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Conseil de
l'Union européenne

Bruxelles, le 15 juin 2022

M. Juan Fernando LÓPEZ AGUILAR
Président de la Commission des libertés civiles, de la justice et des affaires intérieures,
Parlement européen
60, rue Wiertz
1047 Bruxelles
Belgique

Objet: **Proposition de règlement du Parlement européen et du Conseil modifiant le règlement (UE) 2021/953 relatif à un cadre pour la délivrance, la vérification et l'acceptation de certificats COVID-19 interopérables de vaccination, de test et de rétablissement (certificat COVID numérique de l'UE) afin de faciliter la libre circulation pendant la pandémie de COVID-19**

Proposition de règlement du Parlement européen et du Conseil modifiant le règlement (UE) 2021/954 relatif à un cadre pour la délivrance, la vérification et l'acceptation de certificats COVID-19 interopérables de vaccination, de test et de rétablissement (certificat COVID numérique de l'UE) destinés aux ressortissants de pays tiers séjournant ou résidant légalement sur le territoire des États membres pendant la pandémie de COVID-19

Monsieur le Président, cher Monsieur López Aguilar,

Aujourd'hui, le Comité des représentants permanents a approuvé le texte de compromis global sur les propositions de règlement en objet à la suite du trilogue du 13 juin dernier.

Je suis donc à présent en mesure de confirmer que, si le Parlement européen adopte sa position en première lecture, conformément à l'article 294, paragraphe 3, du traité sur le fonctionnement de l'Union européenne, dans les termes qui figurent à l'annexe de la présente lettre, après la mise au point par les juristes-linguistes des deux institutions, le Conseil approuvera la position du Parlement conformément à l'article 294, paragraphe 4, du traité sur le fonctionnement de l'Union européenne et adoptera les deux actes législatifs.

Au nom du Conseil, je tiens également à vous remercier pour votre étroite collaboration, qui devrait nous permettre de parvenir à un accord en première lecture sur ce dossier.

Je vous prie d'agréer, Monsieur le Président, l'expression de ma haute considération.

pcsc

Philippe LÉGLISE-COSTA
Président du Comité des représentants permanents (2e partie)

Copie: M. Didier REYNDERS, Membre de la Commission européenne

ANNEX

REGULATION (EU) 2022/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic

(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[1],

[1] Position of the European Parliament of … (not yet published in the Official Journal) and decision of the Council of ….

Whereas:

(1) Regulation (EU) 2021/953 of the European Parliament and of the Council[2] lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It is also to contribute to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

(2) According to Regulation (EU) 2021/953, test certificates are to be issued based on two types of tests for SARS-CoV-2 infection, namely molecular nucleic acid amplification tests ('NAAT'), including those using reverse transcription polymerase chain reaction ('RT-PCR'), and rapid antigen tests, which rely on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes, provided they are carried out by health professionals or by skilled testing personnel. However, Regulation (EU) 2021/953 does not cover antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays, which test for antigens in a laboratory setting. As of July 2021, the technical working group on COVID-19 diagnostic tests, responsible for preparing updates to the EU common list of COVID-19 rapid antigen tests agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council[3], also reviews proposals put forward by Member States and manufacturers for COVID-19 laboratory-based antigenic assays. Those proposals are assessed against the same criteria as those used for rapid antigen tests, and the Health Security Committee has established a list of the laboratory-based antigenic assays that meet those criteria.

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2 Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 1).

3 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).

As a result, and in an effort to enlarge the scope of the different types of diagnostic tests that may be used as the basis for the issuance of an EU Digital COVID Certificate, the definition for rapid antigen tests should be adapted to include laboratory-based antigenic assays. It should thus be possible for Member States to issue test certificates and, following the adoption of Commission Delegated Regulation (EU) 2022/256[4], certificates of recovery on the basis of the antigen tests included in the EU common list of COVID-19 rapid antigen tests agreed, and regularly updated, by the Health Security Committee as meeting the established quality criteria. In this context, it is necessary to take into account that COVID-19 testing strategies differ between Member States. The possibility for Member States to use antigen tests for the issuance of recovery certificates should thus remain optional, to be used in particular when the availability of NAAT tests is scarce due to a high number of infections in the area concerned or another reason. Where sufficient NAAT capacity is available, Member States could continue to issue certificates of recovery only on the basis of NAAT tests, which are considered as the most reliable methodology for the testing of COVID-19 cases and contacts. Similarly, Member States could issue certificates of recovery based on antigen tests during periods of increased SARS-CoV-2 infections and a resulting high testing demand or shortage of NAAT capacity, and could return to issuing certificates of recovery only based on NAAT tests once infections decrease.

[4] Commission Delegated Regulation (EU) 2022/256 of 22 February 2022 amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery based on rapid antigen tests (OJ L 42, 23.2.2022, p. 4).

(3) In accordance with Article 5 of Regulation (EU) 2021/953, vaccination certificates issued by Member States are to contain the number of doses administered to the holder. It should be clarified in the text of the Regulation that this is intended to reflect all doses administered, in any Member State, not just those administered in the Member State issuing the certificate. Limiting the indication of previous doses to those received in the Member State issuing the certificate could lead to a divergence between the number actually administered and that indicated on the certificate, and could prevent holders from making use of their certificate when exercising the right to free movement within the Union. The administration of previous doses in other Member States is proven by means of valid EU Digital COVID Certificates, and a Member State should not require additional information or evidence from citizens holding such certificates, such as the batch number of previous doses. A Member State may require a person to submit a valid proof of identity and a previous valid EU vaccination or recovery certificate. In this context, the rules for accepting vaccination certificates issued by other Member States set out in Article 5(5) of Regulation (EU) 2021/953 apply. In addition, vaccination certificates covered by an implementing act adopted pursuant to Articles 3(10) and 8(2) of Regulation (EU) 2021/953 are, for the purpose of facilitating the holders' exercise of their right to free movement, to be accepted under the same conditions as EU Digital COVID Certificates issued by Member States. According to Article 3(4) of Regulation (EU) 2021/953, the holder of an EU Digital COVID Certificate is entitled to request the issuance of a new certificate if the personal data contained in the original certificate are not accurate, including with regard to the vaccination of the holder.

(3a) In accordance with Article 5(1) of Regulation (EU) 2021/953, each Member State is to issue vaccination certificates to persons to whom a COVID-19 vaccine has been administered. As also noted in Recital 23 of that Regulation, a vaccination certificate is thus to be issued by the Member State where the vaccination was administered. Nevertheless, this should not be understood as preventing a Member State from issuing vaccination certificates in the EU Digital COVID Certificate format to persons who provide proof of vaccination in another Member State.

(4) In particular in light of the emergence of new SARS-CoV-2 variants of concern, the continued development and study of COVID-19 vaccines is a crucial aspect in the fight against the COVID-19 pandemic. In this context, it is important to facilitate the participation of volunteers in clinical trials, that is, studies performed to investigate the safety or efficacy of a medicine, such as a COVID-19 vaccine. Clinical research plays a fundamental role in the development of vaccines, and voluntary participation in clinical trials should therefore be encouraged. Depriving volunteers from access to EU Digital COVID Certificates could constitute a major disincentive to participate, delaying the conclusion of clinical trials and negatively impacting public health more generally. In addition, the integrity of clinical trials, including in terms of data blinding and confidentiality, should be preserved to ensure the validity of their results. It should thus be clarified that Member States may issue EU Digital COVID Certificates to participants in clinical trials that have been approved by Member States' ethical committees and competent authorities, regardless whether they have received the COVID-19 vaccine candidate or, to avoid undermining the studies, the dose administered to the control group. In addition, it should be clarified that other Member States may accept vaccination certificates for COVID-19 vaccines undergoing clinical trials in order to waive restrictions to free movement put in place, in accordance with Union law, in response to the COVID-19 pandemic. The acceptance period of such vaccination certificates should not be longer than that of certificates issued based on COVID-19 vaccines that have been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council[5], and may depend on whether the vaccine was administered as part of the primary vaccination series or as a booster. Within this period, such vaccination certificates should be accepted unless they have been revoked following the conclusion of the clinical trial, in particular where the COVID-19 vaccine is subsequently not granted a marketing authorisation, or where the certificates were issued for a placebo as part of a blinded trial.

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[5] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union 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).

In this regard, the issuance of vaccination certificates to participants in clinical trials for COVID-19 vaccines and the acceptance of those certificates is a Member States' competence. If a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, vaccination certificates for that vaccine fall, as of that moment, within the scope of the first subparagraph of Article 5(5) of Regulation (EU) 2021/953. To ensure a coherent approach, the Commission should be empowered to ask the Health Security Committee, the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA) to issue guidance with regards to the acceptance of certificates issued for a COVID-19 vaccine undergoing clinical trials that has not yet received a marketing authorisation, which should take into account the ethical and scientific criteria necessary for carrying out clinical trials.

(5) Since the adoption of Regulation (EU) 2021/953, the epidemiological situation with regard to the COVID-19 pandemic has evolved considerably. On the one hand, by 31 January 2022, more than 80% of the adult population in the Union have completed their primary vaccination cycle, and more than 50% have received a booster dose, despite significant differences between Member States. Increasing vaccine uptake remains a crucial objective in the fight against the COVID-19 pandemic, given the increased protection against hospitalisation and severe disease afforded by vaccination, and thus plays an important role in ensuring that restrictions to the free movement of persons can be lifted.

(6) On the other hand, the spread of the SARS-CoV-2 variant of concern 'Delta' in the second half of 2021 caused an increase in the number of infections, hospitalisation and deaths, requiring Member States to adopt strict public health measures in an effort to protect healthcare system capacity. In early 2022, the SARS-CoV-2 variant of concern 'Omicron' caused sharp increases in the number of COVID-19 cases, rapidly replacing Delta and reaching an unprecedented intensity of community transmission across the Union. As noted by ECDC in its Rapid Risk Assessment of 27 January 2022, Omicron infections appear less likely to lead to a severe clinical outcome that requires hospitalisation or admission to intensive care units. Although the reduction in severity is partially due to inherent characteristics of the virus, results from vaccine effectiveness studies have shown that vaccination plays a significant role in preventing severe clinical outcomes from Omicron infection, with effectiveness against severe illness increasing significantly among people having received three vaccine doses. Furthermore, given the very high levels of community transmission, leading to many people being sick at the same time, Member States are likely to undergo a period of substantial pressure on their healthcare systems and on the functioning of the society as a whole, mainly through absence from work and education.

(7) After a peak in Omicron cases, a high proportion of the population is expected to enjoy, at least for a certain period, protection from COVID-19 either due to vaccination or prior infection, or both. A significantly higher percentage of the population is better protected from falling seriously ill and dying from COVID-19 as a result of the currently available COVID-19 vaccines. However, it is not possible to predict the impact of a possible increase in infections in the second half of 2022. In addition, the possibility of a worsening of the pandemic situation because of the emergence of new SARS-CoV-2 variants of concern cannot be ruled out. As also noted by ECDC, significant uncertainties remain at this stage of the COVID-19 pandemic.

(7a) When imposing restrictions to free movement on grounds of public health, Member States should pay particular attention to the specificities of the outermost regions, exclaves and geographically isolated areas and the likely impact of such measures on the functioning of cross-border regions, given their strong social and economic ties.

(8) In view of the remaining uncertainties regarding the further evolution of the pandemic, it cannot be excluded that Member States continue to require Union citizens exercising their right to free movement to present proof of COVID-19 vaccination, test or recovery beyond 30 June 2022, the date when Regulation (EU) 2021/953 is set to expire. It is thus important to avoid that, in the event that certain restrictions to free movement based on public health are still in place after 30 June 2022, Union citizens and their family members are deprived of the possibility to make use of their EU Digital COVID Certificates, which are an effective, secure and privacy-preserving way of proving one's COVID-19 status, where their possession is required by Member States in order to exercise their right to free movement.

(8a) In this context, Member States should require Union citizens exercising their right to free movement to present proof of COVID-19 vaccination, test or recovery or impose additional restrictions such as additional travel-related testing for SARS-COV-2 infections or travel-related quarantine or isolation only where such restrictions are non-discriminatory, necessary and proportionate for the purpose of safeguarding public health based on the latest available scientific evidence including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2022/107 and in line with the precautionary principle.

(8b) Any verification of the certificates making up the EU Digital COVID Certificate should not lead to further restrictions to the freedom of movement within the Union or to restrictions on travel within the Schengen area.

(8c) At the same time, given that any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2, including the requirement to present EU Digital COVID Certificates, should be lifted as soon as the epidemiological situation allows, the extension of the application of Regulation (EU) 2021/953 should be limited to 12 months. In addition, the extension of that Regulation should not be understood as requiring Member States, in particular those that lift domestic public health measures, to maintain or impose free movement restrictions. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union delegated to the Commission pursuant to Regulation (EU) 2021/953 should be equally extended. It is necessary to ensure that the EU Digital COVID Certificate system can adapt to new evidence regarding COVID-19 vaccination, reinfection after recovery, or testing and to scientific progress in containing the COVID-19 pandemic.

(8d) By 31 December 2022, the Commission should submit a third report to the European Parliament and to the Council on the application of this Regulation. The report should contain, in particular, an overview of information on the restrictions to free movement put in place by the Member States to limit the spread of SARS-CoV-2 received pursuant to Article 11, an overview describing all developments regarding domestic and international uses of the EU Digital COVID Certificate, any relevant updates to the assessment included in the second report, and an assessment of the appropriateness of the continued use of EU Digital COVID Certificates for the purpose of this Regulation, taking into account epidemiological developments and the latest available scientific evidence, and in the light of the principles of necessity and proportionality. When preparing the report, the Commission should request guidance from ECDC and the Health Security Committee. Without prejudice to the Commission's right of initiative, the report should be accompanied by a legislative proposal to shorten the period of application of this Regulation taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic and any recommendations from ECDC and the Health Security Committee to that effect.

~~(9) The incorrect cross-reference in Article 13 of Regulation (EU) 2021/953 should be corrected.~~

(10) Regulation (EU) 2021/953 should therefore be amended accordingly.

(11) Similarly, Regulation (EU) 2022/XXXX of the European Parliament and of the Council[6] prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council[7], which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing 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 of the European Parliament and of the Council[8].

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6 Reference to be added.

7 Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID 19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID 19 pandemic (OJ L 211, 15.6.2021, p. 24).

8 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 (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).

(12) In order to allow for its prompt application, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*.

(13) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 (1) and (2) of Regulation (EU) 2018/1725 and delivered a joint opinion on 14 March 2022[9],

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2021/953 is amended as follows:

(1) in Article 2, point 5 is replaced by the following:

"(5) "antigen test" means a test, of one of the following categories, that relies on detection of viral proteins (antigens) to reveal the presence of SARS-CoV-2:

(a) rapid antigen tests, such as lateral flow immunoassays that give results in less than 30 minutes,

(b) antigenic assays performed in a laboratory setting, such as enzyme-linked immunosorbent assays or automated immunoassays for detection of viral antigens;";

9 Not yet published in the OJ.

(2) Article 3 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, points (b) and (c) are replaced by the following:

"(b) a certificate confirming that the holder has been subject to a NAAT test, or an antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel in the Member State issuing the certificate and indicating the type of test, the date on which it was carried out and the result of the test (test certificate);

(c) a certificate confirming that, following a positive result of a NAAT test, or an antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel, the holder has recovered from a SARS-CoV-2 infection (certificate of recovery).";

(ii) the second subparagraph is replaced by the following:

"The Commission shall publish the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, including any updates.";

(b) paragraph 11 is replaced by the following:

"11. Where necessary, the Commission shall ask the Health Security Committee, ECDC or EMA 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 with regard to new SARS-CoV-2 variants of concern, and on the acceptance of COVID-19 vaccines undergoing clinical trials in the Member States.";

(2a) in Article 4, paragraph 2 is replaced by the following:

"2. The trust framework shall be based on a public key infrastructure and allow for the reliable and secure issuance and verification of the authenticity, validity and integrity of the certificates referred to in Article 3(1). The trust framework shall allow for the detection of fraud, in particular forgery. In addition, it shall enable the 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 the certificates referred to in Article 3(1) and, where applicable, certificate revocation lists shall not give rise to the issuer being notified of the verification.";

(3) Article 5 is amended as follows:

(a) in paragraph 2, first subparagraph, point (b) is replaced by the following:

"(b) information about the COVID-19 vaccine and the number of doses administered to the holder, regardless of the Member State in which they have been administered;";

(b) in paragraph 5, the following subparagraphs are added:

"Member States may also issue vaccination certificates referred to in point (a) of Article 3(1) to persons participating in clinical trials that concern a COVID-19 vaccine and that have been approved by Member States' ethical committees and competent authorities, regardless whether they have been administered the vaccine candidate or the dose administered to the control group. The information about the COVID-19 vaccine to be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex shall not undermine the integrity of the clinical trial. Member States may accept vaccination certificates issued by other Member States in accordance with the fourth subparagraph in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2, unless their acceptance period has expired or they have been revoked following the conclusion of the clinical trial, in particular where the COVID-19 vaccine is subsequently not granted a marketing authorisation or where the certificates were issued for a placebo as part of a blinded trial.";

(4) in Article 6(2), point (b) is replaced by the following:

"(b) information about the NAAT test or antigen test to which the holder was subject;";

(5) Article 7 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Each Member State shall issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of a NAAT test carried out by health professionals or by skilled testing personnel.

A Member State may also issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of an antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee carried out by health professionals or by skilled testing personnel.

Member States may issue certificates of recovery based on antigen tests carried out by health professionals or by skilled testing personnel on or after 1 October 2021, provided that the antigen test used was included in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee at the time the positive test result was produced.

Certificates of recovery shall be issued at the earliest 11 days after the date on which a person was first subject to a NAAT test or antigen test that produced a positive result.

The Commission is empowered to adopt delegated acts in accordance with Article 12 to amend the number of days after which a certificate of recovery is to be issued, on the basis of guidance received from the Health Security Committee in accordance with Article 3(11) or on scientific evidence reviewed by ECDC.";

(b) paragraph 4 is replaced by the following:

"4. On the basis of guidance received pursuant to Article 3(11), the Commission is empowered to adopt delegated acts in accordance with Article 12 to amend paragraph 1 of this Article and point (c) of Article 3(1) to allow for the issuance of the certificate of recovery on the basis of a positive antigen test, antibody test, including a serological test for antibodies against SARS-CoV-2, or any other scientifically validated method. Such delegated acts shall also amend point 3 of the Annex by adding, modifying or removing the data fields falling under the categories of personal data referred to in points (b) and (c) of paragraph 2 of this Article.";

(5a) in Article 10, paragraph 5 is replaced by the following:

"5. Any certificate revocation lists exchanged pursuant to Article 4(2) shall not be retained after the end of period of the application of this Regulation.";

(5b) Article 11 is replaced by the following:

"1. Without prejudice to Member States' competence to impose restrictions to free movement on grounds of public health, where Member States accept vaccination certificates, test certificates indicating a negative result or certificates of recovery, they shall refrain from imposing additional restrictions to free movement unless such restrictions are non-discriminatory, necessary and proportionate for the purpose of safeguarding public health based on the latest available scientific evidence including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2022/107 and in line with the precautionary principle.

2. Where a Member State imposes, in accordance with Union law including the principles set out in paragraph 1, on holders of the certificates referred to in Article 3(1) additional restrictions in particular as a result of a SARS-CoV-2 variant of concern or interest, it shall inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To that end, the Member State shall provide the following information:

(a) the reasons for such restrictions, including all relevant epidemiological data and scientific evidence supporting those restrictions available and accessible at that stage;

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

(c) the date and duration of such restrictions.

2a. Where a Member State imposes restrictions in accordance with paragraphs 1 and 2, it shall pay particular attention to the likely impact of such measures on the functioning of cross-border regions and the specificities of outermost regions, exclaves and geographically isolated areas.

3. Member States shall inform the Commission and the other Member States of the issuance and the conditions of acceptance of the certificates referred to in Article 3(1), including the COVID-19 vaccines they accept pursuant to the second subparagraph of Article 5(5).

4. Member States shall provide the public with clear, comprehensive and timely information with regard to paragraphs 1, 2 and 3. As a general rule, Member States shall make that information publicly available 24 hours before new restrictions come into effect, taking into account that some flexibility is required for epidemiological emergencies. In addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner.

(6) in Article 12, paragraph 2 is replaced by the following:

"2. The power to adopt delegated acts referred to in Article 5(2), Article 6(2) and Article 7(1) and (2) shall be conferred on the Commission for a period of 24 months from 1 July 2021.";

~~(7) in Article 13, paragraph 2 is replaced by the following:~~

~~"2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12(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.";~~

(7a) Article 16 is replaced by the following:

1. By 31 October 2021, the Commission shall submit a report to the European Parliament and to the Council. The report shall include an overview of:

   (a) the number of certificates issued pursuant to this Regulation;

   (b) guidance requested pursuant to Article 3(11) on the available scientific evidence and level of standardisation regarding the possible issuance of certificates of recovery based on antibody tests, including serological testing for antibodies against SARS-CoV-2, taking into account the availability and accessibility of such tests; and

   (c) the information received pursuant to Article 11.

2. By 31 March 2022, the Commission shall submit a report to the European Parliament and to 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 vaccine, fundamental rights and non-discrimination, as well as on the protection of personal data during the COVID-19 pandemic.

3. By 31 December 2022, the Commission shall submit a report to the European Parliament and to the Council on the application of this Regulation.

The report shall contain, in particular:

(a) an overview of the information received pursuant to Article 11, of the restrictions to free movement put in place by the Member States to limit the spread of SARS-CoV-2;

(b) an overview describing all the developments regarding the domestic and international uses of the certificates referred to in Article 3(1) and the adoption of implementing acts pursuant to Article 8(2) on COVID-19 certificates issued by third countries;

(c) any relevant updates regarding the assessment, set out in the report submitted pursuant to paragraph 2, 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 vaccine, fundamental rights and non-discrimination, as well as the protection of personal data during the COVID-19 pandemic;

(d) an assessment of the appropriateness of the continued use of the certificates referred to in Article 3(1) for the purpose of this Regulation, taking into account epidemiological developments and the latest available scientific evidence.

When preparing the report, the Commission shall request guidance from ECDC and the Health Security Committee, which shall be annexed to the report.

The report may be accompanied by a legislative proposal, in particular to shorten the period of application of this Regulation, taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic and any recommendations from ECDC and the Health Security Committee to that effect."

(8) in Article 17, the second paragraph is replaced by the following:

"It shall apply from 1 July 2021 to 30 June 2023.";

(9) in the Annex, point 2(i) is replaced by the following:

"(i) testing centre or facility (optional for antigen test);".

Article 2

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

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

Done at Brussels,

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

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2021/954 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic

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), point (c) thereof,

Having regard to the proposal from the European Commission,

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[1].

[1] 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 (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).

(2) On 14 June 2021, the European Parliament and the Council adopted Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate[2]. That Regulation sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Regulation (EU) 2021/953 is accompanied by Regulation (EU) 2021/954 of the European Parliament and of the Council[3], which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State's territory and who are entitled to travel to other Member States in accordance with Union law.

(3) Regulations (EU) 2021/953 and (EU) 2021/954 are due to expire on 30 June 2022. Nevertheless, the pandemic is still on-going and the recent outbreak of the 'Omicron' variant of concern continues to negatively impact travel within the Union. Consequently, the EU Digital COVID Certificate remains relevant and it is necessary to allow for its continued use.

(4) The application of Regulation (EU) 2021/953 is to be prolonged by 12 months. Since the objective of Regulation (EU) 2021/954 is to extend the application of Regulation (EU) 2021/953 to certain categories of third country nationals lawfully residing or staying in the Union, the duration of its application should be directly linked to that of Regulation (EU) 2021/953. Regulation (EU) 2021/954 should therefore be amended accordingly.

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2 Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 1).

3 Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

(5) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/953 should not be considered to justify the temporary reintroduction of controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules as set out in Regulation (EU) 2016/399 of the European Parliament and of the Council (Schengen Borders Code).

(6) 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 in its national law.

(7) 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[4]; 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 set out in Regulation (EU) 2021/953, COVID-19 certificates issued by Ireland to third-country nationals legally staying or residing in its territory for the purposes of facilitating travel within the territories of the Member States, Ireland should issue those third-country nationals with COVID-19 certificates that comply with the requirements of the EU Digital COVID Certificate trust framework. Ireland and the other Member States should accept certificates issued to third-country nationals covered by this Regulation on a reciprocal basis.

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4 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).

(8) 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.

(9) 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[5].

(10) 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[6].

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5 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).

6 Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, 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 (OJ L 53, 27.2.2008, p. 1).

(11) 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[7].

(12) Given the urgency of the situation related to the COVID-19 pandemic, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*.

(13) 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[8] and delivered an opinion on […],

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7 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).

8 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

Article 3 of Regulation (EU) 2021/954 is replaced by the following:

'*Article 3*

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

It shall apply from 1 July 2021 for as long as Regulation (EU) 2021/953 is applicable.'

Article 2

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels,

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