**REPORT**


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.
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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION


(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 position in the form of amendments of 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 (A9-0138/2022),

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
(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 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, 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 criteria established by the technical working group on COVID-19 diagnostic tests.

\textit{Text proposed by the Commission}

(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 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, 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, certificates of recovery on the basis of the antigen tests.

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

The use of antigen tests for the issuance of recovery certificates pursuant to Delegated Regulation (EU) 2022/256 entails an increased risk of issuing recovery certificates based on false positive tests. The possibility for Member States to use antigen tests for the issuance of recovery certificates should 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. In particular, 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.

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as regards the issuance of certificates of recovery based on rapid antigen tests (OJ L 42, 23.2.2022, p. 4).

Amendment 2
Proposal for a regulation
Recital 4

Text proposed by the Commission

(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

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 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.

\(^5\) 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...

Amendment 3
Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission

(7a) Overall, however, as Council Recommendation (EU) 2022/107 makes clear, in its recital 13, that 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. In this improving public health environment, it is all the more important to enhance the protection of the right to free movement by setting out common principles on when Member States might activate restrictions for Union citizens travelling with a valid EU Digital COVID Certificate.


Amendment 4
Proposal for a regulation
Recital 8

Text proposed by the Commission

(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

Amendment

(8) It cannot therefore 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.
Amendment 5
Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8a) By 31 December 2022, the Commission should submit a 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 received from Member States on restrictions to free movement, including of the restrictions applied by Member States, 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, the impact on fundamental rights and on the principle of non discrimination, as well as the impact on the protection of personal data during the COVID 19 pandemic. It should also assess any domestic uses by Member States of the EU Digital COVID Certificates for purposes other than freedom of movement, and whether they constitute obstacles to free movement. Furthermore, the report should include an assessment of the necessity and proportionality of using the EU Digital COVID Certificates in view of the pandemic situation and the latest available scientific evidence, taking account of the ECDC and the Health Security Committee opinions and recommendations, which should also be contained in the report. The report may be accompanied by a legislative proposal, in particular to shorten the period of application of this Regulation. The Commission is specifically invited to do so where the ECDC and Health Security Committee opinions and
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.

In order to allow for its prompt application, this Regulation should enter into force on the third day following that of its publication in the Official Journal of the European Union.

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 14 March 2022,

Reference to be added.

Reference to be added.

Regulation (EU) 2021/953

点 (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).”

Amendment 9

Proposal for a regulation
Article 1 – paragraph 1 – point 2 a (new)
Regulation (EU) 2021/953
Article 4 – paragraph 2

Present text

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 may 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 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.

Amendment

(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.”

Amendment 10

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point a
Regulation (EU) 2021/953
Article 5 – paragraph 2 – point b

**Text proposed by the Commission**

(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;

**Amendment**

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

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**Amendment 11**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 3 – point b**

Regulation (EU) 2021/953

**Article 5 – paragraph 5 – subparagraph 3 a (new)**

**Text proposed by the Commission**

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.;

**Amendment**

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. **The validity period of such vaccination certificates shall not be longer than that of other vaccination certificates issued pursuant to this paragraph.** 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. **Where a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation**
(EC) No 726/2004, the vaccination certificates issued in respect of that vaccine continue to be valid in accordance with the first subparagraph of this paragraph. Where a COVID-19 vaccine subsequently receives a negative evaluation of an application for marketing authorisation, or where no marketing authorisation is sought for that vaccine, the certificates issued on the basis of that vaccine shall no longer be valid.

Amendment 12
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
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.

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 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.”

Amendment 13
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
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 produced.

**Amendment 14**

**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**

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.

**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 antigen test that produced a positive result.”

**Amendment 15**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5 a (new)**

Regulation (EU) 2021/953

Article 10 – paragraph 5

**Present text**

5. Any certificate revocation lists exchanged between Member States

**Amendment**

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

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

Amendment 16

Proposal for a regulation
Article 1 – paragraph 1 – point 5 b (new)
Regulation (EU) 2021/953
Article 11

Present text

Article 11
Restrictions to free movement and information exchange
1. Without prejudice to Member States’ competence to impose restrictions 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, such as additional travel-related testing for SARS-CoV-2 infection or travel-related quarantine or self-isolation, unless they are necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, also taking into account available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.

Amendment

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

“Article 11
Restrictions to free movement and information exchange
1. Without prejudice to Member States’ exclusive competence to impose restrictions to free movement on grounds of public health, they shall refrain from introducing restrictions or obstacles to, or requirements for the exercise of the right to free movement, unless they are strictly necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, taking into account fully the available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.

2. Where a Member State requires, in accordance with Union law, holders of the certificates referred to in Article 3(1) to undergo, after entry into its territory, quarantine or self-isolation or to be tested for SARS-CoV-2 infection, or if it imposes other restrictions on the holders of such certificates because, for example, the epidemiological situation in a Member

2. Where a Member State, in response to the COVID-19 pandemic, introduces restrictions to free movement, in accordance with Union law, those restrictions shall not apply to holders of the certificates referred to in Article 3(1).
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 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:

3. Without prejudice to paragraph 2, where a Member State, nevertheless, introduces additional travel restrictions or restrictions limiting free movement applicable to holders of the certificates referred to in Article 3(1), it may do so only in accordance with the following principles as laid down in Council Recommendation (EU) 2022/107:

(a) any restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 shall be based on specific and limited public interest grounds, namely the protection of public health;

(b) any such restrictions shall be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not go beyond what is strictly necessary to safeguard public health;

(c) any such restrictions shall be lifted as soon as the epidemiological situation, including in hospitals, allows it;

(d) Member States shall ensure that any requirements imposed on citizens and businesses provide a concrete benefit to the public health efforts to combat the pandemic and do not create an undue and unnecessary administrative burden;

(e) there may be no discrimination between Member States, for example by applying more generous rules to travel to and from a neighbouring Member State.
as compared to travel to and from other Member States;

(f) restrictions may not be discriminatory, that is, they shall apply equally to returning nationals of the Member State concerned. Restrictions shall not be based on the nationality of the person concerned;

(g) Member States shall always admit their own nationals and Union citizens and their family members resident in their territory. Member States shall, in principle, not refuse the entry of other persons travelling from other Member States, and shall facilitate swift transit through their territories;

(h) Member States shall pay particular attention to the specificities of cross-border regions, outermost regions, exclaves and geographically isolated areas and the need to cooperate at local and regional level;

(i) Member States shall avoid disruptions to supply chains and essential travel and keep transport flows moving, in line with the system of ‘Green Lanes’ system;

(j) Member States shall regularly exchange information on all matters covered by the scope of this recommendation and inform citizens accordingly;

(k) restrictions shall not take the form of prohibitions on the operation of certain transport services;

Moreover, in such a situation, the Member State concerned 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; (a) the reasons for such restrictions,
(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.

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 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.

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Amendment 17

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

including all relevant epidemiological data and scientific evidence supporting those restrictions;

(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.

4. 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).

5. Member States shall provide the public with clear, comprehensive and timely information with regard to paragraphs 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.;
Amendment

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

“Article 16

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.

The report shall contain, in particular, an overview of information received from Member States pursuant to Article 11, including of the restrictions applied by Member States, 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, the impact on fundamental rights and non-discrimination, as well as on the protection of personal data during the COVID-19 pandemic.

It shall also assess any domestic uses by Member States of the EU Digital COVID Certificates for purposes other than freedom of movement.

Present text

Article 16

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.

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.
movement, and whether such uses constitute obstacles to free movement.

The report shall include an assessment of the necessity and proportionality of using the EU Digital COVID Certificates in view of the pandemic situation and the latest available scientific evidence, taking account of the ECDC and the Health Security Committee opinions and recommendations, which shall also be contained in the report.

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.

The report may be accompanied by a legislative proposal to shorten the period of application of this Regulation. The Commission is specifically invited to do so where the ECDC and Health Security Committee opinions and recommendations so allow.”
EXPLANATORY STATEMENT

Background
During the negotiations which led to the adoption of 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, 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.
OPINION OF THE COMMITTEE ON TRANSPORT AND TOURISM

for the Committee on Civil Liberties, Justice and Home Affairs


Rapporteur for opinion: José Ramón Bauzá Díaz

SHORT JUSTIFICATION

Starting point

Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates was adopted in June 2021 with its validity until 30 June 2022. Since its adoption, the EU Digital COVID Certificate has been successfully rolled out across the Union. It also has gained increasing global significance by facilitating safe international travel.

As the period of application for this Regulation expires on 30 June 2022, a targeted revision of this Regulation is needed, aiming to continue the application of the EU Digital COVID Certificate framework for an additional period of time.

The Commission proposes to limit the extension to 12 months (until 30 June 2023), and to amend a small number of other provisions of Regulation (EU) 2021/953, related to the vaccines.

Need of legal certainty and predictability for both citizens and the industry:

Firstly, given the recognition of the EU Digital COVID Certificate system as one of the key digital solutions to restore Intra-EU and international travel, an agreement on its standard validity should be reached, in order to avoid fragmentation and discrepancies between the EU Member States’ national legislations.

Secondly, since the adoption of Regulation (EU) 2021/953, the epidemiological situation concerning the COVID-19 pandemic has evolved considerably. Despite the increasing rates of completed vaccinations, there are still significant discrepancies between vaccination rates among Member States and this remains one of the major reasons preventing the total lift of restrictions to the free movement of persons.

The Rapporteur points out that an extension of the current EU Digital COVID Certificate
system is needed for the following reasons:
1) Necessity of clear, harmonised and coherent rules at EU level in order to ensure the free movement of persons ahead of the 2022 summer season;
2) Legal certainty for the tourism industry ahead of the new holiday season;
3) Predictability and organisational capacity to be secured in order to enable the free movement of persons and ensure the resilience of Intra-EU and international travel;

However, the Rapporteur stands that while the main objective of the revision is to extend the application of the Regulation and maintain a legal and coordinated EU framework, this extension should not be understood as requiring Member States, in particular those that lift domestic health measures, to maintain or impose restrictions to the free movement of persons within the Union during the 2022 summer season. It should also not be understood as requiring Member States to maintain or impose the use of the EU Digital COVID Certificate or other COVID-19 certificates systems for unnecessary and unjustified domestic purposes.

**Two-step approach for the extension of the EU Digital COVID Certificate system:**

The original and primary objective of Regulation (EU) 2021/953 and consequently the use of the EU Digital COVID Certificate is to facilitate the free movement of citizens and avoid that Member States impose unilateral and/or additional measures to the freedom of movement. However, further domestic public health measures imposing free movement restrictions were adopted by Member States since the adoption of the Regulation.

Therefore, the Rapporteur suggests that:
1) Any extension of the EU Digital COVID Certificate system and any restriction to the free movement of persons within the Union, including the requirement to present EU Digital COVID Certificates, should be lifted as soon as epidemiological situation allows;
2) We need to ensure legal certainty and predictability for both citizens and industry ahead of the 2022 summer season. Therefore, a first step should be undertaken - the primary extension should be limited to 4 months - by 31 October 2022;
3) However, 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 31 October 2022. In view of the ECDC recommendations following the epidemiological situation, a further extension of the EU Digital COVID Certificates may be considered necessary;
4) In this case, a second step should be undertaken - the Commission should be enabled to extend the application of Regulation (EU) 2021/953 by 4 months, by 28 February 2023, by means of a delegated acts;
5) Taking into account the evolution of the pandemic as well as the lift of national restrictions by Member States, a step forward should be taken when extending this Regulation in order to send a right and balanced signal to EU citizens. Therefore, this Regulation should prevent Member States and national authorities from imposing unnecessary and unjustified restrictions by making use of the EU Digital COVID Certificate.

**AMENDMENTS**

The Committee on Transport and Tourism calls on the Committee on Civil Liberties, Justice and Home Affairs, as the committee responsible, to take into account the following
amendments:

**Amendment 1**

**Proposal for a regulation**

**Recital 8**

*Text proposed by the Commission*

(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

*Amendment*

(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 eight months, including the possibility for a further extension by four months by the Commission by means of delegated acts, if necessary and following a scientific opinion of the European Centre for Disease Prevention and Control (ECDC). 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. Furthermore, any need for the verification of certificates
established by Regulation (EU) 2021/953 should not be considered to justify the temporary reintroduction of controls at internal borders. 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.

Amendment 2

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8a) The EU Digital COVID Certificate system has proven to be the only functioning COVID-19 certificate system operational at the international level on a large scale. As a result, EUDCC has gained increasing global significance and contributed to addressing the pandemic at the international level, by facilitating safe international travel and economic recovery. By 25 February 2022, 35 non-EU countries and territories are connected to the EUDCC system, with more expected to join in the future. Nevertheless, Regulation (EU) 2021/953 only obliges Member States to accept the EU Digital COVID Certificates issued for vaccines that have been granted a marketing authorisation by the European Medicines Agency. It does not, therefore, include most of the vaccines that are currently administered around the world, including those that have completed the WHO emergency use listing procedure. This undermines the role of the EUDCC system as one of the key digital solutions to restore international mobility and the de-facto global standard. Many of the
vaccines that have completed the WHO Emergency Use Listing procedure have not applied, and are unlikely to do so in the future, for marketing authorisation to EMA or a competent Member State authority simply because the developers do not intend to put those vaccines on the EU market. In many cases, the same vaccines administered around the EU and listed by Regulation (EU) 2021/953 are available under a different trade name in other countries, and therefore fall out of the scope of this Regulation. This also applies to some of the vaccines that the EU is helping deliver under the COVAX scheme.

Amendment 3
Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

(8b) Several Member States have used the EU Digital COVID Certificate for domestic purposes by implementing national measures to allow or ban access to bars, restaurants, hotels, concert halls and other venues, despite the fact that the efficiency of these measures to fight against the spread of the virus is not clearly demonstrated. Therefore, without prejudice to Member States’ competence to impose national restrictions on grounds of public health and taking into account the current phase of the pandemic, the EU Digital COVID Certificate should serve its original and primary objective, namely to be used as a tool to facilitate freedom of movement and EU level coordination. The EU Digital COVID Certificate should not be understood as an alternative measure for Member States to impose unjustified and disproportionate restrictions for domestic purposes such as allowing or banning the access to bars, restaurants, hotels, concert halls and
other venues.

Amendment 4
Proposal for a regulation
Recital 8 c (new)

Text proposed by the Commission

Amendment

(8c) In order to extend, if necessary and justified, the use of the EU Digital COVID certificate, 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 prolonging the reference period during which the measures provided for by Regulation (EU) 2021/953 apply. 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 of 13 April 2016 on Better Law Making. 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.

Amendment 5
Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) Considering that the EU Digital COVID Certificate is the basis for safe free movement and EU level coordination,
it is important that it is implemented in a consistent manner in particular with regard to the rules regarding children and young adults below 18 years of age.

Amendment 6

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

Text proposed by the Commission

Amendment

-1. In Article 1, the following paragraph is added:

“2a. It applies to the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate), established by Regulation (EU) 2021/953, during the period from 1 July 2021 until 28 February 2023 (“the reference period”).”

Amendment 7

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – point b a (new)
Regulation (EU) 2021/953
Article 3 – paragraph 11 a (new)

Text proposed by the Commission

Amendment

(ba) In Article 3, the following paragraph 11a is added:

“11a. Where the Commission finds, on the basis of available scientific evidence and the epidemiological situation in the Union with regard to the COVID-19 pandemic, that the use of the EU Digital COVID Certificate continues to be required, the Commission shall adopt delegated acts in accordance with Article 12 to amend the reference period specified
in subparagraph 2a of Article 1 accordingly. Any such amendment may only extend the reference period by up to four months, and the reference period may not be extended beyond 30 June 2023.”

Amendment 8

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

Present text

(a a) In Article 5 paragraph 5, the first subparagraph is replaced by the following:

"5. 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 shall also accept, under the same conditions, vaccination certificates issued by other Member States in accordance with this Regulation for a COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004.

Amendment 9

Proposal for a regulation
Article 1 – paragraph 1 – point 5 a (new)
Regulation (EU) 2021/953
Article 11 – paragraph 1

Present text

(5 a) In Article 11, paragraph 1 is

1. Without prejudice to Member States’ competence to impose restrictions 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, such as additional travel-related testing for SARS CoV-2 infection or travel-related quarantine or self-isolation, unless they are necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, also taking into account available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.

Without prejudice to Member States’ competence to impose restrictions 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, such as additional travel-related testing for SARS CoV-2 infection or travel-related quarantine or self-isolation, unless they are necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, also taking into account available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.


Amendment 10

Proposal for a regulation
Article 1 – paragraph 1 – point 5 b (new)
Regulation (EU) 2021/953
Article 11 – paragraph 3
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).

(5b) In Article 11, paragraph 3 is replaced by the following:

"3. Member States shall align any national policies on the acceptance of the certificates referred to in Article 3(1) for travel purposes as closely as possible with the conditions as set out in the Council Recommendation (EU)2022/107 of 25 January 2022 ("the recommendation") on a coordinated approach to facilitate safe free movement during the COVID-19 pandemic or, in the case of future changes, the latest amended or applicable recommendation. This includes the acceptance of test certificates based on all types of tests considered as eligible in the Recommendation, the acceptance of the different types of tests for their full duration of validity as specified in the Recommendation, and the acceptance of vaccination and recovery certificates under the conditions and for the full duration as specified in the Recommendation. Member States shall inform the Commission and the other Member States of any derogations for travel purposes from the acceptance conditions agreed in the Recommendation and referred to in Article 3(1), including the COVID-19 vaccines they accept pursuant to the second subparagraph of Article 5(5) of this regulation, by providing a justification for the necessity of such derogation to protect public health."

Amendment 11

Proposal for a regulation
Article 1 – paragraph 1 – point 5 c (new)
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<td>(5c) In Article 11, the following paragraph is added:</td>
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<td>“4a. Member States shall refrain from using this Regulation to introduce further restrictions for domestic purposes”;</td>
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### PROCEDURE – COMMITTEE ASKED FOR OPINION

<p>| Title | 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 |
| References | COM(2022)0050 – C9-0031/2022 – 2022/0031(COD) |
| Committee responsible | LIBE |
| Date announced in plenary | 14.2.2022 |
| Opinion by | TRAN |
| Date announced in plenary | 10.3.2022 |
| Rapporteur for the opinion | José Ramón Bauzá Díaz |
| Date appointed | 7.3.2022 |
| Discussed in committee | 31.3.2022 |
| Date adopted | 20.4.2022 |
| Result of final vote | +: 41 |
| | --: 5 |
| | 0: 0 |
| Members present for the final vote | Magdalena Adamowicz, Andris Ameriks, José Ramón Bauzá Díaz, Erik Bergkvist, Izaskun Bilbao Barandica, Paolo Borchia, Karolin Braunsberger-Reinhold, Marco Campomenosi, Ciarán Cuffe, Jakop G. Dalunde, Karina Delli, Anna Deparnay-Grunenberg, Ismail Ertug, Gheorghe Falcă, Giuseppe Ferrandino, Carlo Fidanza, Mario Furore, Søren Gade, Isabel Garcia Muñoz, Jens Gieseke, Elsi Katainen, Peter Lundgren, Benoît Lutgen, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Tilly Metz, Cláudia Monteiro de Aguiar, Caroline Nagtegaal, Jan-Christoph Oetjen, Rovana Plumb, Tomasz Piotr Poręba, Dominique Riquet, Massimiliano Salini, Vera Tax, István Ujhelyi, Henna Virkkunen, Petar Vitanov, Elissavet Vozemberg-Vrionidi, Lucia Vuolo, Roberts Zile, Kosma Złotowski |
| Substitutes present for the final vote | Clare Daly, Anne-Sophie Pelletier, Annalisa Tardino, Marianne Vind, Jörgen Warborn |</p>
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Key to symbols:
+  : in favour
-  : against
0  : abstention
For the Committee on Civil Liberties, Justice and Home Affairs


On behalf of the Committee on the Environment, Public Health and Food Safety: Pascal Canfin (rapporteur)

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety presents the following amendments to the Committee on Civil Liberties, Justice and Home Affairs, as the committee responsible:

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission

(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

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, responsible for preparing updates to the 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, 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.

The use of antigen tests for the issuance of certificates of recovery pursuant to Commission Delegated Regulation (EU) 2022/256 entails an increased risk for the issuance of such certificates for false positive tests. The possibility for Member States to use antigen tests for the issuance of such certificates should hence be understood as a possibility when the availability of NAAT tests is scarce due to a high number of infections in the area concerned or another reason.

Amendment 2
Proposal for a regulation
Recital 4

Text proposed by the Commission

(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, vaccination certificates for that vaccine

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 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 validity of such vaccination certificates should not be longer than the certificate issued based on products approved by EMA. In this regard, the issuance of 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.

In case of a negative evaluation of an application for marketing authorisation, or if the pharmaceutical company in question states that it does not intend to apply for a marketing authorisation pursuant to Regulation (EC) No 726/2004, the validity of the certificate should be discontinued.

Amendment 3

Proposal for a regulation

Recital 8

_Text proposed by the Commission_ 

(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 certificates to participants in clinical trials for COVID-19 vaccines and acceptance of such 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.

_Amendment_

(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.

Amendment 4

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point a
Regulation (EU) 2021/953
Article 5 – paragraph 2 – point b

*Text proposed by the Commission*

“(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;”;

*Amendment*

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

**Amendment 5**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 3 – point b**

Regulation (EU) 2021/953

**Article 5 – paragraph 5 – subparagraph 3 a (new)**

*Text proposed by the Commission*

“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. The validity of such vaccination certificates, issued by Member States, shall not be longer than the vaccination certificates issued pursuant to Article 5(5) of Regulation (EU) 2021/953. Such certificates shall include information regarding the phase of the clinical trial and the status 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.”;

*Amendment*

“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. The validity of such vaccination certificates, issued by Member States, shall not be longer than the vaccination certificates issued pursuant to Article 5(5) of Regulation (EU) 2021/953. Such certificates shall include information regarding the phase of the clinical trial and the status 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. 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. In the case of a negative evaluation of marketing authorisation application for the specific product, or in case the incumbent pharmaceutical company states it does not intend to apply for a marketing authorisation, the validity of the certificate shall be discontinued.”;

Amendment 6
Proposal for a regulation
Article 1 – paragraph 1 – point 5
Regulation (EU) 2021/953
Article 7 – paragraph 4

Text proposed by the Commission

“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.”;

Amendment

“4. On the basis of guidance received pursuant to Article 3(11), recommendations by the ECDC and where relevant other union agencies, based on the latest scientific evidence, 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.”;
Amendment 7
Proposal for a regulation
Article 1 – paragraph 1 – point 7 a (new)
Regulation (EU) 2021/953
Article 16 – paragraph 2

Present Text

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.

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.

Amendment

7a in Article 16, paragraph 2 is replaced by the following:

“2. 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 proportionality and 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 assessment shall be accompanied by a recommendation of the ECDC and the HSC to either withdraw the Regulation after the initial 6 months extension or to extend the period of application of this Regulation up to 12 months;”

Amendment 8
Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EU) 2021/953
Article 17 – paragraph 2

Text proposed by the Commission

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

Amendment

“It shall apply from 1 July 2021 to 30 June 2023, with a possibility of withdrawal after 6 months pursuant to the evaluation
and recommendation of the ECDC and the HSC.”;
## PROCEDURE – COMMITTEE RESPONSIBLE

| Title | 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 |
| References | COM(2022)0050 – C9-0031/2022 – 2022/0031(COD) |
| Date submitted to Parliament | 3.2.2022 |
| Committee responsible | LIBE 14.2.2022 |
| Committees asked for opinions | ENVI 14.2.2022  TRAN 10.3.2022 |
| Rapporteurs | Juan Fernando López Aguilar 16.3.2022 |
| Discussed in committee | 31.3.2022  28.4.2022 |
| Date adopted | 28.4.2022 |
| Result of final vote | +: 48  —: 16  0: 0 |
| Members present for the final vote | Magdalena Adamowicz, Abir Al-Sahlani, Katarina Barley, Pietro Bartolo, Vladimír Bilčík, Vasile Blaga, Karolin Braunsberger-Reinhold, Saskia Bricmont, Joachim Stanislaw Brudziński, Jorge Buxadé Villalba, Damien Carême, Caterina Chinnici, Clare Daly, Marcel de Graaff, Anna Júlia Donáth, Lena Dupont, Lucia Đuriš Nicholsonová, Cornelia Ernst, Laura Ferrara, Nicolaus Fest, Jean-Paul Garraud, Maria Grapini, Evin Incir, Sophia in ’t Veld, Patryk Jaki, Assita Kanko, Fabienne Keller, Peter Kofod, Łukasz Kohut, Moritz Körner, Alice Kuhnke, Hélène Laporte, Jeroen Lenaers, Juan Fernando López Aguilar, Lukas Mandl, Nuno Melo, Nadine Morano, Javier Moreno Sánchez, Emil Radev, Karlo Ressler, Diana Riba i Giner, Birgit Sippel, Sara Skyttedal, Vincenzo Sofo, Tineke Strik, Ramona Strugariu, Annalisa Tardino, Tomas Tóbé, Yana Toom, Milan Uhrík, Tom Vandendriessche, Bettina Vollath, Elissavet Vozenberg-Vrionidi, Jadwiga Wiśniewska, Elena Yoncheva |
| Substitutes present for the final vote | Bartosz Arłukowicz, Olivier Chastel, Daniel Freund, Anne-Sophie Pelletier, Morten Petersen, Domènec Ruiz Devesa, Isabel Santos, Petar Vitanov, Juan Ignacio Zoido Álvarez |
| Date tabled | 2.5.2022 |
## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

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### Key to symbols:
- **+** : in favour
- **-** : against
- **0** : abstention