Council of the European Union

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COVID-19 219	**TRANS 320**
JAI 583	**COCON 35**
POLGEN 77	**COMIX 275**
FRONT 194	**CODEC 742**
FREMP 140	**SCHENGEN 43**
IPCR 66	**AVIATION 131**
VISA 103	**PHARM 95**
MI 378	**RELEX 464**
SAN 316	**TOUR 35**

OUTCOME OF PROCEEDINGS

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To:	Delegations
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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 (EU Digital COVID Certificate) – 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 third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (EU Digital COVID Certificate) = Confirmation of the final compromise text with a view to agreement

At its meeting on 21 May 2021, the Permanent Representatives Committee agreed the final compromise texts, as set out in the Annex to this note, with a view to reaching agreement with the European Parliament.

Council of the European Union
General Secretariat

SGS 21 / 002394

Brussels, 21 May 2021

Mr Juan Fernando López Aguilar
Chairman, European Parliament Committee on LIBE
BRUSSELS

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 (EU Digital COVID Certificate)**

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 third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (EU Digital COVID Certificate)

Dear Mr López Aguilar,

Following the informal meeting between the representatives of the three institutions, a draft overall compromise package was agreed today by the Permanent Representatives' Committee.

I am therefore now in a position to confirm that, should the European Parliament adopt its position at first reading, in accordance with Article 294 paragraph 3 of the Treaty, in the form set out in the compromise package contained in the Annex to this letter (subject to revision by the lawyer linguists of both institutions), the Council would, in accordance with Article 294, paragraph 4 of the Treaty, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position.

On behalf of the Council I wish to warmly thank the Rapporteur and the Shadow Rapporteurs for the flexibility shown in particular during the last phase of the negotiations, as well as all the staff involved for the hard work on this file.

Yours sincerely,
Nuno Brito

Nuno BRITO
Chair of the Permanent Representatives Committee (Part 2)

Copy to: Didier Reynders, Commissioner

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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 (EU Digital COVID 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 fundamental 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.

[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).

(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 Union 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 pandemic. 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 general 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[2].

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

(6) Member States may, in accordance with Union law, limit the fundamental right of free movement for reasons of public health. 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 be strictly limited in scope and time, in line with the efforts to restore free movement within the Union, and should 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 medical and healthcare 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[3].

(6a) Although this Regulation is without prejudice to Member States' competence to impose restrictions, in compliance with Union law, to limit the spread of COVID-19, it should contribute to facilitating the gradual lifting of such restrictions in a coordinated manner, whenever possible in accordance with Council recommendation 1475/2020. Such travel restrictions could be waived in particular for vaccinated persons, in line with the precautionary principle, to the extent scientific advice on the effects of vaccination becomes increasingly available and consistently conclusive on the fact that vaccination helps in breaking the transmission chain.

[3] OJ C 96I, 24.3.2020, p. 1.

(7) Persons who are vaccinated or have a recent negative diagnostic test or persons, who have recovered from COVID-19 within the last 6 months, seem to have a reduced risk of infecting people with SARS-CoV-2, according to current scientific knowledge which is still evolving. The free movement of persons who based on sound scientific evidence do not pose a significant 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. When the epidemiological situation allows for it, such persons should not be subject to additional restrictions of free movement linked to the COVID-19 pandemic, such as travel-related testing for SARS-CoV-2 infection or travel-related self-isolation/quarantine, unless such additional restrictions are, based on the latest available scientific evidence and in line with the precautionary principle, necessary and proportionate and non-discriminatory to safeguard public health.

(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 vaccination certificates need to be fully interoperable, compatible, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles, technical standards and level of protection of such certificates.

(9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, and to hinder the proper functioning of the internal market, including the tourism sector, 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.

(9a) The European Parliament called in its resolution of 3 March 2021 on establishing an EU strategy for sustainable tourism for a harmonised approach across the EU on tourism, both implementing common criteria for safe travel, with an EU Health Safety protocol for testing and quarantine requirements and calling for a common vaccination certificate, once there is sufficient evidence that vaccinated persons do not transmit the virus, or mutual recognition of vaccination procedures.

(9b) In their statement of 25 March 2021, the Members of the European Council called for preparations to start on a common approach to the gradual lifting of restrictions, to ensure that efforts are coordinated when the epidemiological situation allows for an easing of current measures, and for the legislative and technical work on COVID-19 interoperable and non-discriminatory digital certificates to be taken forward as a matter of urgency.

(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 "EU Digital COVID Certificate" should be established, which should be binding and directly applicable in all Member States. It should facilitate, whenever possible on the basis of scientific evidence, a gradual lifting of restrictions in a coordinated manner by the Member States, also taking into account the lifting of restrictions within their territory. Regulation XXX/2021 (twin Regulation) extends this common framework to third-country nationals who are legally resident or staying in the Schengen area without controls at internal borders and applies as a matter of Schengen acquis, without prejudice to the specific rules on the crossing of internal borders set out in Regulation (EU) 2016/399 (Schengen Borders Code). Facilitating freedom of movement is one of the key preconditions for starting an economic recovery.

(11) This Regulation is intended to facilitate the application of the principles of proportionality and non-discrimination with regard to possible restrictions to free movement during the COVID-19 pandemic, while pursuing a high level of public health protection, and should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic, given their detrimental effects on citizens and businesses. Any verification of the certificates making up the EU Digital COVID Certificate should not lead to further restrictions on the freedom of movement within the Union or restrictions on travel within the Schengen area. 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 and the specific situation of cross-border communities, who have been particularly affected by such restrictions, should be taken into account. At the same time, the "EU Digital COVID Certificate" framework will ensure that interoperable certificates are also available to essential travellers.

(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[4]. 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.

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

(13a) It is important that sufficient resources are made available to implement this Regulation and to prevent, detect, investigate and prosecute fraud and illicit practices regarding the issuance and use of the EU Digital COVID Certificate.

(14) To ensure interoperability and equal access, including for vulnerable persons such as persons with disabilities and for persons with limited access to digital technologies, Member States should issue the certificates making up the EU Digital COVID Certificate in a digital or paper-based format, or both. The prospective holders should be entitled to receive the certificate in the format of their choice. This should allow the prospective holder to request and receive a paper copy of the certificate and/or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode only 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. To ensure a high level of confidence in the integrity and authenticity of certificates, Member States should, where possible, prioritise the use of advanced electronic seals as defined in Regulation (EU) 910/2014. 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, the certificates should be issued free of charge, and citizens should have a right to have them issued. To prevent abuse or fraud, appropriate fees may be charged in case of repeated loss. Member States should issue the certificates making up the EU Digital COVID Certificate automatically or upon request, ensuring that they can be obtained easily and swiftly, and providing, where needed, the necessary support to allow for equal access by all citizens. A separate certificate is to be issued for each vaccination, test or recovery, which is not to contain data from any previous certificates except where information contained in a prior certificate is to be included in a later certificate.

(14a) Authentic certificates making up the EU Digital COVID Certificate should be individually identifiable by means of a unique certificate identifier, taking into account that citizens might be issued more than one certificate during the course of the COVID-19 pandemic. The unique certificate identifier is composed of an alphanumeric string, and Member States should ensure that it does not contain any data linking it to other documents or identifiers, such as to passport or identity card numbers, in order to prevent linkage to directly identify the holder. The unique certificate identifier may only be used for its intended purpose, including for requests for the issuance of a new certificate if the certificate is no longer available to the holder, and the revocation of certificates. The unique certificate identifier also avoid the need to process other personal data that would otherwise be necessary to identify individual certificates. For medical and public health reasons and in the event of fraudulent certificates, Member States may establish and exchange with other Member States for the purpose of this Regulation certificate revocation lists in limited cases in particular in order to revoke certificates that have been issued erroneously, fraudulently or following the suspension of a vaccine batch found to be defective. Certificate revocation lists should contain no personal data with the exception of the unique certificate identifiers. Holders of revoked certificates should be promptly informed about the revocation of their certificates and the reasons for the revocation.

(14b) Issuance of certificates pursuant to this Regulation should not lead to discrimination based on the possession of a specific certificate.

(14c) Universal, timely and affordable access to COVID-19 vaccines and tests for SARS-CoV-2 infection, which form the bases for the issuance of the certificates making up the EU Digital COVID Certificate, are crucial in the fight against the COVID-19 pandemic and essential to restore the freedom of movement within the European Union. To facilitate travel, Member States are encouraged to ensure affordable and widely available testing possibilities, taking into account that not the entire population will have had the opportunity to be vaccinated by the date of application of this Regulation.

(15) The security, authenticity, integrity and validity of the certificates making up the EU Digital COVID 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 infrastructure should be developed, with a strong preference for the use of open source technology, to function on different major operating systems while ensuring that that infrastructure is protected from cybersecurity threats. The trust framework should ensure that the verification of a certificate can happen offline and without informing the issuer or any other third party about the verification. The trust framework should be based on a public-key infrastructure with a trust chain from Member States' health authorities or other trusted authorities to the individual entities issuing the certificates. The trust framework should allow for detection against fraud, in particular forgery. The outline on the interoperability of health certificates[5] adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU[6] should form the basis for the trust framework.

(16) Pursuant to this Regulation, the certificates making up the EU Digital COVID 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, whatever their nationality, 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, including when they are issued in Overseas Countries and Territories or the Faroe Islands on behalf of a Member State. Where relevant or appropriate, the certificates should be issued to another person on behalf of the vaccinated, tested or recovered person, for example to the legal guardian on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or any other similar formalities.

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

6 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).

(16b) In accordance with Council Recommendation (EU) 2020/1475, Member States should pay particular attention to persons who are considered to be frontier workers, cross-border workers and border residents and who reside in another Member State to which they return as a rule daily or at least once a week.

(17) The certificates making up the EU Digital COVID Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See.

(18) 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 and the International Civil Aviation Organisation (ICAO). This should include, where possible, interoperability between technological systems established at global level or by third countries with which the European Union has close links 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 or tested by third countries or by Overseas Countries or Territories referred to in Article 355 (2) TFEU or listed in Annex II thereto or the Faroe Islands, this Regulation should provide for the acceptance of certificates issued by third countries or by Overseas Countries or Territories or the Faroe Islands 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) For the purpose of facilitating 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 and guidance made available by the Health Security Committee, ECDC and the European Medicines Agency (EMA), 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 and should contribute to the gradual lifting of travel restrictions. 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 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[7], for vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the European Parliament and of the Council[8], or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.

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7 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).

8 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 right to obtain a certificate on COVID-19 vaccination that complies with this Regulation given that the EU Digital COVID Certificate provides the mutually accepted framework to facilitate free movement. Where Union citizens or their family members are not in possession of a certificate that complies with the requirements of this Regulation, in particular because they have been vaccinated before the date of application of this Regulation, they should be given every reasonable opportunity to corroborate or prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State. This should not be understood as affecting the obligation of Member States to issue certificates that comply with the requirements of this Regulation nor the right of Union citizens or their family members to receive, from Member States, certificates that comply with the requirements of 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 may also issue upon request such vaccination certificates to persons who have been vaccinated in a third country and provide all necessary information, including reliable proof to that effect. This is of particular importance to allow the persons concerned to make use of an interoperable and accepted vaccination certificate when exercising their right of free movement within the Union. This should apply in particular to EU citizens and family members vaccinated in a third country for whom the health system of a Member State allows for the issuance of a EU Digital COVID Certificate and provided that the Member State has been provided with the reliable proof of vaccination. A Member State should not be required to issue a certificate where the vaccine concerned is not authorised for use on its territory. There is no requirement for Member States to issue such vaccination certificates at consular posts.

(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021[9]. 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. Where Member States lift restrictions to free movement on the basis of a proof of vaccination, they should not subject the vaccinated persons to additional restrictions of free movement linked to the COVID-19 pandemic, such as travel-related testing for SARS-CoV-2 infection or travel-related self- isolation/quarantine, unless such additional restrictions are, based on the latest available scientific evidence, necessary and proportionate and non-discriminatory to safeguard public health.

[9] 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 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 cover COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. In order to support the work of WHO and to strive for better global interoperability, Member States are in particular encouraged to accept vaccination certificates issued for other COVID-19 vaccines having completed the WHO Emergency Use Listing process.

(25b) 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 completed the WHO Emergency Use Listing process. Where one of these COVID-19 vaccines is subsequently granted marketing authorisation pursuant to Regulation (EC) No 726/2004, the obligation to accept, under the same conditions, would also cover valid vaccination certificates issued by a Member States for that COVID-19 vaccine, regardless whether the certificates were issued before or after the authorisation via the centralised procedure.

(26) It is necessary to prevent direct or indirect 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 administered 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 and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries or any other means of transport. In addition, this Regulation cannot be interpreted as establishing an obligation or right to be vaccinated.

(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[10]. 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[11].

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

[11] OJ L 392, 23.11.2020, p. 63.

(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[12], 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[13].

(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. In this context, the cost of tests needs also to be taken into account. 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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12 OJ C 24, 22.1.2021, p. 1.

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

(30a) The use of rapid antigen tests would serve to facilitate the issuance of test certificates on an affordable basis. Universal and affordable access to COVID-19 vaccines and tests for SARS-CoV-2 infection, which form the basis for the issuance of the certificates making up the EU Digital Covid Certificate , are crucial in the fight against the COVID-19 pandemic. Among others, easy access to inexpensive rapid antigen tests meeting quality criteria can contribute to lower costs for citizens, in particular for persons who cross borders daily or frequently for work or education, to visit close relatives, to seek medical care, or to take care of loved ones, for other essential travellers, for economically disadvantaged persons, and students. On 11 May 2021, the Health Security Committee adopted an updated list of rapid antigen tests, increasing the number of rapid antigen tests recognised as meeting quality criteria to 83. Several Member States are already providing large-scale testing possibilities to their populations on this basis. To support Member States' testing capacity, the Commission has mobilised 100 million Euros to purchase over 20 million rapid antigen tests. EUR 35 million were also mobilised through an agreement with Red Cross to increase testing capacity in Member States through mobile testing capacities.

(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. Where the epidemiological situation allows for it, holders of negative test certificates should not be subject to additional restrictions of free movement linked to the COVID-19 pandemic, such as additional travel-related testing for SARS-CoV-2 infection upon arrival or travel-related self-isolation/quarantine, unless such additional restrictions are, based on the latest available scientific evidence, necessary and proportionate and non-discriminatory to safeguard public health.

(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[14]. 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. For the purpose of facilitating 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 eleven days after the date on which the person was first subject to a NAAT test for SARS-CoV-2 infection which produced a positive result 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. Where Member States lift restrictions to free movement on the basis of a certificate of recovery they should not subject the recovered persons to additional restrictions of free movement linked to the COVID-19 pandemic, such as travel-related testing for SARS-CoV-2 infection or travel-related self-isolation/quarantine, unless such additional restrictions are, based on the latest available scientific evidence, necessary and proportionate and non-discriminatory to safeguard public health.

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

(33a) Taking into account the latest scientific and technological developments, the Commission should be empowered to adapt the provisions on the certificate of recovery by providing for its issuance on the basis of a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically reliable method by means of a delegated act. This delegated act should include the necessary data fields on the categories of data defined by this Regulation to be included in the certificate. It should also contain specific provisions on the maximum validity period as it might depend on the type of the test carried out.

(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[15], the European Center for Disease Prevention and Control or the European Medicines Agency 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 infected.

(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[16].

(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.

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15 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).

16 OJ L 55, 28.2.2011, p. 13.

(37) Regulation (EU) 2016/679 of the European Parliament and of the Council[17] 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 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. Member States may process such data for other purposes, if the legal basis for processing of such data for other purposes, including the related retention periods, is provided for in national law, which must comply with Union data protection legislation, the principles of effectiveness, necessity and proportionality, and should contain provisions clearly identifying the scope and extent of the processing, the specific purpose involved, the categories of entities that can verify the certificate as well as the relevant safeguards to prevent discrimination and abuse, taking into account the risks to the rights and freedoms of data subjects. As provided for in this Regulation, personal data accessed during the verification process is not to be retained where the certificate is used for non-medical purposes.

(37a) Where a Member State has adopted or adopts, based on national law, a system of COVID-19 certificate for domestic purposes, it should ensure that certificates making up the EU Digital COVID Certificate can also be used and are also accepted for this purpose, in order to avoid that persons travelling to another Member States using a certificate making up the EU Digital COVID Certificate are obliged to obtain an additional national certificate for the duration of this Regulation.

(38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data strictly 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.

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[17] 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).

(39) For the purposes of this Regulation, personal data on individual certificates do not need to be transmitted/exchanged across borders. In line with the public-key infrastructure approach, only the public keys of the issuers need to be transferred or accessed across borders, which will be ensured by an interoperability gateway set up and maintained by the Commission. In particular, the presence of the certificate combined with the public key of the issuer should allow for the verification of the authenticity and integrity of the certificate. For the prevention and detection of fraud, Member States may exchange lists of revoked certificates. In line with the principle of data protection by default, verification techniques not requiring transmission of personal data on individual certificates should be employed.

(40) This Regulation prohibits retention of personal data obtained from the certificate by the Member State of destination or transit or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic. This Regulation does not provide a legal basis for setting up or maintaining a centralised database at Union level containing personal data.

(40a) In accordance with Regulation (EU) 2018/1725, the Commission is to consult the European Data Protection Supervisor when preparing delegated acts or implementing acts that impact on the protection of individuals' rights and freedoms with regard to the processing of personal data. The Commission may also consult the European Data Protection Board where such acts are of particular importance for the protection of individuals' rights and freedoms with regard to the processing of personal data.

(40b) In accordance with Regulation 2016/679, the data controllers and processors of personal data are to take adequate technical and organisational measures to ensure a level of security appropriate to the risk of the processing.

(40c) The authorities or other designated bodies responsible for issuing the certificates making up the EU Digital COVID Certificate, as controllers under Regulation (EU) 2016/679, are accountable for how they process personal data in the scope of this Regulation. This includes ensuring a level of security appropriate to the risks, including by establishing a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing. The powers of the supervisory authorities established under Regulation (EU) 2016/679 apply in full, in order to protect natural persons in relation to the processing of their personal data.

(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 imposes other restrictions on holders of such certificates.

(41a) Clear, comprehensive and timely communication to the public including holders, on the purpose, issuance and acceptance of each type of certificate making up the EU Digital COVID Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.

(41b) A phasing-in should be provided to give Member States which are unable to issue certificates in the format that complies with the requirements of this Regulation from the date of its application, the possibility to continue issuing certificates which are not yet in compliance with this Regulation. During the phasing-in period, such certificates as well as certificates issued before the date of application of this Regulation should be accepted by Member States provided they contain the necessary data.

(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. This Regulation should apply for 12 months from the date of its application. Four months after the date of application of this Regulation, the Commission should present a report to the European Parliament and the Council. At the latest 3 months before the end of the application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic, the Commission should publish a second report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection.

(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 data fields to be included in the certificates based on the categories of data defined 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. 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.

(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 and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725[18] and delivered a joint opinion on 31 March 2021,

[18] 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).

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 recovery for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic ("EU Digital COVID Certificate"). It shall also contribute to facilitating the gradual lifting of restrictions of free movement put in place, in compliance with Union law, to limit the spread of COVID-19, in a coordinated manner.

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 in full compliance with Regulation (EU) 2016/679.

Article 2

Definitions

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

(1) "holder" means the person 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) "EU Digital COVID 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 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

(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;

(5a) “antibody test” means a laboratory-based test aiming to detect if a person has developed antibodies against SARS-CoV-2, thus indicating that the holder has been exposed to SARS-CoV-2 and has developed antibodies, regardless of whether he or she was symptomatic or not;

(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 electronic seal as defined in Article 3(25) of Regulation (EU) 910/2014 of the European Parliament and the Council;

(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, by the use of electronic seals.

Article 3

EU Digital COVID Certificate

1. The interoperable EU Digital COVID 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[19] carried out by health professionals or by skilled testing personnel in the Member State issuing the certificate ('test certificate');

   (c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test carried out by health professionals or by skilled testing personnel ('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.

2. Member States, or designated bodies acting on behalf of Member States, shall issue the certificates referred to in paragraph 1 in a digital or paper-based format, or both. The prospective holders shall be entitled to receive the certificates in the format of their choice. The certificates issued by Member States shall be user-friendly and 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.

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[19] 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).

2a. A separate certificate shall be issued for each vaccination, test or recovery, which shall not contain data from any previous certificates except where information contained in a prior certificate is to be included in a later certificate as provided for in this Regulation.

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, including with regard to the vaccination, test or recovery status of the holder, or if 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 travelling, please check the applicable public health measures and related restrictions applied at the point of destination."

Member States shall provide the holder with clear, comprehensive and timely information on the issuance and purpose of the vaccination certificate, test certificate, and/or recovery certificate for the purposes of this Regulation.

3b. Possession of a EU Digital COVID Certificate shall not be a precondition to exercise free movement rights.

3c. Issuance of certificates pursuant to paragraph 1 shall not lead to discrimination based on the possession of a specific certificate referred to in Articles 5, 6 and 7.

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.

4a. Cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic shall ensure that the verification of the certificates is integrated into the operation of cross-border transport infrastructure such as airports, ports, and railway and bus stations, where appropriate.

5. Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates equivalent to those 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 Articles 5(5), 6(5) and 7(5).

The Commission shall assess whether such a third country issues certificates equivalent to those issued 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 Centre 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

EU Digital COVID 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.

1a. The trust framework shall be based on a public key infrastructure to verify the integrity and the authenticity of the certificates referred to in Article 3. The trust framework shall allow for detection against fraud, in particular forgery, and may also support the bilateral exchange of certificate revocation lists containing the unique certificate identifiers of revoked certificates. Such certificate revocation lists shall not contain any other personal data. The verification of certificates referred to in Article 3, and where applicable, certificate revocation lists shall not result in the notification of the issuer about the verification.

2. The trust framework shall seek to ensure interoperability with technological systems established at international level.

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. That person shall be informed of his/her right to a vaccination certificate.

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 and information about the number of doses;

(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 modifying or removing data fields, or by adding data fields falling under the categories of personal data mentioned in points (b) and (c) of 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) after the administration of each dose 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 completed the WHO Emergency Use Listing process. Where Member States accept valid vaccination certificates issued 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 completed the WHO Emergency Use Listing process, they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States.

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. That person shall be informed of his/her right to a test certificate.

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 modifying or removing data fields, or by adding data fields falling under the categories of personal data mentioned in points (b) and (c) of 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 and taking into account the specific situation of cross-border communities, 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).

The certificate of recovery shall be issued at the earliest eleven days after the date on which the person was first subject to a NAAT test for SARS-CoV-2 infection which produced a positive result.

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 modifying or removing data fields, or by adding data fields falling under the categories of personal data mentioned in points (b) and (c) of 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 certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).

3a. Based on guidance received pursuant to Article 3(6), the Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the provisions in Article 3(1)(c) and Article 7(1) to allow for the issuance of the certificate of recovery also based on a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically validated method. Any such delegated act shall add, modify or remove the data fields falling under the categories of personal data mentioned in paragraph 2 points (b) and (c).

3b. Following the adoption of the delegated act referred to in Article 3a, the Commission shall publish the list of antibodies tests on the basis of which a certificate of recovery may be issued, to be established by the Health Security Committee, including any updates.

3c. The Commission shall assess, when presenting the first report provided for in Article 14a (1), the appropriateness and feasibility, based on available scientific evidence, to adopt a delegated act as referred to in paragraph 3a. Until that point in time, the Commission shall seek regular guidance pursuant to Article 3(6) on the available scientific evidence and level of standardisation regarding the possible issuance of certificates of recovery based on serological testing for antibodies against SARS-CoV-2, also taking into account the availability and accessibility of such tests.

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.

Article 7a

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

1. Where a vaccination certificate has been issued in a third country for a vaccine medicinal product that corresponds to one of the COVID-19 vaccines referred to Article 5(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 on its territory.

2. Where the Commission has adopted an implementing act pursuant to the second sub-paragraph, certificates referred to in Article 3 issued by third countries according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation that allow 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 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).

   The Commission shall make publicly available the list of implementing acts adopted pursuant to this subparagraph.

3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuant 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.

5. This Article shall also apply to COVID-19 certificates and other documentation issued by Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and by the Faroe Islands. It shall not apply to COVID-19 certificates and other documentation issued in Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and in the Faroe Islands, issued on behalf of 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) seek to ensure interoperability with international standards and/or technological systems;

(g) allocate responsibilities amongst controllers and as regards processors, in accordance with Chapter IV of Regulation 2016/679;

(gb) ensure accessibility for persons with disabilities to the human-readable information contained in the digital certificate and in the paper-based certificate in line with the accessibility requirements included in Union law legislation.

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). Implementing acts adopted on the basis of this sub-paragraph shall remain in force for the duration of the applicability of this Regulation.

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. For the purpose of this Regulation, 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. After the end of applicability of this Regulation, no further processing shall occur.

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 transit, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, only 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 by the issuer longer than is strictly 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.

3a. Any certificate revocation lists exchanged between Member States in the context of the trust framework established in Article 4 shall not be retained longer than the duration of the applicability of this Regulation.

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.

4a. The natural or legal person, public authority, agency or other body that has administered the vaccine or carried out the test for which a certificate is to be issued shall transmit to the authorities or other designated bodies responsible for issuing the certificates the categories of data referred to in Articles 5(2), 6(2) and 7(2) necessary to complete the data fields set out in the Annex.

6. Where a controller referred to in paragraph 4 enlists a processor, in application of Article 28(3) of Regulation (EU) 2016/679, no transfer of personal data by the processor to a third country may take place.

Article 10

Travel restrictions and information exchange

Without prejudice to Member States' competence to impose restrictions on grounds of public health, where Member States accept certificates of vaccination, test or recovery, they shall refrain from imposing additional travel restrictions, such as additional travel-related testing for SARS-CoV-2 infection or travel-related self-isolation/quarantine, unless they are necessary and proportionate to safeguard public health in response to the COVID-19 pandemic, also taking into account available scientific evidence, including epidemiological data published by the European Centre for Disease Prevention and Control on the basis of Council Recommendation 1475/2020.

Where a Member State requires, in compliance with Union law, 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, for example where the epidemiological situation in a Member State, or in a region within a Member State, worsens quickly, in particular as a result of a SARS-CoV-2 variant of concern or interest, it shall inform the other Member States and the Commission thereof, if possible 48 hours in advance of the introduction of new measures. To that end, the Member State shall supply the following information:

a) the reasons for such restrictions;

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

c) the date and duration of the restrictions.

Member States shall also inform other Member States and the Commission on the issuance and the conditions of acceptance of the certificates referred to in Article 3, including which vaccines they accept pursuant to Article 5(5) second subparagraph.

Member States shall provide the public with clear, comprehensive and timely information on the topics covered by paragraphs 1 and 2. As a general rule, this information should be published 24 hours before the measures come into effect, taking into account that some flexibility is required for epidemiological emergences. The information provided by the Member States may also be made publicly available by the Commission in a centralised manner.

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) shall be conferred on the Commission for a period of 12 months from the date of application of this Regulation.

3. The delegation of power referred to in Articles 5(2), 6(2), 7(1) and 7(2) 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) 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

Phasing-in

1. Until 6 weeks after the date of application of this Regulation, certificates issued before the date of its application shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5) where they contain the data fields set out in the Annex.

2. Where a Member State is not able to issue the certificates referred to in Article 3 in a format that complies with the requirements of this Regulation as of the date of its application, it shall inform the other Member States and the Commission thereof. On this basis, the certificates issued by the Member State concerned shall be accepted by other Member States in accordance with Articles 5(5), 6(5) and 7(5) where they contain the data fields set out in the Annex until 6 weeks after the date of application of this Regulation.

Article 14a

Reporting

1. Four months after the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council, which shall include an overview of:

   a) the number of certificates issued pursuant to this Regulation,

   b) guidance requested pursuant to Article 3(6) on the available scientific evidence and level of standardisation regarding the possible issuance of certificates of recovery based on serological testing for antibodies against SARS-CoV-2, also taking into account the availability and accessibility of such tests, and

   c) the information received pursuant to Article 10.

2. At the latest 3 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, including on travel and tourism and the acceptance of the different types of vaccines, fundamental rights and non-discrimination, 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 period of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.

Article 15

Entry into force and applicability

1. This Regulation shall enter into force on the day of its publication in the Official Journal of the European Union.

2. It shall apply from 1 July 2021.

3. It shall apply for 12 months from the date of its application.

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

ANNEX

Certificate datasets

1. Data fields to be included in the vaccination certificate:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent targeted: COVID-19 (meaning also SARS-CoV-2 or one of its variants);

(d) vaccine/prophylaxis;

(e) vaccine medicinal product;

(f) vaccine marketing authorization holder or manufacturer;

(g) number in a series of vaccinations/doses and the overall number of doses in the series;

(h) date of vaccination, indicating the date of the latest dose received;

(i) Member State of vaccination;

(j) certificate issuer;

(k) a unique certificate identifier.

2. Data fields to be included in the test certificate:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent targeted: COVID-19 (meaning also SARS-CoV-2 or one of its variants);

(d) the type of test;

(e) test name (optional for NAAT test);

(f) test manufacturer (optional for NAAT test);

(g) date and time of the test sample collection;

(i) result of the test;

(j) testing centre or facility (optional for rapid antigen test);

(k) Member State of test;

(l) certificate issuer;

(m) a unique certificate identifier.

3. Data fields to be included in the certificate of recovery:

(a) name: surname(s) and forename(s), in that order;

(b) date of birth;

(c) disease or agent the citizen has recovered from: COVID-19 (meaning also SARS-CoV-2 or one of its variants);

(d) date of first positive NAAT test result;

(e) Member State of test;

(f) certificate issuer;

(g) certificate valid from;

(h) certificate valid until (not more than 180 days after the date of first positive test result);

(i) a unique certificate identifier.

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 third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (EU Digital COVID 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 77(2)(c) 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) Under the Schengen acquis, third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180-day period.

(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 travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine. Such restrictions have detrimental effects on persons and businesses, especially cross-border workers, commuters and seasonal workers.

(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 pandemic[20].

(5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen acquis to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.

(6) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in connection with cross-border travel within the Union, such vaccination certificates need to be fully interoperable, compatible, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles, technical standards and level of protection of such certificates.

[20] OJ L 337, 14.10.2020, p. 3.

(7) Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions 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 the proposal for a Regulation on a EU Digital COVID Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, 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 of the European Parliament and of the Council[21]. 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 of the European Parliament and the Council , vaccines whose distribution has been temporarily authorised based on Article 5(2) of that Directive 2001/83/EC, or vaccines having completed the WHO Emergency Use Listing process. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.

(8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States.

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[21] 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).

(9) Without prejudice to the common measures on the crossing of internal borders as laid down in Regulation (EU) 2016/399, and for the purpose of facilitating travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.

(10) For certificates to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable.

(11) This Regulation is intended to facilitate the application of the principles of proportionality and non-discrimination with regard to possible travel restrictions during the COVID-19 pandemic, while pursuing a high level of public health protection, and 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 addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code)[22].

(11a) Since this Regulation applies to third country nationals already legally staying or residing in the territories of the Member States, it should not be understood as granting third country nationals wishing to travel to a Member State the right to a EU Digital COVID Certificate from that Member State before arrival on its territory. There is no requirement for Member States to issue such vaccination certificates at consular posts.

[22] Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

(11b) On 30 June 2020, the Council adopted Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction. This Regulation does not cover the temporary restrictions on non-essential travel into the Union.

(12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.

(13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC[23]; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. In order to allow Member States to accept, under the conditions of the Regulation (EU) 2021/XXXX [Regulation on a EU Digital COVID Certificate], certificates issued by Ireland to third country nationals legally residing or legally staying in its territory for the purposes of facilitating travel within the Union, Ireland should issue these third-country nationals with certificates that comply with the requirements of the EU Digital COVID Certificate trust framework. Ireland and the other Member States should mutually accept certificates issued to third country nationals covered by this Regulation based on reciprocity.

(14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.

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[23] Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

(15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC[24].

(16) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC.

(17) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen acquis within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU[25].

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[24] Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

[25] Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council[26] and delivered an joint opinion on 31 March 2021,

HAVE ADOPTED THIS REGULATION

Article 1

Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a EU Digital COVID Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.

Article 1a

Provided that Ireland has notified the Council and the Commission that it accepts certificates issued by Member States to persons covered by this Regulation, Member States shall accept, under the conditions of Regulation (EU) 2021/XXXX [Regulation on a EU Digital COVID Certificate], certificates making up the EU Digital COVID Certificate issued by Ireland to third country nationals who may travel freely within the territory of the Member States.

Article 2

1. This Regulation shall enter into force on the day of its publication in the Official Journal of the European Union.

2. It shall apply from 1 July 2021.

3. It shall apply for 12 months from the date of its application.

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

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[26] 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).