

COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

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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 releases State of the Union 2021 report, including on COVID-related State aid
- European Commission consults on availability of private short-term export credit insurance capacity for exports in light of economic impact of pandemic
- European Commission distributes pre-financing under Recovery and Resilience Plans to an additional 3 Member States
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission launches Wise Persons Group on Challenges Facing the Customs Union
- European Union and ASEAN countries affirm strong trade and investment relations in most recent bilateral exchange

Medicines and Medical Devices

• European Commission establishes the Health Emergency Preparedness and Response Authority

Cybersecurity, Privacy & Data Protection

- Release of Third Country EU Digital COVID certificate Equivalence Decision Procedure
- EXPH issues draft Opinion on European Solidarity in Public Health Emergencies
- European Commission releases State of the Union 2021 report, including on EU Digital COVID Certificate

COMPETITION & STATE AID

State Aid

European Commission releases State of the Union 2021 report, including on COVID-related State aid (see here) On 15 September 2021, the Commission published the State of the Union 2021 report on the Commission's work and achievements over the past year and future goals, particularly in dealing with the pandemic, which made 2020 one of the most difficult years in Europe's history (for further details, see below Section on Cybersecurity).

On the issue of the path to economic recovery, the State of the Union report cites, in particular, the rapid adoption of the State aid temporary framework enabling Member States to exercise the full flexibility of EU State aid rules to provide necessary support to the economy during the pandemic, while maintaining a level playing field.

The report indicates that since March 2020, the Commission reached more than 629 decisions approving over EUR 3.08 trillion in COVID-19-related aid across the EU.

European
Commission
consults on
availability of
private short-term
export credit
insurance capacity
for exports in light
of economic
impact of
pandemic (see
here)

On 20 September 2021, the Commission opened a public consultation to assess the availability of private short-term export credit insurance capacity for exports to all countries listed as "marketable risk countries" in the 2012 Short-term export credit Communication ("STEC").* Export credit insurance shields sellers against risks raised by export credit used by foreign buyers to defer payment of goods and services.

To recall, under the STEC, trade within the EU and certain non-EU countries listed in its Annex with a maximum risk period of up to two years entails marketable risk and, in principle, should not be insured by the State or State-supported insurers. As private insurers may offer such insurance, the Commission considers that the State is not needed to offer similar insurance.

However, with the COVID-19 outbreak, the Commission decided on 27 March 2020 to temporarily remove all countries from the list of marketable risk countries under the STEC. This enabled Member States to make available public short-term export credit insurance in light of the increasing insufficiency of private insurance capacity for exports to all countries in the current crisis.

Based on the results of the public consultation, the Commission will assess whether the current temporary removal of all countries from the list of "marketable risk" countries remains justified and should be further prolonged after 31 December 2021.

Towards establishing the current sufficiency of private capacity for insurance of exports to those countries, the Commission seeks feedback from Member States, credit insurers and other interested parties on:

- Private credit insurance capacity, in view of determining availability of credit insurance from private insurers in all Members States in light of the pandemic.
- Activity of insurers acting on behalf of, or with State guarantee or the State itself in provision of short-term credit insurance for exports to all

countries in light of the pandemic.

 Corporate sector performance across the countries (e.g. forecast for 2022 in light of the pandemic, in particular on insolvencies).

The consultation is open for comments until 8 October 2021.

* The STEC is also undergoing review, and its public consultation closed on 23 September 2021. Adoption of the revised STEC is anticipated in Q4 2021. (see Jones Day COVID-19 Update No. 57 of 26 July 2021).

European
Commission
distributes prefinancing under
Recovery and
Resilience Plans
to an additional 3
Member States
(see here, here,
and here)

As of 20 September 2021, an <u>additional 3 Member States received prefinancing disbursements from the Commission</u> (Cyprus (€157 million); Latvia (€237 million); Slovenia (€231 million)) under the Recovery and Resilience Facility (RRF) towards boosting their economies and recovering from the COVID-19 fallout. This follows the preceding disbursements to 10 Member States: Belgium (€770 million); Denmark (€201 million); France (€5.1 billion); Germany (€2.25 billion); Greece (€4 billion); Italy (€24.9 billion); Lithuania (€289 million); Luxembourg (€12.1 million); Portugal (€2.2 billion); and Spain (€9 billion)). These sums are equivalent to approximately 13% of the respective countries' financial allocations.

The Commission will subsequently authorize additional disbursements based on satisfactorily fulfilling the milestones and targets, as set out in each of the Council Implementing Decisions, concerning investments and reforms covered in each Member State's Recovery and Resilience plan. The total amounts foreseen for these initial Member States receiving pre-financing are €5.9 billion (Belgium); €1.2 billion (Cyprus); €1.5 billion (Denmark); €39.4 billion (France); €25.6 billion (Germany); €30.5 billion (Greece); €191.5 billion (Italy); €1.8 billion (Latvia); €2.2 billion (Lithuania); €93.4 million (Luxembourg); €16.6 billion (Portugal); €1.8 billion (Slovenia); and €69.5 billion (Spain).

The disbursements follow the adoption of the <u>initial set of Council Implementing Decisions</u>, allowing up to 13% pre-financing, for the <u>approval of national Recovery and Resilience plans for 16 Member States</u> (Austria, Belgium, Croatia, Cyprus, Denmark, France, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia and Spain), who received the first green lights for use of EU recovery and resilience funds in July 2021 (see here).

Following positive assessments on 6 September 2021, <u>Council approvals are anticipated for 2 additional Member State Recovery and Resilience plans</u>, as earlier approved by the Commission: Czechia (€7 billion) and Ireland (€989 million). In addition, Malta's plan (€316.4 million) will undergo Council assessment following its recent approval by the Commission on 16 September 2021 (see here).

To recall, the Member State plans set out the reforms and public investment projects foreseen for implementation with the support of the RRF, the key component of NextGenerationEU, the EU's plan for rebounding from the COVID-19 crisis. The RRF will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5 billion and €360 billion in loans).

6 Member State plans also remain pending Commission approval (see here), with the following total amounts requested under the RRF: Estonia (€982.5 million); Finland (€2.1 billion); Hungary (€7.2 billion); Poland (€23.9 billion); Romania (€29.3 billion); and Sweden (€3.2 billion).

<u>Commission assessment of plans</u>. In evaluating the Member State plans under the criteria set out in the RRF Regulation, notably, the RRF guidelines make clear that the investment projects included in Member State recovery plans must comply with State aid rules.

The Commission published practical guidance for swift treatment of projects under State aid rules, as well as a number of sector-specific templates to help Member States design and prepare the State aid elements of their recovery plans (Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see here).

The Commission's appraisal of Member State plans will also, in particular, determine whether the plans dedicate at least 37% of expenditure to investments and reforms that pursue climate objectives and 20% to the digital transition.

Member State plans pending submission. The Commission will continue to closely engage with the 2 remaining Member States (i.e. Bulgaria and The Netherlands) to deliver robust national recovery plans. While Member States were invited to notify their plans before 30 April 2021, they may do so until mid-2022.

European
Commission
approves new and
amended Member
State measures to
support the
economy (see here
and here
and here)

Since the onset of the coronavirus outbreak, the Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework.

- €65 million Slovak scheme to support travel agencies in the context of the coronavirus outbreak.
- €3 billion French scheme to support companies in the context of the coronavirus outbreak.
- €1.8 million Latvian scheme to support cattle farmers in the context of the coronavirus outbreak.
- €500,000 Portuguese scheme to further support the passenger transport sector in Azores in the context of the coronavirus outbreak.
- €200 million Italian scheme to support companies active in the tourist-accommodation sector in the context of the coronavirus outbreak.
- €10 million Slovenian scheme to support companies active in certain tourism sectors in the context of the coronavirus outbreak.
- €1.24 billion Italian scheme to support companies hiring young workers in the context of the coronavirus outbreak.

TRADE / EXPORT CONTROLS

European
Commission
launches Wise
Persons Group on
Challenges Facing
the Customs
Union (see here)

On 17 September 2021, the Commission announced the launch of a new experts group, the Wise Persons Group ("WPG"), which will focus on identifying solutions for the most pressing challenges facing the EU Customs Union.

The Commission highlighted the significance of the EU trading block, the largest in the world (followed by the US and China), which accounts for over

15% of world trade. Imports from third countries into the EU reached over EUR 2 trillion in 2019, and in recent years, a large proportion of these imports comes from e-commerce.

During the COVID-19 pandemic, the Commission indicates that customs authorities were very effective in dealing with the challenges that emerged by:

- serving an essential role in speeding up the delivery of critical medical goods and preventing the entry of dangerous goods from the EU external border.
- prioritizing the delivery of PPE, medical devices and medicines, as well as food supplies, when shortages in several Member States were reported.
- contributing to efforts to control the export of COVID vaccines.

Despite these successes, the Commission considers that the EU Customs Union faces multiple other challenges, including the continued rise of ecommerce, fulfilling the twin green and digital transitions, and finding ways to guard against unsafe and/or counterfeit goods, etc. Therefore, the WPG's main task will be to develop innovative solutions to such challenges and to identify other potential challenges that the EU Customs Union could face in the future.

The WPG aims to finalize a report by Spring 2022 to be presented, in particular, to Commissioner Gentiloni, head of the EU Customs Union, to the Council, and to the European Parliament.

European Union and ASEAN countries affirm strong trade and investment relations in most recent bilateral exchange (see here) On 14 September 2021, the European Union and ASEAN Member States met virtually for the Seventeenth ASEAN Economic Ministers (AEM)-EU Trade Commissioner Consultations. The meeting underlined the strong trade and investment relations between the two regions, with the EU representing ASEAN's second largest trading partner in 2020, and endorsed the ASEAN-EU Trade and Investment Work Programme 2020-2021.

Representatives of the two blocs, in particular, recognized the adverse consequences of the COVID-19 pandemic and emphasized the importance of global cooperation, to promote equitable access and distribution of quality vaccines, including COVID-19 vaccines, and related goods.

The representatives also noted the importance of leveraging digitalization and sustainable development to bolster economic resilience, as well as the improved outlook of global economic and trade growth. To build on this, it will be key for the EU and ASEAN to pursue closer economic engagement and strengthen their economic cooperation.

MEDICINES AND MEDICAL DEVICES

European Commission establishes the Health Emergency Preparedness and Response On 16 September 2021, the Commission adopted a Decision establishing the European Health Emergency Preparedness and Response Authority (HERA), which will become fully operational by early 2022.

Drawing on the lessons of the COVID-19 pandemic, HERA aims at strengthening the ability of the European Union to prevent, detect and swiftly

Authority (see here)

respond to cross-border health emergencies by means of coordinated action.

The HERA will be tasked with two functional "modes":

(i) under the <u>preparedness mode</u>, HERA will anticipate threats and potential health crises by carrying out threat assessments, gathering intelligence, advanced R&D for medical countermeasures, boosting industrial capacity, procuring and distributing medical countermeasures, increasing stockpiling capacity and strengthening knowledge and skills.

In particular, in addressing market challenges and boosting industrial capacity, HERA will build on the work done by the Task Force for Industrial Scale up of COVID-19 vaccines. HERA, in this respect, will establish a close dialogue with industry, a long-term strategy for manufacturing capacity and investment, and address supply chain bottlenecks.

(ii) under the <u>emergency mode</u>, in case of a public health emergency at EU level, HERA can rapidly switch to emergency operations, including swift decision making and the activation of emergency measures (e.g., emergency funding and launching mechanisms for monitoring, and new targeted development and purchase of medical countermeasures and raw materials).

HERA activities will rely on a budget of €6 billion from the current Multiannual Financial Framework for the period 2022-2027. HERA's functioning will be annually reviewed and adapted until 2025, when it will undergo a full review.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Release of Third Country EU Digital COVID certificate Equivalence Decision Procedure (see here) On 16 September 2021, the European Union set out its Third Country EU Digital COVID certificate Equivalence Decision Procedure. Third countries can follow this procedure in view of linking their certificates with the EU's Digital COVID Certificate and further assuring the right to free movement within the EU.

Under the Regulation on EU Digital COVID Certificates (Regulation 2021/953), the European Commission may adopt an implementing act establishing that COVID-19 certificates issued by a third country are to be considered as equivalent to certificates issued by Member States.

The Equivalence Decision Procedure, which will help third countries to receive such implementing act for its certificates, generally provides as follows:

- First, third countries must self-assess whether its system complies with EU's specifications covering data structure and encoding mechanisms by use of a provided checklist.
- Second, third countries should submit a conclusive, formal request to receive an equivalence decision from the Commission. The compatibility of the certificate will be tested through a technical screening process.
- Third, a positive decision by the Commission's technical team will result in an implementing act that will allow the third country's certificate to go live within the EU.

Currently, 16 third countries have received an Equivalence Decision (i.e., Albania, Andorra, Faroe Islands, Iceland, Israel, Liechtenstein, Monaco,

Morocco, North Macedonia, Norway, Panama, San Marino, Switzerland, Turkey, Ukraine, and the Vatican City State), and 5 countries are at the technical screening stage (see here).

EXPH issues draft **Opinion on** European Health **Emergencies** (see here)

On 13 September 2021, the European Commission's Expert Panel on Effective Ways of Investing in Health (EXPH) issued its draft Opinion on European solidarity in public health emergencies. According to the Panel, the Solidarity in Public COVID-19 pandemic exposed many weaknesses in solidarity between the EU and its Member States. Shortcomings in acting in a concerted matter have led to calls to strengthen coordination at EU level.

> With regard to digital health data, the Opinion's view is that solidarity can be achieved by transparent use, collection and analysis of data, international collaboration, cross-border data sharing and incorporation of wide legal obligations protecting individuals from the misuse of personal data. In addition, centralized databases, Al and data science could help authorities in evaluating and improving capabilities and responses.

> On transforming and fostering transparent and accountable governance of public and private sector data, the Panel advocates a leading role for the EU in view of safeguarding privacy. The EU has done so, for example, by creating a common framework to exchange data via the European Health Data Space and proposed Data Governance Act.

Furthermore, the EU should ensure global cooperation by initiating or enhancing international dialogues enabling reciprocity in privacy-enhanced data sharing.

On 16 September 2021, stakeholders participated in a Commission hearing to share their views on the draft Opinion (see here). Participants may provide any additional comments by 1 October 2021, and the Panel is expected to finalize its work on the Opinion in the coming months.

European Commission releases State of the Union 2021 report, including on EU Digital **COVID Certificate** (see here)

On 15 September 2021, the Commission published the State of the Union 2021 report on the Commission's work and achievements over the past year and future goals, particularly in dealing with the pandemic, which made 2020 one of the most difficult years in Europe's history (for further details, see above Section on State aid).

On the issue of re-opening Europe, the report cites, in particular, the EU Digital COVID Certificate, which aims to facilitate safe travel within the EU and the verification of necessary documentation by authorities and airlines (see also Jones Day COVID-19 Update No. 57 of 26 July 2021). By end-August 2021, some 400 million COVID Certificates had been generated, and aviation activity had reportedly recovered to over 70% of the pre-crisis level.

To recall, the COVID Certificate can be used as proof of vaccination, recent negative test result, or recovery from the virus. Each EU Digital COVID Certificate contains a QR code with a digital signature to protect it against falsification. To ensure proper verification of the certificates across the EU, the Commission also developed a secure digital infrastructure to connect the national systems, which went live on 1 June 2021.

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