <u>Update No. 90 of 28 October 2022</u>); and
	 <u>Global cooperation in health should be improved</u>, as it is essential to safeguard EU societies and economies. In response, the Commission has adopted an EU Global Health Strategy (see also <u>Jones Day</u> <u>COVID-19 Update No. 93 of 1 December 2022</u>) and is currently negotiating a legally binding international pandemic agreement.
	<u>Europe and the international response to COVID-19</u> : The report states that the EU's health security will be aligned with the WHO and the International Health Regulations (IHRs), in particular to prevent duplication of member state activities and with objectives such as building permanent support for vaccines and medical countermeasures. IHRs are currently under revision and seek to include the "7-1-7" target (i.e., spotting a health crisis in seven days, delivering a report in one day, and taking an effective response in seven days).
	<u>Continued action</u> : The report concludes by emphasizing the need for sustained vigilance and surveillance, as COVID-19 is not yet over, and future pandemics will occur. The Commission in particular, is planning to put a process in action following the conference, including webinars through the Health Policy Platform (HPP), which gathers public and private sector stakeholders. Regional workshops will focus on gaps in defences against cross-border health threats.
European Commission publishes report on survey on implementation of Clinical Trials Regulation (see <u>here</u>)	On 31 January 2023, the European Commission, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) published a Factual summary report of an EU Survey carried out on Targeted consultation on the implementation of the Clinical Trials Regulation (EU) No 536/2014.
	The Clinical Trials Regulation (CTR) became applicable on 31 January 2022 (see also Jones Day COVID-19 Update No. 75 of 1 February 2023) and is currently in its three year transition period. The CTR, in particular, introduced the Clinical Trial Information System (CTIS), a single entry point for clinical trials in the EU. The CTIS sought to respond to the COVID-19 pandemic, which revealed hurdles to carrying out multinational clinical trials. The CTIS aims to foster such multinational trials and to allow conducting coordinated assessments.
	As of 31 January 2023, all new clinical trial applications must be submitted to the CTIS, and no longer the procedure under the Clinical Trials Directive 2001/20/EC (implicating submitting applications to each concerned Member State (MS)). However, there is uncertainty among sponsors on the CTR's implementation. The survey aimed to collect feedback from sponsors on CTR implementation hurdles and whether the new requirements were clear to them.
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	Respondents raised various implementation difficulties related to:
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	 Use of CTIS, e.g., numerous technical problems; uncertainty over preserving confidentiality of commercially confidential information; The CTR itself, e.g., uncertainty over transparency obligations and requirements for patient facing materials; difficulties managing

requests for IMP (Investigational Medicinal Product) import permits; lack of harmonized document naming convention; and

 MS lack of preparedness, e.g., unprepared regarding access to CTIS; lack of communication between Ethics Committees and National Competent Authorities.

Responses to specific survey questions included, e.g.:

- On whether the CTR facilitates multinational clinical trials, a majority of responses indicated obstacles due to the rigidity of the process under CTR rules; the lack of certain CTIS functionalities; and different MS requirements;
- On whether the CTR ensures an attractive and favorable environment to carry out large-scale clinical research, two-thirds of respondents agreed that while the environment is rather attractive, this has not reached expected levels, due to, e.g., continued MS requests for largely the same information; difficulties using CTIS; and
- On whether there are inconsistencies between the CTR and other EU initiatives (e.g., the GDPR (General Data Protection Regulation) and European Health Data Space), the majority of respondents found none. Some respondents found inconsistencies between the GDPR and the In-Vitro Medical Devices Regulation.

The survey resulted in identifying 181 problems. The report indicates that some of these had already been resolved (e.g. fixes to CTIS functionalities); some were rejected (e.g., unclear response); and others issues persist, either in the absence of a solution, or because of lack of agreement on which solution to apply.

The Commission will continue to work with EMA and MSs to provide solutions to the issues raised in the survey. For example, on 13 January 2023, the Commission, the EMA and the HMA published a Q&A on the protection of commercially confidential information and personal data while using CTIS (see <u>here</u>), potentially resolving the issue of uncertainty over transparency requirements.

CYBERSECURITY, PRIVACY & DATA PROTECTION

ENISA publishes report on Engineering Personal Data Sharing (see <u>here</u> and <u>here</u>)	On 23 January 2023, the European Union Agency for Cybersecurity (ENISA) published the report on Engineering Personal Data Sharing – Emerging Use Cases and Technologies.
	The report highlights data's central role in the economy and for individuals. For example, the COVID-19 pandemic made evident the need for large-scale data gathering projects, in view of treating patients and scientific research.
	The report aims to show how data protection principles under the GDPR can be applied in practice by using technological solutions relying on advanced cryptographic techniques.
	First, the report focuses on <u>data sharing practices in the health sector</u> , which can strengthen coordination between public and private healthcare entities towards providing effective personalized healthcare, achieving public health goals and conducting scientific research. The report explores how specific technologies can support data protection needs. For example:

<u>Health data sharing for medical and research purposes</u>, whereby healthcare providers manage Electronic Health Records (EHRs) of patients' medical history. From a data protection perspective, the aim is to ensure that only authorized health service providers can access personalized information and that data shared for research purposes will include safeguards such as pseudonymization to avoid disclosure of patient identities.

Towards addressing these data protection concerns, the report refers to Polymorphic Encryption and Pseudonymization (PEP), which is viewed as an advanced cryptographic technique for data protection engineering that has demonstrated its applicability, e.g., in a Large-Scale Parkinson's Disease Study and as a proposal for the Dutch eID scheme.

Second, the report discusses <u>data sharing that occurs as part of another</u> <u>process or service</u>, whereby the data is processed through some secondary channel or entity before reaching its primary recipient. Often, this data sharing is not transparent to users. For example:

 <u>Mobile push notifications</u> use a third-party service to send push notifications, either in bulk or individually, to mobile phone users and transmitting various content, such as text and pictures. For personalized notifications, the information transmitted may include personal data, which then requires measures to address threats to privacy.

The report notes that, among other solutions, <u>encryption</u> of notification messages is the most straightforward measure to address at least certain privacy threats raised by mobile push notifications. However, currently, push notification deliveries are typically not performed using end-to-end encryption.

Lastly, the report identifies challenges and possible solutions regarding exercising the rights of data subjects, and in particular, regarding the principles of <u>lawfulness</u>, fairness and transparency (e.g., right of information and access) and <u>intervenability</u> (e.g., right to erasure, to rectification, to object). In particular:

- The role of data intermediaries is increasingly relevant, as these actors mediate between the suppliers of data, the data subjects, data storage providers, and data utilizers. Their role typically is not to use the data they share themselves or, if so, only for very limited primary purposes (such as hospitals using the personal data of patients to provide medical services to these patients).

For data intermediaries handling such data, the report raises the concept of <u>data altruism</u>, e.g., when a patient decides to allow processing of her medical data collected not just at the hospital, but also by research institutions that develop treatments, typically without compensation. Consideration could be given to flagging such data as released to the data intermediary under a data altruism "license", in order to correctly address subsequent demands from data utilizers with respect to this data.

<u>Conclusion</u>. Among the report's conclusions on data sharing, it notes that while relevant EU policy and law exist, uncertainties remain as to the type of appropriate technical and organizational measures and how these should be implemented. To ensure data sharing across the EU, practitioners should receive further guidance on relevant technologies and techniques and under which circumstances data protection principles can be met.

EDPB adopts 2022 report on first Coordinated Enforcement Action – Use of cloud-based services by the public sector (see <u>here</u> and <u>here</u>)

EDPB adopts 2022
report on first
CoordinatedOn 17 January 2023, the European Data Protection Board (EDPB) adopted a
report on the findings of its first Coordinated Enforcement Action,* which
focused on use of cloud-based services by the public sector. This focus was
selected for three main reasons:

- (i) all public administrations must guarantee the fundamental right to the protection of personal data;
- (ii) public authorities process large amounts of personal (and sometimes sensitive) data; and
- (iii) rapidly developing cloud technology in all sectors is creating new risks that must be addressed.

As noted by the EDPB, the uptake of cloud services doubled for enterprises across the EU between 2016 and 2021. Furthermore, the COVID-19 pandemic intensified a digital transformation of organizations, with many public sector organizations turning to cloud services.

In 2022, 22 Supervisory Authorities (SAs) across the EEA launched coordinated investigations into the use of cloud-based services by the public sector. The SAs addressed some 100 stakeholders from multiple public bodies, such as government ministries and independent public entities, and buyers and vendor managers for the central government.

The report analyzes the challenges faced by public bodies when procuring cloud services, and in particular, in using such services in compliance with the GDPR (General Data Protection Regulation) and EUDPR (Regulation on protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data). Among these challenges:

- Undertaking a Data Protection Impact Assessment (DPIA);
- Identifying the role and responsibilities of the parties when using a Cloud Service Provider (CSP);
- Difficulties of negotiating a tailored contract between public bodies and CSPs; and
- Difficulties of complying with the Schrems II judgment of the EU Court of Justice when carrying out international data transfers.

Moreover, the report provides an overview of the actions already taken by SAs at the national level, including guidance, letters, enforcement actions, as well as potential actions by SAs or stakeholders.

The report concludes that to ensure a GDPR-compliant implementation of cloud services, public bodies should assess and, if necessary, renegotiate cloud contracts with close involvement of the Data Protection Officer. Other follow-up actions may include, for instance, further engaging with the public bodies/stakeholders and the CSPs concerned on the issues raised, including by setting up technical working groups, or finalizing ongoing inspections, launching new investigations, and taking corrective measures where appropriate.

* This Coordinated Enforcement Action took place in the context of the EDPB's Coordinated Enforcement Framework (CEF). The CEF, established in October 2020, is a key action under the second pillar of EDPB's 2021-2023 Strategy, aiming at streamlining enforcement and cooperation among Supervisory Authorities.

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