

COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 97 | 14 February 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

- European Commission releases Green Deal Industrial Plan
- European Commission consults Member States on proposed Temporary Crisis and Transition Framework
- European Commission seeks feedback on implementation of Foreign Subsidies Regulation
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

Trade / Export Controls

- European Commission releases Green Deal Industrial Plan
- Proposed CBAM Regulation (Carbon Border Adjustment Mechanism) moves forward
- EU-India Trade and Technology Council established

Medicines and Medical Devices

• Launch of DURABLE laboratory network

Cybersecurity, Privacy & Data Protection

• European Commission publishes guidance on Digital Services Act on requirement to publish number of users

COMPETITION & STATE AID

State Aid

European Commission releases Green Deal Industrial Plan (see here) On 1 February 2023, the European Commission published the Communication on A Green Deal Industrial Plan for the Net-Zero Age to boost the competitiveness of Europe's net-zero industry (the International Energy Agency estimates that the global market for key mass-manufactured clean energy technologies will be worth some EUR 600 billion by 2030 – more than three-fold today's level) and support the rapid transition to climate neutrality (this Plan "sets in stone" Europe's green transition ambitions, including climate targets towards net-zero by 2050). The Plan complements ongoing initiatives under the European Green Deal and REPowerEU.

The Plan aims at making Europe a leader in the green and digital transitions, in line with the EU's Industrial Policy devised in light of the pandemic and lessons learned (see also <u>Jones Day COVID-19 Update No. 47 of 12 May 2021</u>). The Plan notes, in particular, that industry faces numerous challenges, such as high inflation, post-COVID supply chains disruptions, spikes in energy costs and input prices, and labor shortages.

The Plan is based on <u>four pillars</u>: (1) a <u>predictable and simplified regulatory environment</u>; (2) <u>speeding up access to finance</u>; (3) <u>enhancing skills</u>; and (4) open trade for resilient supply chains.

On <u>speeding up access to finance</u> (second pillar), the Plan indicates that access to funding for net-zero industry is to be broadened and accelerated, particularly since EU industry's market shares are under strong pressure, which the Commission attributes to a "great extent" to subsidies abroad that it views as disrupting the level playing field. The Plan thus foresees the following revisions to State aid rules, and in particular:

- Adapting the existing Ukraine Temporary Crisis Framework, to be transformed into the proposed Temporary Crisis and Transition Framework (TCTF) for State aid (for further details on the proposed TCTF, see below). This aims at enabling Member States to boost investments in strategic sectors for the transition to a net-zero economy, in light of challenges facing industry due to the current Ukraine-Russia crisis and in view of the Commission's green and digital objectives. The proposed TCTF would focus on:
 - The rapid roll-out of aid to support renewable energy and decarbonizing the industry;
 - Investments in producing the strategic equipment necessary for the net-zero transition.

Timing. The draft State TCTF was sent to Member States on 1 February 2023 for consultation. The Commission intends to adopt the TCTF in the coming weeks, taking into account Member State feedback (*for further details, see below on Commission consulting with Member States on TCTF).*

 Revising the General Block Exemption Regulation (GBER) in light of the Green Deal, notably by:

- Increasing notification thresholds for support for green investments (e.g., hydrogen, carbon capture/storage, zeroemission vehicles and energy performance of buildings), which will afford Member States with greater flexibility to directly implement aid measures, without having to notify them ex ante to the Commission for approval; and
- Enlarging the scope of investment aid for recharging and refueling infrastructures.

Timing. The revised GBER's adoption is expected in the coming weeks.

 Important Projects of Common European Interest (IPCEI) related <u>projects</u>* would benefit, in particular, from the above GBER modifications, which would contribute to further streamlining and simplifying the approval implementation of smaller innovative IPCEI-related projects by small and medium-sized enterprises.

Furthermore, the Commission is working with Member States on a code of good practices for a transparent, inclusive and swifter design of IPCEIs that will facilitate a streamlined assessment.

Timing. The Commission and Member States are expected to endorse the code of good practice by spring 2023.

The Commission will also facilitate the use of existing EU funds for financing clean tech innovation, manufacturing and deployment, in addition to exploring ways to attain greater common financing at EU level to support investments in net-zero technology manufacturing.

For further details on the Green Deal Industrial Plan, see below section on Trade / Export Controls.

* Currently, the EU has five IPCEI projects undertaken by several Member States to fund new technologies in strategic areas: one in microelectronics; two in batteries; and two in hydrogen. Additional projects are in preparation (possibly additional batteries and hydrogen, or possibly solar or heat pumps projects).

European
Commission
consults Member
States on
proposed
Temporary Crisis
and Transition
Framework (see
here)

On 1 February 2023, the Commission announced the launch of its consultation with Member States on a draft proposal for a Temporary Crisis and Transition Framework (TCTF), which would transform the Ukraine Temporary Crisis Framework for State aid in view of further accelerating Europe's green transition. The proposed TCTF is part of the Green Deal Industrial Plan (for further details, see above on Industrial Plan).

European Commissioner for Competition and Executive Vice-President Margrethe Vestager also provided remarks on the proposed TCTF (see <u>here</u>).

Potential amendments under the proposed TCTF seek to promote renewable energy and decarbonizing of industry through measures aimed at, in particular:

Simplifying / expanding the scope of State aid rules and accelerating

their use by easing approvals by, e.g.:

- Broadening the current Ukraine Temporary Crisis Framework to allow Member States to support the deployment of <u>all possible</u> renewable sources of energy;
- Granting aid for less mature technologies (e.g., renewable hydrogen), without competitive bidding, but subject to certain safeguards to ensure its proportionality;
- Extending the deadline for project delivery to 36 months (the current Ukraine Temporary Crisis Framework limits Member States to supporting projects implemented within 30 months), in view of covering more projects while maintaining the incentive to accelerate renewable project deployment.
- Raising aid ceilings to spur investments aimed at significantly lowering emissions, in addition to <u>simplified aid calculations</u> (e.g., enabling Member States to provide aid as a fixed percentage of total investment costs).
- New provisions for green investments in strategic sectors at risk of relocation to the US or other third countries. Such provisions seek to address the current investment gap, and in particular:
 - Enabling Member State <u>support for those sectors affected by the US Inflation Reduction Act</u> (e.g., production of batteries, solar panels, wind turbines, heat-pumps, electrolyzers and carbon capture usage and storage, as well as related critical raw materials necessary to produce such equipment).
 - Allowing "matching aid" for projects occurring in disadvantaged regions in the EU (where the GDP per capita is below 75% of the EU average), or which involve an investment in several Member States and for which support in a third country is available. Such aid, intended to help to prevent diverting investments to higher bidders outside of Europe, will allow Member States to provide further proportionate aid to match the level of support offered in third countries, up to what is deemed necessary to enable the investment to be made in Europe.

Commissioner Vestager emphasized that <u>matching aid would be</u> <u>subject to various conditions</u> regarding how the aid is calculated, whether the investment is indispensable to the Green Deal, whether third country aid is actually present, and most importantly, whether other Member States would benefit from the project (such that other than in disadvantaged regions, aid should only be granted if the investment involves cooperation across different Member States).

Commissioner Vestager further underscored the <u>temporary nature of the measures</u> under the proposed TCTF. The new provisions would be in place until 31 December 2025, with aid to be granted within this period.

Member States may now comment on the Commission's draft proposal. The Commission intends to adopt the TCTF in the coming weeks, taking into account Member States' views.

European
Commission seeks
feedback on
implementation of
Foreign Subsidies
Regulation (see
here)

On 6 February 2023, the Commission opened its public consultation on the draft Implementing Regulation on detailed arrangements for the conduct of Commission proceedings pursuant to the Foreign Subsidies Regulation (FSR) (Regulation (EU) 2022/2560 on foreign subsidies distorting the internal market).

The FSR, which entered into force on 12 January 2023, affords the European Commission extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market (see also <u>Jones Day COVID-19</u> <u>Update No. 96 of 27 January 2023</u>).

To recall, the FSR enables the Commission to investigate financial contributions granted by non-EU authorities to companies active in the EU, based on (i) mandatory *ex ante* notifications of certain mergers and public procurement procedures benefitting from foreign financial contributions, in addition to (ii) investigations started on the Commission's own initiative (exofficio) in all other market situations.

The draft Implementing Regulation seeks to clarify the practical and procedural aspects related to applying the FSR, such as:

- Rules on, e.g., the calculation of time limits; timeline for submission of views following an opening of an in-depth investigation; access to the file, and rights of the parties (e.g., protection of confidential information); and
- Information required in the <u>notification forms</u> for <u>concentrations</u> (draft Annex I) and for public procurement procedures (draft Annex II).

The draft Implementing Regulation and notification forms will be finalized and adopted before the start of the FSR's application 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 (see also Jones Day Alert, "EU Foreign Subsidies Regulation Filings Mandatory Starting in October 2023" of December 2022, here).

Stakeholders may provide comments on the draft Implementing Regulation until 6 March 2023.

European
Commission
approves further
schemes under
Ukraine Temporary
Crisis Framework
(see here)

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 (see <u>Jones Day COVID-19 Update No. 90 of 28 October 2022</u>).

Among the latest schemes under the Crisis Framework (up to 14 February 2023):

- €116 million Belgian scheme to support companies in the context of Russia's war against Ukraine.
- €5.8 million Bulgarian measure to support the Burgas and Varna airports in the context of Russia's war against Ukraine.
- €100 million Slovenian scheme to support companies in the context of Russia's war against Ukraine.
- €15 million Finnish guarantee scheme to support electricity-trading companies in the Åland region in the context of Russia's war against Ukraine.
- Swedish scheme to reduce peak electricity consumption in the context of Russia's war against Ukraine, providing financial support to achieve the consumption reduction target set by Regulation (EU) 2022/1854 and moderate electricity prices. The aid will be allocated through a competitive bidding process open to all technologies that can deliver consumption reduction.
- Amendment to an existing Italian scheme to support companies active in the Region of Friuli Venezia Giulia in the context of Russia's war against Ukraine, including (i) a budget increase by €240 million; (ii) an extension of the scheme until 31 December 2023; and (iii) an increase of the maximum aid ceilings.
- €600 million Slovak scheme to support its economy in the context of Russia's war against Ukraine.
- €60 million Greek scheme to support the primary agricultural production sector in the context of the Russia's war against Ukraine.
- €5 million Italian measure to support bus operators providing tourist transport services 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. The Commission is now seeking to convert this Crisis Framework into a proposed new Temporary Crisis and Transition Framework (TCTF) (see above on Commission consulting with Member States on TCTF).

TRADE / EXPORT CONTROLS

European Commission releases Green Deal Industrial Plan (see here) On 1 February 2023, the European Commission published the Communication on A Green Deal Industrial Plan for the Net-Zero Age to boost the competitiveness of Europe's net-zero industry and support the rapid transition to climate neutrality. The Plan complements ongoing initiatives under the European Green Deal and REPowerEU.

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On <u>open trade for resilient supply chains</u> (fourth pillar), the Commission notes the vital role of trade policy in sustaining the EU's leadership in net-zero technologies by keeping the Single Market connected to growth outside of the EU, while securing access to key inputs for the clean transition. On <u>promoting</u> global cooperation, the EU will focus on, for instance:

- Continuing to develop the EU's network of Free Trade Agreements, while making full use of those already in place through effective implementation and enforcement.
- Pursuing cooperation with partners to support the green transition, such as the EU-US Task Force on the Inflation Reduction Act, launched in October 2022 (see here).
- Exploring raw materials partnerships with like-minded partners to create a Critical Raw Materials Club to bring together raw material "consumers" and resource-rich countries to safeguard global security of supply through a competitive and diversified industrial base.

The Commission also emphasized that <u>trade and competition on net-zero</u> <u>industry must be fair</u>, noting that some trade partner initiatives can negatively impact the EU's net-zero industries. In particular, the Commission indicates that China's subsidies have long surpassed the EU's by two-fold (relative to GDP), leading to market distortions such that China currently dominates various net-zero technologies.

Towards better combating the effect of unfair subsidies, prolonged market distortions, and unfair trade practices like dumping, the Commission will continue to defend the Single Market, in particular, by fully utilizing:

- Trade defence instruments (TDI) and rules-based international trade;
- The EU framework on foreign direct investment screening (see also Jones Day COVID-19 Update No. 69 of 29 November 2021); and
- The Regulation on Foreign Subsidies (FSR), which aims at ensuring that non-EU countries' subsidies do not distort competition in the Single Market (for further details, see above Section on State aid on Commission seeks feedback on implementation of the FSR).

Additionally, to boost industrial competitiveness, the Commission will <u>propose</u> a <u>Critical Raw Materials Act</u> to ensure security of supply. As manufacturing of EU net-zero technologies depends on access to relevant critical raw materials, the Act will aim at diversifying sourcing and recycling raw materials to lower the EU's dependence on highly concentrated supplies from third countries and promote growth in the circular economy.

For further details on the Green Deal Industrial Plan, see above section on State aid.

Proposed CBAM Regulation (Carbon Border Adjustment Mechanism) moves forward (see here) On 8 February 2023, the provisional agreement on the proposed CBAM Regulation (Carbon Border Adjustment Mechanism) was approved by the European Parliament (Environment Committee) and Council (Committee of Permanent Representatives (COREPER)). This provisional agreement had been reached on 15 December 2022 by negotiators of the Council and the European Parliament.

The proposed CBAM addresses greenhouse gas emissions embedded in imports into the EU of certain products in carbon-intensive industries, with the objective of ensuring equivalent carbon pricing for imports and domestic products. In this respect, the CBAM seeks to prevent the risk of so-called carbon leakage, whereby the EU's greenhouse gas emissions reduction efforts are jeopardized when businesses (i) increase emissions outside EU borders by relocating production to non-EU countries with less stringent policies to tackle climate change, or (i) increase imports of carbon-intensive products.

The proposed CBAM's <u>scope</u> would initially cover, in particular, specific products in some of the most carbon-intensive sectors: iron and steel, cement, fertilizers, aluminium, electricity and hydrogen. Indirect emissions would also be included in a well-defined manner.

The proposed CBAM is designed to operate in parallel with the <u>EU Emissions Trading System</u> (EU ETS),* to mirror and complement its functioning on imported goods. CBAM would gradually replace the existing EU mechanisms to address the risk of carbon leakage, and in particular the free allocation of EU ETS allowances for sectors covered by CBAM. The CBAM would equalize the price of carbon paid for EU products operating under the EU ETS and the one for imported goods. This would be done by requiring companies importing into the EU to purchase so-called CBAM certificates to pay the difference between the carbon price paid in the country of production and the price of carbon allowances in the EU ETS.

By way of background, CBAM is a key element of the <u>Fit for 55</u> package, a set of Commission proposals announced in July 2021 to update existing EU law to ensure that EU policies align with EU climate goals, and in particular, the reduction of net greenhouse gas emissions by at least 55% by 2030. Fit for 55 is part of the 2019 <u>European Green Deal</u> package of policy initiatives, which aims at guiding the EU to sustainability through a socially just transition. The Commission states that the importance of this basic goal has only been reinforced with the COVID-19 pandemic and the war in Ukraine. The European Green Deal's ultimate target is to attain climate neutrality by 2050.

<u>CBAM timing</u>: Under the provisional agreement, CBAM would begin to operate as from October 2023. Initially, a simplified CBAM would apply, essentially limited to reporting obligations. The full CBAM would be phased in gradually. To avoid double protection of EU industries, the length of the transition period and CBAM's full phase-in would be linked to the phase-out of the free allowances under the EU ETS. This would ensure compatibility of CBAM with international rules on trade.

The provisional agreement on the CBAM will now need formal approval by the European Parliament and Council. However, its formally adoption also depends on resolving other elements relevant for CBAM (e.g., reaching agreement on phasing out free allowances for CBAM sectors in the context of the ongoing negotiations to revise the EU ETS).

^{*} The EU ETS is one of the EU's key climate change mitigation policies and is the

world's first carbon market, aiming at providing an efficient mechanism to reduce emissions. Under the EU ETS companies must obtain emission allowances covering their carbon emissions. The default option is to purchase allowances at an auction, but these can also be allocated for free, which is a transitional method of allocating allowances.

EU-India Trade and Technology Council established (see here)

On 6 February 2023, the EU and India announced the establishment of the EU-India Trade and Technology Council (TTC) to tackle digital transformation, green technologies and trade, particularly in view of a rapidly changing geopolitical environment.

Both sides have agreed to work on the following critical areas, based on three working groups:

- Strategic technologies, digital governance and digital connectivity to work jointly on areas of mutual interest (e.g., digital connectivity, Artificial Intelligence, 5G/6G, high performance and quantum computing, semiconductors, cloud systems, cybersecurity, digital skills and digital platforms);
- Green & clean energy technologies, including focusing on exploring investment and standards, with emphasis on research and innovation (e.g., clean energy, circular economy, waste management, plastic and rubbish in the ocean); and
- Trade, investment and resilient value chains, focusing on supply chain resilience and access to critical components, energy, and raw materials. The group will also seek to resolve identified trade barriers and global trade challenges by promoting cooperation in multilateral fora.

The EU-India TTC is the EU's second such bilateral forum and the first one established by India with any partner. The EU-US TTC was launched in June 2021 (see also Jones Day COVID-19 Update No. 94 of 19 December 2022).

The EU-India TTC reinforces other initiatives such as the EU-India Strategic Partnership for strengthening the EU-India trade and investment relationship (see also <u>Jones Day COVID-19 Update No. 47 of 12 May 2021</u>). This includes promoting inclusive and sustainable economic growth and recovery from the COVID-19 pandemic.

<u>Next steps</u>. EU-India TCC Ministerial meetings will take place at least annually, with the first meeting anticipated in spring 2023.

The EU-India TCC Terms of Reference provide further details (here).

MEDICINES AND MEDICAL DEVICES

Launch of DURABLE laboratory network (see here)

On 1 February 2023, the Commission announced that DURABLE, the Health Emergency and Response Authority (HERA)* laboratory network, became operational. The Commission indicated that the launch of the DURABLE network is an important step in HERA's work to better prepare Europe for pandemics and other large-scale health threats.

DURABLE will aim at providing rapid and high-quality scientific information to support the EU in preparing for and responding to cross-border health threats and evaluating the impact of medical countermeasures. In particular, DURABLE will contribute to swift and effective testing, and enhanced characterization of pathogens that will inform the identification, development and purchase of appropriate medical countermeasures.

Complementing existing networks, DURABLE will be coordinated by Institut Pasteur and includes eighteen top-level laboratories within the EU.

DURABLE is funded with €25 million under the EU4Health Programme which, to recall, is the EU's €5.3 billion initiative for action in the field of health for the period 2021-2027 (see here). Established in 2021, the Programme aims at prioritizing financial resources to enable healthcare systems to cope with unforeseeable events, such as the COVID-19 pandemic, to foster innovation, and to modernize the public and private healthcare sectors in the long-term (see also Jones Day COVID-19 Update No. 93 of 1 December 2022).

* HERA is a Directorate-General of the European Commission, working to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, in particular by strengthening health security cooperation within the Union during preparedness and crisis times and by enabling the development, rapid availability, access and distribution of needed countermeasures and bolstering pandemic architecture for the EU.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European
Commission
publishes
guidance on
Digital Services
Act on
requirement to
publish number of
users (see here
and here)

On 1 February 2023, the European Commission released guidance on applying the Digital Services Act (DSA), publishing a "Questions and Answers on identification and counting of active recipients of the service under the Digital Services Act" (Q&A).

The DSA, which entered into force on 16 November 2022, is one of the measures taken as part of the EU Recovery Plan to lead Europe out of the COVID-19 pandemic (see <u>Jones Day COVID-19 Update No. 10 of 29 May 2020</u>).

To recall, the DSA introduces a uniform framework across the EU of rules and obligations on digital services that act as intermediaries in their role of connecting consumers with goods, services and content (e.g., online marketplaces, internet service providers, cloud services, messaging, social networks). The DSA complements other existing rules, and in particular, the GDPR (see also Jones Day COVID-19 Update No. 92 of 18 November 2022).

The Q&A; which is non-binding, aims to address practical questions from online platforms and online search engines regarding the DSA requirement to publish information on the "average monthly active recipients" of their services in the EU. Where such user numbers reach more than 10% of the EU's population (45 million users), the Commission may designate such providers as very large online platforms (VLOPs) or very large online search engines (VLOSEs). Consequently, they would be subject to additional obligations, such as making a risk assessment and undertaking corresponding risk mitigation measures.

The Q&A highlights, in particular, the following:

- Providers of online platform and of online search engine service(s)
 are not required to notify the average monthly active recipients to the
 Commission or competent Digital Service Coordinator/national
 authority, unless subject to a specific request by the Commission or
 Digital Service Coordinator under the DSA;
- On counting "active recipients" of online platform services, all recipients engaging with the service must be counted as active recipients of the service under the DSA. In particular, the concept of active recipient of the service does not necessarily coincide with that of a registered user of a service or a user that has carried out a transaction on the online platform;
- On <u>counting "active recipients" of online search engine services</u>, only those recipients that actively submit a query and are exposed to the content indexed and presented on the provider's online interface must be counted as active recipients; and
- With regard to <u>hybrid online platforms that allow consumers to conclude distance contracts with traders</u> (i.e. those providers that offer their own products/services alongside third-party products and services), all recipients interacting with their services (including both consumers and traders) must be counted as active recipients. Furthermore, even where their online interface contains content unrelated to the intermediary service, such as the provider's own content, all recipients of the service must be counted.

Moreover, the Q&A clarifies that providers of online platforms and online search engines should <u>avoid "double-counting" users</u> where possible, but shall not profile and track users in order to avoid such double-counting. The <u>DSA may not be understood as providing a ground to process personal data</u> or track users.

The DSA will be directly applicable across the EU and most provisions will apply as of 17 February 2024. Providers of online platform services were required to publish their number of active users by 17 February 2023.

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