Conseil de
l'Union européenne

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Dossier interinstitutionnel:
2022/0031(COD)

LIMITE

COVID-19 46
JAI 206
FRONT 69
FREMP 35
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SAN 102
TRANS 90
COCON 16
COMIX 81
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RELEX 200
TOUR 17
CODEC 173

NOTE

Origine:	la présidence
Destinataire:	Groupe ad hoc sur les propositions liées au certificat COVID numérique/ Comité mixte (UE-Islande/Norvège et Suisse/Liechtenstein)
N° doc. Cion:	5942/22
Objet:	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 - Texte de compromis de la présidence

En vue de la discussion au groupe ad hoc sur les propositions liées au certificat COVID numérique du 25 février 2022, les délégations trouveront en annexe un texte de compromis de la présidence sur la proposition susmentionnée.

Les changements par rapport à la proposition de la Commission sont indiqués en **gras/souligné** pour les ajouts et en ~~barré~~ pour les suppressions.

ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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,

Whereas:

(1) Regulation (EU) 2021/953 of the European Parliament and of the Council[1] 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.

[1] 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).

(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[2], responsible for preparing updates to the common list of COVID-19 rapid antigen tests[3] agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council[4], 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. 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 on the basis of the antigen tests included in the EU common list agreed, and regularly updated, by the Health Security Committee as meeting the established quality criteria.

(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

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2 https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

3 https://ec.europa.eu/health/system/files/2022-01/covid-19_rat_common-list_en.pdf

4 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)

contained in the original certificate are not accurate, including with regard to the vaccination of the holder.

(3a) The acceptance of vaccination certificates remains governed by Article 5(5) of Regulation (EU) 2021/953, which provides that where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2, they also are to accept, under the same conditions, vaccination certificates issued by other Member States in accordance with that Regulation for a COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council[5]. As the vaccination certificate contains information on the latest COVID-19 vaccine administered to the holder, this obligation is independent of the type of marketing authorisation of previous doses administered to the holder of the vaccination certificate.

(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. If a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004[6], 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.

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5 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).

6 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).

(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[7]. Increasing vaccine uptake remains a crucial objective in the fight against the 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[8], 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. 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.

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7 https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html

8 https://www.ecdc.europa.eu/sites/default/files/documents/RRA-19th%20update-27-jan-2022.pdf

(8) As a result, 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. 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 scientific progress in containing the COVID-19 pandemic.

(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[9] prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council[10], 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[11].

(12) Given the urgency of the situation related to the COVID-19 pandemic, this Regulation should enter into force on the third day following that 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 of Regulation (EU) 2018/1725 and delivered a joint opinion on XXXX[12],

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9 Reference to be added.

10 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).

11 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 Reference to be added.

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) in Article 2, paragraph 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;";

(2) Article 3 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (b) is 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);";

(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 amended as follows:

"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.";

(3) Article 5 is amended as follows:

(a) in paragraph 2, 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 is 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 this paragraph in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2.";

(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) in Article 7, 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.";

(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:**

"By 1 February 2023, 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 the 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.

The report may be accompanied by a legislative proposal to shorten or extend the period of application of this Regulation, taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic.";

(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 ~~3~~2

This Regulation shall enter into force on the third day following that 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*