



COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 95 | 9 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.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- European Commission extends anonymous whistleblower tool to cover all types of potential breaches of EU competition law
- European Commission approves further schemes under COVID Temporary Crisis Framework
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

Trade / Export Controls

- Council of the European Union adopts Regulation on a temporary market correction mechanism to protect against excessively high gas prices
- Council of the European Union adopts Regulation on temporary measures enhancing solidarity through better coordination of gas purchases and reliable price benchmarks

Medicines and Medical Devices

- European Commission publishes updated Rolling Plan on Implementation of Regulation on Health Technology Assessment
- European Commission's Health Security Committee issues Opinion for a common EU approach in response to COVID-19 situation in China
- Three Regulations forming the European Health Union enter into force
- HaDEA issues call for proposals to support implementing relevant results of innovative public health research related to COVID-19 vaccination

Cybersecurity, Privacy & Data Protection

- European Commission adopts third Report on EU Digital COVID Certificate
- European Data Protection Supervisor adopts Opinion on Proposal for Instant Credit Transfers Regulation

COMPETITION & STATE AID

Competition

European Commission extends anonymous whistleblower tool to cover all types of potential breaches of EU competition law (see [here](#))

On 9 January 2023, the European Commission announced the broadened scope of its anonymous antitrust whistleblower tool. By adding mergers and State Aid issues, the tool will now encompass all types of possible breaches of EU competition rules. The Commission expects that this full-scale approach will also create synergies across all areas of EU competition law.

The whistleblower tool, introduced in 2017, enables any person to anonymously report to the Commission cartels and other antitrust violations. With its expanded reach, persons may now also report potential merger-related infringements (e.g., gun jumping) and State aid violations.

To recall, the Commission encouraged use of the whistleblower tool to support its commitment during the COVID-19 pandemic to “*closely and actively monitor ... [and] detect companies which take advantage of the current situation to breach EU antitrust law*” (see also [Jones Day COVID-19 Update No. 2 of 3 April 2020](#)).

Since its launch, the tool has served to detect unlawful practices more quickly and strengthen existing cases to contribute to the success of the Commission's competition investigations. The whistleblowing tool receives some 100 messages each year.

Further details on the whistleblower tool are provide [here](#).

State Aid

European Commission approves further schemes under COVID Temporary Crisis Framework (see [here](#) and [here](#))

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.

With certain exceptions, the Temporary Framework applied until 30 June 2022.* Among the latest schemes (since 20 December 2022):

- €119.3 million in restructuring aid euros to allow the return to viability of the airline Air Austral; and €17.5 million in aid to compensate this company for damages suffered following the coronavirus pandemic.

** Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments (until 31 December 2022) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies*

European Commission approves further schemes under Ukraine Temporary

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

Crisis Framework
(see [here](#))

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 (see [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)).

Among the latest schemes under the Crisis Framework (since 20 December 2022):

- Amendments to an existing Slovenian scheme to support companies in the context of Russia's war against Ukraine, including, e.g., (i) an overall budget increase by €230 million; and (ii) an extension of the period, in relation to which aid may be granted, until 31 December 2023.
- €3 billion Polish scheme to support companies active in the Polish gas market in the context of Russia's war against Ukraine.
- €49 billion German scheme to support the economy in the context of Russia's war against Ukraine.
- Amendments to Irish scheme, including €200 million budget increase, to further support companies in the context of Russia's war against Ukraine.
- Amendments to Italian scheme, including up to €23 billion budget increase, to support companies in context of Russia's war against Ukraine.
- €6.3 billion German measure to recapitalize energy company SEFE GmbH in context of Russia's war against Ukraine.
- €34.5 billion German measure to recapitalize energy company Uniper SE in context of Russia's war against Ukraine.
- €1.1 billion Polish scheme to support particularly affected energy intensive companies in the context of Russia's war against Ukraine.
- French aid scheme aimed at supporting wind power capacity in the context of the war waged by Russia against Ukraine.
- Modification of a French aid scheme intended to support companies in the fishing sector in the context of the war led by Russia against Ukraine.
- Modification of a French aid scheme aimed at supporting companies in the fishing sector in the context of the war led by Russia against Ukraine, including, e.g., (i) an extension of the scheme until 31 December 2023; and (ii) an increase in the budget of €16.7 million.
- €50 million Slovak scheme to support the agricultural sector in the context of Russia's war against Ukraine.

- €80 million Finnish recapitalization measure to support Meyer Turku Oy in the context of Russia's war against 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

Council of the European Union adopts Regulation on a temporary market correction mechanism to protect against excessively high gas prices (see [here](#))

On 22 December 2022, the Council of the European Union adopted a Regulation establishing a temporary Market Correction Mechanism to protect against excessively high gas prices (*Council Regulation (EU) 2022/2578 of 22 December 2022*).

The Mechanism aims at reducing volatility on European gas markets while safeguarding the security of gas supply (see also [Jones Day COVID-19 Update No. 93 of 1 December 2022](#)).

Scope. The Mechanism will limit excessively high prices spikes on the main European gas exchange, the Dutch Title Transfer Facility (TTF)*. As the most commonly used European price benchmark, many gas contracts in Europe are currently indexed to the TTF.

The Mechanism will apply to month-ahead, three months-ahead and a year-ahead derivative contracts, which refer to the time during which the contract can be purchased at a certain price before it expires.**

Automatic activation. The Mechanism will be automatically activated if the following “market correction event” occurs: (i) the month-ahead price on the TTF exceeds 180€/MWh for three working days; and (ii) the month-ahead TTF price is 35€ higher than a reference price for LNG (Liquified Natural Gas) on global markets for the same three working days. Once activated, transactions will be prohibited where these concern natural gas futures that fall within the Mechanism's scope and where such transactions exceed a so-called “dynamic bidding limit” (i.e., the reference price for LNG on global markets (based on an international basket of LNG transaction hubs) plus 35€/MWh).

Automatic deactivation / suspension. The dynamic bidding limit is automatically deactivated if (i) it is below 180€/MWh for the last three consecutive working days; or (ii) if a regional or a Union emergency is declared by the European Commission according to the Regulation on Security of Supply (see [here](#)), notably where gas supply is inadequate to meet gas demand.

The Mechanism can be suspended by Commission decision in the event of

unintended market disturbances or manifest risks that negatively impact security of supply, intra-EU gas flows or financial stability, or if risks of increased gas demand are identified.

The Regulation enters into force on 1 February 2023 and shall apply for one year. The provisions related to the bidding limit will enter into force on 15 February 2023.

An infographic on the market correction mechanism provides further details (see [here](#)).

** The TTF is a “hub” or a “virtual trading point” of a so-called entry / exit system, where market players can transfer gas between each other. In addition to the Dutch TTF, other main gas hubs in Europe include, e.g., German Trading Hub Europe (THE); French Gas exchange point - North (PEG); Belgian Zeebrugge (Beach).*

*** Derivatives markets, notably with contracts concerning the future delivery of gas (e.g. month-ahead or longer) are essential for gas companies to hedge their financial risks when purchasing gas in volatile markets.*

Council of the European Union adopts Regulation on temporary measures enhancing solidarity through better coordination of gas purchases and reliable price benchmarks (see [here](#))

On 19 December 2022, the Council of the European Union adopted a Regulation on establishing temporary measures on enhancing solidarity through better coordination of gas purchases, reliable price benchmarks and exchanges of gas across borders (*Council Regulation (EU) 2022/2576 of 19 December 2022*).

The Regulation aims at containing high energy prices and improving supply security, including measures for strengthening solidarity in case of emergency and gas supply shortage, enhancing coordination of joint gas purchases, limiting gas and electricity price volatility, and setting reliable gas price benchmarks.

To recall, in announcing its proposal for this Regulation, the Commission noted the considerable worsening of the energy market situation since Russia's invasion of Ukraine, which aggravated an already constricted supply situation after the COVID-19 pandemic (see also [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)).

Joint gas purchasing is among the Regulation's main features, whereby gas companies and companies consuming gas in the EU and the Energy Community countries* will submit their gas import needs. The Commission will engage a service provider to calculate aggregated demand and pursue offers on the global markets to meet the total demand. Member States will require domestic undertakings to use the service provider to aggregate demand for volumes of gas equivalent to 15% of their respective gas storage filling obligations for 2023 (estimated 13.5 billion cubic metres for the entire EU).

To support organizing demand aggregation and joint purchasing of gas, the EU Energy Platform (a Commission-led coordination mechanism to secure the supply of gas, LNG, and hydrogen) will play a pivotal role in working with Member States and industry (see also [Jones Day COVID-19 Update No. 82 of 15 April 2022](#)).

Among the Regulation's other measures:

- Default rules and extended solidarity measures. The Regulation sets out default rules for sharing gas in case of a genuine emergency,

which will apply only if Member States have not concluded bilateral agreements setting the modalities of solidarity, as required under the Regulation on Security of Supply (see [here](#)). At present, only 6 out of the expected 40 solidarity agreements have been concluded.

The Regulation also extends solidarity measures, for example, by enabling Member States to request solidarity from other Member States to cases where they are unable to secure critical gas volumes needed for their electricity system. Clarified exceptions to these rules include, for instance, essential volumes of gas supplies for solidarity-protected customers (e.g., households), gas supplies for electricity needed to produce and transport gas, certain critical infrastructures and installations crucial to military, national security and humanitarian aid services.

- A new benchmark for gas prices, whereby the Agency for Cooperation of Energy Regulators (ACER) shall develop a new complementary price benchmark in view of providing stable and predictable pricing for LNG transactions, to be available by 31 March 2023. The reason for the new benchmark is that many gas contracts in Europe are indexed to the main European gas exchange, the Dutch Title Transfer Facility (TTF, as above-referred). The TTF, according to the Commission, no longer accurately reflects the price of LNG transactions in the EU.

The Regulation entered into force on 30 December 2022 and shall apply for one year.

An infographic on EU gas market measures to secure and share supply provides further details (see [here](#)).

** The Energy Community is an international organization bringing together the EU and its neighbors to create an integrated pan-European energy market. The EU is a Party to the Energy Community Treaty. The Community has nine Contracting Parties - Albania, Bosnia and Herzegovina, Kosovo, North Macedonia, Georgia, Moldova, Montenegro, Serbia and Ukraine. Armenia, Norway and Turkey take part as Observers.*

MEDICINES AND MEDICAL DEVICES

European Commission publishes updated Rolling Plan on Implementation of Regulation on Health Technology Assessment (see [here](#))

On 9 January 2023, the European Commission published an updated Rolling Plan on the Implementation of the Regulation on Health Technology Assessment (*Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021*, see [here](#) and [Jones Day COVID-19 Update No. 71 of 13 December 2021](#)).

The Regulation, to recall, aims to expand the availability of vital and innovative health technologies (e.g., new medicines, medical devices and equipment, as well as prevention and treatment methods) by ensuring the efficient use of resources and strengthening the quality of health technology assessment (HTA) across the EU. It establishes a support framework and procedures for cooperation on HTA at EU level. In particular, it lays down harmonized rules for the clinical assessments of medicinal products and medical devices conducted by competent authorities of the Member States.

When announcing the Regulation's adoption, European Commissioner for

Health and Food Safety, Stella Kyriakides, stated: “*With COVID-19, we have seen the importance of producing safe and efficient treatments and medical devices for all Europeans. The new rules will secure inclusiveness and transparency in the assessment process and increase predictability for Member States’ authorities and for the industry.*” (see [here](#)).

The updated Rolling Plan contains a list of key activities that the Commission has undertaken or plans to undertake to prepare for the implementation of the Regulation. These include, for instance:

- Meetings of the Member State Coordination Group on HTA (HTACG) (e.g., to nominate members of the subgroup on identification of emerging health technologies);
- Preparing implementing acts of the Regulation (e.g., on conflict of interest management);
- Meetings of the stakeholder network (e.g., assessment of applications to join the stakeholder network and publication of the list of selected stakeholder organizations).

The updated Rolling Plan also lists accomplishments in 2022 in relation to carrying out the Regulation’s provisions.

The Rolling Plan is subject to regular review in order to provide the most current information.

The HTAR entered into force on January 11, 2022. It will be applicable as of January 12, 2025.

European Commission’s Health Security Committee issues Opinion for a common EU approach in response to COVID-19 situation in China (see [here](#))

On 5 January 2023, the European Commission’s Health Security Committee (HSC)* of Directorate-General for Health and Food Safety issued an Opinion for a common EU approach in response to the COVID-19 situation in China.

According to the Opinion, COVID-19 cases in China have increased rapidly to reach record levels, while data remains limited and unreliable in relation to COVID-19 cases, hospital admissions, deaths, as well as ICU capacity and occupancy in China.

Given this ongoing situation in China, the HSC states that common and coordinated response at EU level is required. It proposes seven steps for a phased and proportionate EU approach by Member States:

1. Wastewater monitoring, in particular waters from airports with flights coming from China. The Commission and EU agencies will develop a protocol for the sampling of wastewater from aircraft;
2. Introducing a genomic surveillance program for SARS-CoV-2 based on random travelers at international airports, particularly focusing on passenger flights from China;
3. Carrying out epidemiological and virological surveillance, aiming to enhance the number and representativeness of sentinel sites and increase the number of tests performed. This includes encouraging the sequencing of hospitalized/ICU cases with a history of recent travel from China and sharing such data;
4. Issuing hygiene and health advice to travellers and aircraft and airport

personnel coming from or destined for China;

5. Considering introducing a pre-departure negative antigen test (taken not more than 48 hours before entry) or a negative Nucleic Acid Amplification Test (NAAT) COVID-19 test (taken not more than 48 hours and at latest 72 hours before departure), and where appropriate, randomly undertaking COVID-19 antigen tests upon arrival in EU/EEA countries;
6. Continue efforts to increase COVID-19 vaccination coverage, in particular in low coverage levels population groups and vulnerable groups; and
7. Additionally, the EU Integrated Political Crisis Response Arrangements** should deliberate on whether to require travellers arriving from China to the EU (if possible, also if travelling via a 3rd country) to show a pre-departure negative antigen test according to EU common list of COVID-19 antigen tests or a negative NAAT COVID-19 test, based on Council Recommendation (EU) 2022/2548 (point 2) on a coordinated approach to travel to the Union during the COVID-19 pandemic (see [here](#)).

The above approach is set out in view of taking a precautionary approach and with the aim to detect as early as possible a new SARS-CoV-2 variant in the EU/EEA.

* *The HSC is an advisory group composed by EU Health Ministers and chaired by a representative of the Commission. Its role is to strengthen coordination between Member States and exchange of good practices and information on national preparedness activities and national responses to serious cross-border health threats.*

** *The Integrated Political Crisis Response (IPCR) arrangements support rapid and coordinated decision-making at EU political level for major and complex crises, including acts of terrorism (further details [here](#)).*

Three Regulations forming the European Health Union enter into force (see [here](#), [here](#) and [here](#))

On 26 December 2022, three Regulations that are part of the European Health Union entered into force, following their publication in the EU Official Journal on 6 December 2022 (see also [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)).

The three Regulations include:

- Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU;
- Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (see [here](#)); and
- Consolidated Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control.

The Regulations are now directly applicable in all Member States.

HaDEA issues call for proposals to support implementing relevant results of innovative public health research related to COVID-19 vaccination (see [here](#))

On 21 December 2022, the Commission's European Health and Digital Executive Agency (HaDEA) announced a call for proposals to support Member States and other relevant actors to implement relevant results of innovative public health research in relation to vaccination against COVID-19.

In presenting this call for proposals, the Commission explained that the COVID-19 pandemic's need for rapid vaccination of entire populations created an unprecedented challenge for EU Member States (e.g., creating vaccination plans, adequate infrastructure and resourced vaccination services, communication and outreach activities to ensure high vaccine uptake).

The Commission also emphasized the need to improve efficiency and develop large-scale vaccination strategies, including in view of contributing to enhanced "catch-up" vaccination in the context of routine Member State vaccination programmes that may have been disrupted during the COVID-19 health crisis.

The call for proposals will fund actions that include, in particular:

- Mapping public health evidence and research results on COVID-19 large-scale vaccination in the EU and third states;
- Identifying challenges and assess solutions for its implementation at national level based on country-specific factors;
- Developing implementation plans and pilot activities to respond to the current or future for health crisis, and to optimize routine vaccination practices;
- Implementing pilot activities in volunteering EU countries (e.g. awareness-raising campaigns to tackle vaccine hesitancy, health preparedness training programmes, etc.); and
- Identifying successful pilot activities and, based on these, developing a robust sustainability plan for implementation and toolkits and recommendations for upscaling in other Member States.

The expected results and impact of these actions is to deliver an inventory of relevant innovative public health research on COVID-19 large-scale vaccination and implement plans in relevant Member States taking into account feasibility and country specific factors This will result, based on pilot projects implemented in several Member States and, after assessing these, in developing sustainability plans and toolkits and recommendations.

The call for proposals is open until 16 March 2023.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts third Report on EU Digital COVID Certificate (see [here](#))

On 22 December 2022, the European Commission adopted the third Report on the EU Digital COVID Certificate and its impact and implementation across the EU. This follows the second Report issued in March 2022 (see [Jones Day COVID-19 Update No. 79 of 16 March 2022](#)) and was issued pursuant to the EU Digital COVID-19 Certificate Regulation (Regulation (EU) 2021/953, see [here](#) and [Jones Day COVID-19 Update No. 83 of 28 April 2022](#)).

The Report notes that as of 31 October 2022, Member States had issued over 2.2 billion EU Digital COVID Certificates, comprised of 1.4 billion vaccination certificates, 660.8 million test certificates, and 96.4 million certificates of recovery.

As concerns the protection of personal data under the EU Digital COVID Certificate Regulation, the Report noted, in particular:

- The assessment of compliance of the EU Digital COVID Certificate Regulation with EU data protection rules included in the March 2022 Report still stands. Moreover, the Commission has ensured that all implementing and delegated acts adopted pursuant to the Regulation comply with the principle of data minimization.
- With regard to third countries connected to the system, participating countries must comply with relevant cybersecurity and data protection legislation. Additionally, the Commission systematically requires all Member States and third countries to submit a self-assessment to provide assurance that the country has taken specific account of particular risks, including as regards data protection. Finally, a rigorous “onboarding” process applies to all participating countries, and any failure to adhere to any of these requirements prevents connection to the EU Digital COVID Certificate framework.
- As EU law neither prescribes nor prohibits it, the domestic use of EU Digital COVID Certificates is a matter for Member States to decide. However, Member States are required to provide for a legal basis in national law, which must comply, among others, with data protection requirements.
- In the context of revoking certificates, the EU Digital COVID Certificate Regulation already provided that its trust framework may support the bilateral exchange of certificate revocation lists (i.e., lists that contain the unique certificate identifiers of revoked certificates).

For the purpose of facilitating the cross-border automatic exchange of certificate revocation lists via the central EU Digital COVID Certificate Gateway* in compliance with data protection requirements, the Commission, in cooperation with the Member States, developed the revocation mechanism specifications (see *Commission Implementing Decision 2022/483*, [here](#)).

The Report concludes that, for reasons of epidemiological vigilance, it remains prudent to maintain the EU Digital COVID Certificate system during the 2022-23 winter period. The Commission will continue to follow the epidemiological situation closely and re-assess the situation by end-March 2023. It will then decide whether to propose a further extension, or to have the Regulation expire in June 2023.

**To recall, the EU Digital COVID Certificate Gateway is the technical backbone of the COVID Certificate trust framework and enables verification of the digital signatures contained in the QR codes of all COVID certificates, without the processing of personal data (see [Jones Day COVID-19 Update No. 49 of 2 June 2021](#)).*

European Data Protection Supervisor adopts

On 19 December 2022, the European Data Protection Supervisor (“EDPS”) adopted an Opinion on the Proposal for a Regulation on instant credit transfers in euro (see [here](#) and [Jones Day COVID-19 Update No. 91 of 9](#)

**Opinion on
Proposal for
Instant Credit
Transfers
Regulation (see
[here](#))**

[November 2022](#)).

The proposed Regulation responds to the Commission's 2020 Retail Payment Strategy (see [here](#)), which noted that the COVID-19 pandemic further reinforced the shift to digital payments and included a call for an initiative aimed at the prompt and full uptake of instant payments (IPs) in the EU.

As underlined by the Commission in the Impact Assessment Report accompanying the proposed Regulation ([here](#)), the broad-scale adoption of IPs can also serve to support a quicker post-pandemic recovery of the European economy, as money is reinjected into the economy at a faster pace (i.e., IPs' very nature induces a higher velocity of money circulation in the economy).

The Regulation introduces, *inter alia*, two obligations relevant to data protection. The EDPS Opinion welcomed these two proposed measures aimed at solving problems related to instant credit transfers:

- Payment service providers must verify whether there is a match between the payment account identifier and the name of the payee provided by the payer. Where these do not match, that payment service provider shall notify the payer of any discrepancies detected and the degree of such discrepancies.

With regard to this first obligation, the EDPS notes that it would give payers the ability to compare their data with the system's response and make an informed decision as to whether it is safe to authorize the payment. Where this security feature is not necessary, the Proposal gives payers the possibility to opt-out, resulting in less processing of personal data.

Payment service providers must verify whether any of their payment services users is a listed person or entity immediately after the entry into force of any new or amended restrictive measure adopted pursuant to Article 215 TFEU providing for asset freezing or prohibition on making funds or economic resources available.

Regarding this second obligation, the EDPS welcomes the fact that it would direct practice towards a periodic verification method that can be implemented with the necessary diligence, such that false positives can be avoided and data subjects do not suffer from unwarranted payment refusals.

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