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NOTE

From:	Presidency
To:	Ad hoc Working Party on the propsals on Digital Green Certificate
No. Cion doc.:	7128/21
Subject:	Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

Delegations will find in the Annex a Presidency compromise text on the above-mentioned proposal for further discussion at the Ad Hoc Working Party on the proposals for a Digital Green Certificate on 29 March 2021.

Changes compared to the Commission proposal are marked in **bold/underline** for additions and in ~~bold/strikethrough~~ for deletions. New changes compared to the previous version are also grey shaded.

ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Every citizen of the Union has the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council[1] lays down detailed rules as regards the exercise of that right.

(2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.

(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19

[1] Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

pandemic[2]. That Recommendation establishes a coordinated approach on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas. In view of their specific situation, the Recommendation also emphasises that essential travellers, as listed in its point 19, and cross-border commuters, whose lives are particularly affected by such restrictions, in particular those exercising critical functions or essential for critical infrastructure, should in principle be exempted from travel restrictions linked to COVID-19.

(5) Using the criteria and thresholds established in Recommendation (EU) 2020/1475, the European Centre for Disease Prevention and Control ('ECDC') has been publishing, once a week, a map of Member States, broken down by regions, in order to support Member States' decision-making[3].

(6) ~~As emphasised by Recommendation (EU) 2020/1475 any,~~ **Member States may restrict free movement for public health reasons. Any** restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health **as emphasised by Recommendation (EU) 2020/1475**. It is necessary for such limitations to be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services[4].

(7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.

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2 OJ L 337, 14.10.2020, p. 3.

3 Available at: https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement

4 OJ C 96I, 24.3.2020, p. 1.

(8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their free movement rights, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.

(9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID-19.

(10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery, entitled "Digital Green Certificate" should be established.

(11) This Regulation should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.

(11a) This Regulation should not cover Member States' decisions to impose or waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19. The use of the digital green certificate in view of lifting restrictions should remain the responsibilty of Member States.

(12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.

(13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates[5]. Given the available and easily accessible technological means, such as high-resolution printers and various graphics editor software, fraudsters are able to produce high-quality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.

5 https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates

(14) To ensure interoperability and equal access, **including for persons with disabilities**, Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both. This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. To avoid obstacles to free movement, **and although there may be a charge for related services, such as the tests carried out**, the certificates **themselves** should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.

(15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates[6] adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU[7] should form the basis for the trust framework.

(16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, by the Member State of vaccination or test, or where the recovered person is located. **Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States.** Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or other similar formalities.

(17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See. ~~in particular where they are vaccinated by a Member State.~~

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6 Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf

7 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

(18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be conditional on an implementing act to be adopted by the Commission establishing that such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it would accept certificates issued by the Member States.

(19) Regulation (EU) 2021/XXXX applies to third-country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.

(20) The framework to be established for the purpose of this Regulation should seek to ensure coherence with global initiatives, in particular involving the WHO. This should include, where possible, interoperability between technological systems established at global level and the systems established for the purpose of this Regulation to facilitate free movement within the Union, including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated by third countries, this Regulation should provide for the acceptance of certificates issued by third countries to Union citizens and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.

(21) To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates **to** ~~for~~ persons receiving vaccines that have been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council[8], ~~for~~ vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the European Parliament and of the Council[9], or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.

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8 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

9 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

(22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the possibility to obtain a certificate on COVID-19 vaccination that complies with this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.

(23) Member States should also issue such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide reliable proof to that effect.

(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021[10]. These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

(25) Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.

[10] Available at : https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

(25a) Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No 726/2004, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, [efficacy follow-up and] supervision procedures of medicinal products authorised pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follows shared standards and is done in a consistent way on behalf of all Member States. Member States' participation in the review and endorsement of the assessment is ensured through various committees and groups, which also benefits from the expertise from across the EU Medicines Regulatory Network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the authorisation and data on efficacy as well as safety and on the consistency of the batches being used for vaccination of citizens.The obligation to accept, under the same conditions, valid vaccination certificates issued by other Member States should therefore coverCOVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.

(26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended **or allowed, such as children**, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.

(27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts[11]. As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection[12].

(28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU[13], which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates[14].

(29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown. **Such problems are compounded for persons who cannot be vaccinated yet, in particular children, for whom test results may be the only way to travel in case restrictions are in place.**

(30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

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11 https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

12 OJ L 392, 23.11.2020, p. 63.

13 OJ C 24, 22.1.2021, p. 1.

14 https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

(31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.

(32) According to existing evidence, persons who have recovered from COVID-19 can continue to test positive for SARS-CoV-2 for a certain period after symptom onset[15]. Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.

(33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS-CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.

(33a) Taking into account the latest scientific and technological developments and in light of the epidemiological evolution of the COVID-19 pandemic, the Commission should be empowered to address, based on relevant guidance from the ECDC, Member States' need to further supplement the certificates making up the Digital Green Certificate by establishing a certificate confirming that the holder has immunity or is at low risk of reinfection with COVID-19 based on a reliable test, such as serological testing for antibodies against SARS-CoV-2.

[15] https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

(34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council[16] to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.

(35) In order to ensure uniform conditions for the implementation of the trust framework certificates established by this Regulation, implementing powers should be conferred on the Commission. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[17].

(36) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the technical specifications necessary to establish interoperable certificates, imperative grounds of urgency so require or when new scientific evidence becomes available.

(37) Regulation (EU) 2016/679 of the European Parliament and of the Council[18] applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. The legal basis for processing for other purposes is to be provided for in national law, which must comply with Union data protection legislation.

(38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the certificates should be set out in this Regulation.

(39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.

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16 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

17 OJ L 55, 28.2.2011, p. 13.

18 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

(40) This Regulation does not create a legal basis for retaining personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.

(41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it denies entry to such persons.

(42) In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. ~~Therefore, the Regulation's provisions on the "Digital Green Certificate" framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director-General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended.~~ **This Regulation should apply for [18] months from the date of its entry into force.** ~~(43)~~ **At the latest** [Six] months before the end of the application of this Regulation, taking into account he evolution of the epidemiological situation on the pandemic, the Commission should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection. ~~one year after the Director-General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended~~.

(44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[19]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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19 OJ L 123, 12.5.2016, p. 1.

(45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non-discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.

(47) The European Data Protection Supervisor has been consulted pursuant to Article 42(1) of Regulation (EU) 2018/1725[20],

HAVE ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").

It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.

[20] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the 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, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 2
Definitions

For the purposes of this Regulation, the following definitions apply:

(1) "holder" means the Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.

(2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;

(3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID-19;

(4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA);

(5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;

(6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;

(7) "barcode" means a method of storing and representing data in a visual, machine-readable format;

(8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;

(9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;

(10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.

Article 3
Digital Green Certificate

1. The interoperable Digital Green Certificate **framework** shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:

   (a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');

   (b) a certificate indicating the holder's result**, type** and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01[21] ('test certificate');

   (c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test ~~or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01~~ ('certificate of recovery').

The Commission shall publish the list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01, including any updates.

1a. The Commission is empowered to adopt delegated acts in accordance with Article 11 to supplement the certificates referred to in paragraph 1 by adding provisions on the issuance and cross-border verification and acceptance of a certificate confirming that the holder has immunity or is at low risk of reinfection with COVID-19 based on a reliable test, in particular serological testing for antibodies against SARS-CoV-2, where the Commission has received guidance to this effect pursuant to paragraph 6 ('immunity certificate').

This certificate shall contain the following categories of data:

(a) identification of the holder;

(b) information about the test carried out;

(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

Any such delegated act shall also set out the data fields on the categories of data to be included in the certificate. The acceptance of such certificates shall take place under the conditions referred to in Article 7(5).

[21] Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

2. Member States shall issue the certificates referred to in paragraph 1 in a digital or paper-based format, or both. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.

3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder. **Appropriate fees may be charged in case of repeated loss.**

3a **The certificate shall include the following text:**

"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures applied at the point of destination."

4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other purposes, in particular for medical purposes.

5. Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Article 5(5).

   The Commission shall assess whether such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

6. **Where necessary,** the Commission **shall** ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU**, the European Center for Disease Prevention and Control or the European Medicines Agency** to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, **in particular in view of newly emerging SARS-CoV-2 variants of concern**.

Article 4
Digital Green Certificate trust framework

1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.

2. The trust framework shall **seek to** ensure~~, where possible,~~ interoperability with technological systems established at international level.

3. ~~Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this sub-paragraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5).~~

   ~~The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).~~

Article 5
Vaccination certificate

1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.

2. The vaccination certificate shall contain the following categories of ~~personal~~ data:

   (a) identification of the holder;

   (b) information about the vaccine medicinal product administered;

   (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

   The ~~personal~~ data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, ~~on the categories of personal data mentioned in this paragraph~~ **where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.**

3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) and shall clearly indicate whether or not the vaccination course has been completed.

4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.

Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID-19 vaccine having received a WHO Emergency Use Listing.

5a. **Possession of a vaccination certificate shall not be a precondition to exercise free movement rights.**

Article 6
Test certificate

1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.

2. The test certificate shall contain the following categories of ~~personal~~ data:

(a) identification of the holder;

(b) information about the test carried out;

(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The ~~personal~~ data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields ~~on the categories of personal data mentioned in this paragraph~~ **where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.**

3. The test certificate shall be issued in a secure and interoperable format as provided for in Article 3(2).

4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept**, under the same conditions,** valid test certificates issued by other Member States in compliance with this Regulation.

Article 7
Certificate of recovery

1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.

   The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.

2. The certificate of recovery shall contain the following categories of ~~personal~~ data:

   (a) identification of the holder;

   (b) information about past SARS-CoV-2 infection **following a positive test**;

   (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

   The ~~personal~~ data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields ~~on the categories of personal data mentioned in this paragraph~~, including until when a certificate of recovery shall be valid, **where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.**

3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).

4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

5. Where Member States accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.

New Article 7a

COVID-19 certificates and other documentation issued by a third-country

1. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with a vaccine medicinal product that corresponds to one of the types of COVID-19 vaccines referred to in paragraph 5 of Article 5 and where the authorities in a Member State have been provided with all necessary information, including reliable proof of vaccination, they may, upon request, issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. A Member State shall not be required to issue a certificate for a vaccine not authorised for use in its territory.

2. Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates issued by third countries or Overseas Countries and Territories, to Union citizens and their family members according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.

The Commission shall assess whether certificates issued by a third country or Overseas Countries and Territories fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuat to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).

4. **If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article 5 (5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.**

Article 8
Technical specifications

To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:

(a) securely issue and verify the certificates referred to Article 3;

(b) ensure the security of the personal data, taking into account the nature of the data;

(c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;

(d) lay down the common structure of the unique certificate identifier;

(e) issue a valid, secure and interoperable barcode;

(f) ensure**, where possible,** interoperability with international standards and/or technological systems;

(g) allocate responsibilities amongst controllers and as regards processors, **in accordance with Article 28(3) of Regulation 2016/679**.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).

On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).

Article 9
Protection of personal data

0. **Regulation (EU) 2016/679 shall apply to the processing of personal data carried out when implementing this Regulation.**

1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed **only** for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.

2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.

3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.

4. The authorities **or other designated bodies** responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.

Article 10
Notification procedure

~~1.~~ **Member States shall notify Member States and the Commission on the acceptance of the certificates referred to in Article 3 and the conditions thereof.** Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it **imposes other restrictions on holders of such certificates** ~~denies entry to such persons~~, it shall notify the other Member States and the Commission **thereof.** ~~before the planned introduction of such restrictions.~~ To that end, the Member State shall supply the following information:

(a) the reasons for such restrictions ~~including all relevant epidemiological data supporting such restrictions~~;

(b) the scope of such restrictions, specifying **the holders of which certificates** ~~which travellers~~ are subject to or exempt from such restrictions;

(c) the date and duration of the restrictions.

The Commission may make this information publicly available.

~~Where necessary, the Commission may request additional information from the Member State concerned.~~

Article 11
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 5(2), 6(2), 7(1) **and** ~~,~~ 7(2) ~~and 15~~ shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].

3. The delegation of power referred to in Articles 5(2), 6(2), 7(1) **and** ~~,~~ 7(2) ~~and 15~~ may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) **and** ~~,~~ 7(2) ~~and 15~~ shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 12
Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 13
Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 14

Transitional provisions

Member States may issue the certificates referred to in Article 3 in a format which does not comply with the requirements of this Regulation until [1month] after the entry into force of this Regulation. During this period, certificates issued in accordance with this Article shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5) .

~~*Reporting*~~

~~One year after the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.~~

~~The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID-19 pandemic.~~

Article 15

*Entry into force, applicability **and reporting***

1. This Regulation shall enter into force on**, and apply from,** the ~~third~~ day ~~following that~~ of its publication in the *Official Journal of the European Union*.

2. **The Regulation shall apply for [18] months from the date of its entry into force.**

At the latest [six] months before the end of the application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement as well as on the protection of personal data during the COVID-19 pandemic.

This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.

~~2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended.~~

~~*3.* The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director-General of the World Health Organization declares a public health emergency of international concern in relation to *SARS-CoV-2, a variant thereof, or similar* infectious diseases with epidemic potential. *Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.*~~

~~4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.~~

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*