European Parliament
2019-2024

Committee on Civil Liberties, Justice and Home Affairs

2022/0031(COD)

18.3.2022

***I
DRAFT REPORT

on the 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
(COM(2022)0050 – C9-0031/2022 – 2022/0031(COD))

Committee on Civil Liberties, Justice and Home Affairs

Rapporteur: Juan Fernando López Aguilar

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the 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 (COM(2022)0050 – C9-0031/2022 – 2022/0031(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2022)0050),

– having regard to Article 294(2) and Article 21(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0031/2022),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the opinion of the Committee on Transport and Tourism,

– having regard to the letter from the Committee on the Environment, Public Health and Food Safety,

– having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs (A9-0000/2022),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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	(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 ***and, following the adoption of Commission Delegated Regulation (EU) 2022/256[4a], certificates of recovery*** on the basis of the antigen tests

established quality criteria.

included in the EU common list agreed, and regularly updated, by the Health Security Committee as meeting the established quality criteria.

[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).

[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).

[4a] 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).

Or. en

Amendment 2

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(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	(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[5], 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.

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[5], 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. ***Where a COVID-19 vaccine, having undergone clinical trials, is not granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, certificates issued for that clinically-trialled COVID-19 vaccine should no longer be valid.*** 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] 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] 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).

Or. en

Amendment 3

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point a – point i a (new)
Regulation (EU) 2021/953
Article 3 – paragraph 1 – point c

Present text	*Amendment*
	(ia) point (c) is replaced by the following:
(c) a certificate confirming that, following a positive result of a NAAT test, or ***a rapid*** 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).	***"***(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).***"***

Or. en

Amendment 4

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point -a (new)
Regulation (EU) 2021/953
Article 7 – paragraph 1 – subparagraph 2

Present text	*Amendment*
	(-a) in Article 7(1), the second subparagraph is replaced by the following:
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 ***a rapid*** 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.	***"***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.***"***

Or. en

Amendment 5

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point -a a (new)
Regulation (EU) 2021/953
Article 7 – paragraph 1 – subparagraph 3

Present text	*Amendment*
	(-aa) In Article 7(1), the third subparagraph is replaced by the following:
Member States may issue certificates of recovery based on ***rapid*** antigen tests carried out by health professionals or by skilled testing personnel on or after 1 October 2021, provided that the ***rapid*** 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	***"***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.***"***

produced.

Or. en

Amendment 6

Proposal for a regulation
Article 1 – paragraph 1 – point 5 – point -a b (new)
Regulation (EU) 2021/953
Article 7 – paragraph 1 – subparagraph 4

Preset text	*Amendment*
	(-ab) In Article 7(1), the fourth subparagraph is replaced by the following:
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 ***rapid*** antigen test that produced a positive result.	***"***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.***"***

Or. en

Amendment 7

Proposal for a regulation
Article 1 – paragraph 1 – point 7 a (new)
Regulation (EU) 2021/953
Article 16

Present text	*Amendment*
	(7a) Article 16 is replaced by the following:
Article 16	***"Article 16***
Commission reports	***Commission report***
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.	***1.*** 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***, 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.	The report shall ***include an overview of information received from Member States pursuant to Article 11***, an assessment of the impact of this Regulation on the facilitation of free movement, including on travel and tourism***,*** the acceptance of the different types of vaccine, ***the impact on*** fundamental rights and ***on the principle of*** non-discrimination, ***and any impact*** on the protection of personal data during the COVID-19 pandemic.***”***
The report may be accompanied by legislative proposals, in particular to extend the period of application of this Regulation, taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic.	

Or. en

EXPLANATORY STATEMENT

Background

During the negotiations which led to the adoption of Regulation (EU) 2021/952 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, the European Parliament sought to defend the right to move and reside freely within the territory of the Member States, to defend the principle of non-discrimination, and to defend the right to protection of personal data. It sought to do so while acknowledging that certain measures were necessary to protect public health in the time of the COVID-19 pandemic, and sought to ensure that such measures were coordinated and practical.

Position of the Rapporteur

With the evolution of the pandemic over the course of the last twelve months, it is clear that the COVID-19 pandemic is still with us, even if we are very hopeful that the worst is behind us. This proposal seeks to extend the period of application of the EU Digital Covid Certificate. The Rapporteur's approach is to defend the same principles that the Parliament sought to defend during the negotiations one year ago, namely protecting free movement, ensuring respect for the principle of non-discrimination and protecting personal data. The Rapporteur is also very aware of the need to ensure that the use of the EU Digital Covid Certificate must be limited in time and should end once the public health situation so allows. Ensuring the right to free movement and preserving the Schengen Area without internal border controls require us to move away from the concept of certificates required for travel between Member States as soon as possible.