



2022/0031(COD)

8.4.2022

AMENDMENTS

8 - 85

Draft report

Juan Fernando López Aguilar
(PE729.927v01-00)

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

Proposal for a regulation

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

Amendment 8

Rob Rooker, Cristian Terheş, Charlie Weimers, Tom Vandendriessche, Vincenzo Sofo, Jorge Buxadé Villalba, Jaak Madison, Laura Huhtasaari, Nicolaus Fest

Proposal for a regulation

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Proposal for rejection

The European Parliament rejects the Commission proposal.

Or. en

Justification

The EU Digital Covid Certificate (EUDCC) has been introduced through an urgency procedure in order to facilitate safe cross-border movement during the COVID-19 pandemic, but in reality has been a coercive instrument with far-reaching negative implications on fundamental rights. Since then, the situation has changed. The Omicron variant is three times less likely to require hospitalisation than the Delta variant. Furthermore, evidence illustrates that the existing vaccines are substantially unsuccessful at preventing Omicron transmission, undermining vaccine mandates as well as the EUDCC as a measure to protect EU citizens from infection. Hence, this restrictive measure is unnecessary and the extension is no longer justified. We should therefore reject the extension of the corona passport and revoke the regulation establishing the framework of the EUDCC. The time has come to end these discriminatory measures.

Amendment 9

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Nicolaus Fest, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

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Proposal for rejection

The European Parliament rejects the Commission proposal.

Or. en

Amendment 10

Tineke Strik

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) Regulation (EU) 2021/953 of the European Parliament and of the Council¹ lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. ***It is also to contribute to facilitating the gradual*** lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

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

Amendment

(1) Regulation (EU) 2021/953 of the European Parliament and of the Council¹ lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. ***Regulation (EU) 2021/953 has never represented and will never constitute legal basis to introduce additional requirements for the exercise of the right to free movement and to derogate from the provisions of Directive 2004/38/EC of the European Parliament and of the Council^{1a}. Rather, it aims to facilitate the*** lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

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

^{1a} Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and

Amendment 11

Jean-Paul Garraud, H el ene Laporte, Tom Vandendriessche, Nicolaus Fest

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) Regulation (EU) 2021/953 of the European Parliament and of the Council¹ lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It is also to contribute to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

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

Amendment

(1) Regulation (EU) 2021/953 of the European Parliament and of the Council¹ lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic, ***even though there have been operational issues with the digital certificate that have reduced its effectiveness, particularly involving fraudulent use of secret cryptographic keys***. It is also to contribute to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

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

Amendment 12 Tudor Ciuhodaru

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 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 tests², responsible for preparing updates to the common list of COVID-19 rapid antigen tests³ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council⁴, 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

Amendment

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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.

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).

antibodies, should be adapted to include laboratory-based antigenic assays *and antibody detection tests, including serological tests for SARS-CoV-2 antibodies*. It should thus be possible for Member States to issue test certificates on the basis of the antigen tests *or the antibody tests, including serological tests for SARS-CoV-2 antibodies*, 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

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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).

Or. ro

Amendment 13 **Tineke Strik**

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

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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 tests², responsible for preparing updates to the common list of COVID-19 rapid antigen tests³ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council⁴, 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.

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

³

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

⁴ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

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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 14

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

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

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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 tests², responsible for preparing updates to the common list of COVID-19 rapid antigen tests³ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council⁴, 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.

² <https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis->

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² <https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis->

management/covid-19-diagnostic-tests_en

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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).

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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 15 **Jeroen Lenaers**

Proposal for a regulation **Recital 2**

Text proposed by the Commission

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technical working group on COVID-19 diagnostic tests², responsible for preparing updates to the common list of COVID-19 rapid antigen tests³ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council⁴, 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.

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

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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).

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Or. en

Amendment 16

Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest

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 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 tests², responsible for preparing updates to the common list of COVID-19 rapid antigen tests³ agreed by the Health Security Committee established by

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

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Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council⁴, 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. ***Tests confirming the presence of COVID-19 antibodies should also enable a Digital COVID Certificate to be obtained for a renewable period of 90 days in order to facilitate free movement, as is the case in Switzerland, a member of the Schengen Area.*** 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.

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

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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).

Or. fr

Amendment 17

Jean-Paul Garraud, H el ene Laporte, Tom Vandendriessche, Nicolaus Fest

Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) Notes a blind spot in the application of Regulation (EU) 2021/953 regarding the validity period of the COVID certificate after the booster dose (3rd dose).

Or. fr

Amendment 18

Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest

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 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

(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 **and drug treatments** 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 **or drug treatment**. Clinical research plays a fundamental role in the development of vaccines **and treatments**, and voluntary participation in clinical trials should therefore be encouraged. Depriving **vaccine trial** 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

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 726/2004⁵, 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.

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 726/2004⁵, 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.

It would, however, be irresponsible if volunteers who have participated in clinical trials, whose certificate is deactivated due to non-authorisation of the trialled vaccine, were forced to be re-vaccinated with an authorised product whose possible short-, medium- or long-term interactions with the trialled vaccine have not been evaluated, particularly given the proximity in time of the vaccine

administration. Following the precautionary principle, their certificates should therefore be valid for life.

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. fr

Amendment 19

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

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

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,

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 726/2004⁵, 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.

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 that of the certificates issued based on products approved by the European Medicines Agency (EMA). In this regard, the issuance of vaccination 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 726/2004⁵, 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. ***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.

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 20

Tineke Strik

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

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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 726/2004⁵, vaccination certificates for that vaccine fall, as of that moment, within the scope of the first subparagraph of Article 5(5) of Regulation (EU) 2021/953. To ensure a coherent approach, the Commission should be empowered to ask the Health Security Committee, the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA) to issue guidance with regards to the acceptance of certificates issued for a COVID-19 vaccine undergoing clinical trials that has not yet received a marketing authorisation, which should take into account the ethical and scientific criteria necessary for carrying out clinical trials.

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

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 21

Cornelia Ernst

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

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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 726/2004⁵, 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 a European Medicines Agency (OJ L 136,

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 *should* 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 726/2004⁵, 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 a European Medicines Agency (OJ L 136,

Amendment 22
Balázs Hidvéghi

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) During 2021, around 2 million Union citizens were vaccinated by COVID-19 vaccines the distribution of which has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC of the European Parliament and of the Council^{1a}. The emergence of Omicron variant considerably changed vaccination policies throughout the Union. Booster vaccination became indispensable to prevent severe diseases resulting from infection. For preventing severe diseases, it is important that everyone obtains booster vaccination and those persons who, during the primary course of vaccination, did not receive vaccines authorised under Regulation (EC) No 726/2004 are also assured that all their vaccination certificates should be recognized in case a booster vaccine is authorised under that Regulation.

^{1a} Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Amendment 23
Jean-Paul Garraud, Hélène Laporte, Tom Vandendriessche, Nicolaus Fest

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) Since the adoption of Regulation (EU) 2021/953, the epidemiological situation with regard to the COVID-19 pandemic has evolved considerably. On the one hand, by 31 January 2022, more than 80% of the adult population in the Union have completed their primary vaccination cycle, and more than 50% have received a booster dose, despite significant differences between Member States⁶. Increasing vaccine uptake remains a crucial objective in the fight against the pandemic, given the increased protection against hospitalisation and severe disease afforded by vaccination, and thus plays an important role in ensuring that restrictions to the free movement of persons can be lifted.

6

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

Amendment

(5) Since the adoption of Regulation (EU) 2021/953, the epidemiological situation with regard to the COVID-19 pandemic has evolved considerably. On the one hand, by 31 January 2022, more than 80% of the adult population in the Union have completed their primary vaccination cycle, and more than 50% have received a booster dose, despite significant differences between Member States⁶. Increasing vaccine uptake remains a crucial objective in the fight against the pandemic, given the increased protection against hospitalisation and severe disease afforded by vaccination, and thus plays an important role in ensuring that restrictions to the free movement of persons can be lifted.

6

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

It would be appropriate to review the legitimacy of the COVID Certificate in the light of the number of vaccinated people in the EU and the lower risk presented by the new variants, as restricting the free movement of persons within the Union should remain an exception.

Or. fr

Amendment 24

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) Since the adoption of Regulation (EU) 2021/953, the epidemiological situation with regard to the COVID-19 pandemic has ***evolved considerably***. On the one hand, by 31 January 2022, more than 80% of the adult population in the Union have completed their primary vaccination cycle, and more than 50% have received a booster dose, despite significant differences between Member States⁶. Increasing vaccine uptake remains a crucial objective in the fight against the pandemic, given the increased protection against hospitalisation and severe disease afforded by vaccination, and thus plays an important role in ensuring that restrictions to the free movement of persons can be lifted.

6

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

Amendment

(5) Since the adoption of Regulation (EU) 2021/953, the epidemiological situation with regard to the COVID-19 pandemic has ***improved substantially***. On the one hand, by 31 January 2022, more than 80% of the adult population in the Union have completed their primary vaccination cycle, and more than 50% have received a booster dose, despite significant differences between Member States⁶. Increasing vaccine uptake remains a crucial objective in the fight against the pandemic, given the increased protection against hospitalisation and severe disease afforded by vaccination, and thus plays an important role in ensuring that restrictions to the free movement of persons can be lifted. ***Nine Member States do not require incoming travellers to provide any kind of COVID-19 certificates to access their national territory.***

6

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

Or. en

Amendment 25

Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) On the other hand, the spread of the SARS-CoV-2 variant of concern ‘Delta’ in the second half of 2021 caused an increase in the number of infections, hospitalisation and deaths, requiring Member States to adopt strict public health measures in an effort to protect healthcare system

Amendment

(6) On the other hand, the spread of the SARS-CoV-2 variant of concern ‘Delta’ in the second half of 2021 caused an increase in the number of infections, hospitalisation and deaths, requiring Member States to adopt strict public health measures in an effort to protect healthcare system

capacity. In early 2022, the SARS-CoV-2 variant of concern ‘Omicron’ caused sharp increases in the number of COVID-19 cases, rapidly replacing Delta and reaching an unprecedented intensity of community transmission across the Union. As noted by ECDC in its Rapid Risk Assessment of 27 January 2022⁷, Omicron infections appear less likely to lead to a severe clinical outcome that requires hospitalisation or admission to intensive care units. Although the reduction in severity is partially due to inherent characteristics of the virus, results from vaccine effectiveness studies have shown that vaccination plays a significant role in preventing severe clinical outcomes from Omicron infection, with effectiveness against severe illness increasing significantly among people having received three vaccine doses. Furthermore, given the very high levels of community transmission, leading to many people being sick at the same time, Member States are likely to undergo a period of substantial pressure on their healthcare systems and on the functioning of the society as a whole, mainly through absence from work and education.

capacity, *which is often under pressure as a result of budget cuts due mainly to austerity policies, promoted by the European Commission in its recommendations to Member States as part of the European Semester*. In early 2022, the SARS-CoV-2 variant ‘Omicron’ caused sharp increases in the number of COVID-19 cases, rapidly replacing Delta and reaching an unprecedented intensity of community transmission across the Union. As noted by ECDC in its Rapid Risk Assessment of 27 January 2022⁷, Omicron infections appear less likely to lead to a severe clinical outcome that requires hospitalisation or admission to intensive care units, *and notes that some Member States have decided to consider COVID-19 an endemic disease*. Although the reduction in severity is partially due to inherent characteristics of the virus, results from vaccine effectiveness studies have shown that vaccination plays a significant role in preventing severe clinical outcomes from Omicron infection, with effectiveness against severe illness increasing significantly among people having received three vaccine doses. *However, the vaccine’s efficacy against infectiousness has proven to be limited*. Furthermore, given the very high levels of community transmission, leading to many people being sick at the same time, Member States are likely to undergo a period of substantial pressure on their healthcare systems and on the functioning of the society as a whole, mainly through absence from work and education. *Member States should therefore be encouraged to maintain or increase their budgetary provisions such that the number of hospital beds is at least equal to the number prior to the pandemic. In the light of the shortage of healthcare workers, Member States should exempt such workers from the obligation to be vaccinated, since vaccination has been shown not to prevent transmission*.

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

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

Or. fr

Amendment 26 **Jeroen Lenaers**

Proposal for a regulation **Recital 7**

Text proposed by the Commission

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

Amendment

(7) After a peak in Omicron cases, a high proportion of the population is expected to enjoy, at least for a certain period, protection from COVID-19 either due to vaccination or prior infection, or both. However, it is not possible to predict the impact of a possible increase in infections in the second half of 2022. In addition, the possibility of a worsening of the pandemic situation because of the emergence of new SARS-CoV-2 variants of concern cannot be ruled out. As also noted by ECDC, ***the European Data Protection Board and the European Data Protection Supervisor***, significant uncertainties remain at this stage of the COVID-19 pandemic ***justifying the extension of the period of application of Regulation (EU) 2021/953***.

Or. en

Amendment 27 **Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest**

Proposal for a regulation **Recital 7**

Text proposed by the Commission

Amendment

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

(7) After a peak in Omicron cases, a high proportion of the population is expected to enjoy, at least for a certain period, protection from COVID-19 either due to vaccination or prior infection, or both. However, it is not possible to predict the impact of infections in the second half of 2022. In addition, the possibility of a worsening, **or not**, of the pandemic situation because of the emergence, **or non-emergence**, of new SARS-CoV-2 variants of concern cannot be ruled out. As also noted by ECDC, uncertainties remain at this stage **regarding the evolution** of COVID-19.

Or. fr

Amendment 28

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

Recital 8

Text proposed by the Commission

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

deleted

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.

Or. en

Amendment 29
Tineke Strik

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

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.

Certificates, ***where required by Member States to exercise their right to free movement***, which are an effective, secure and privacy-preserving way of proving one's COVID-19 status. ***The use of EU Digital COVID Certificates should be strictly necessary and proportionate to the epidemiological situation and associated public health risk.*** 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 ***a maximum period of 12 months and subject to a mid-term evaluation after six months, accompanied by an opinion and recommendation of the ECDC and of the Health Security Committee regarding the necessity and proportionality of maintaining the application of the EU Digital COVID Certificates.*** ***The mid-term evaluation might be accompanied by a legislative proposal to shorten the period of application of Regulation (EU) 2021/953 or to repeal that Regulation.*** ***As general rule, Member States should not introduce any free movement restriction if not warranted by the epidemiological situation with regard to the COVID-19 pandemic and where strictly necessary and proportionate for public health reasons based on the latest available scientific evidence.*** ***In this regard***, the extension of that Regulation should not be understood ***nor be a justification*** as requiring Member States, in particular those that lift domestic public health measures, to maintain or impose free movement restrictions ***or request additional formalities to exercise the right to free movement, including the requirement to present the EU Digital COVID Certificates.*** The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European

Union delegated to the Commission pursuant to Regulation (EU) 2021/953 should be equally extended. It is necessary to ensure that the EU Digital COVID Certificate system can adapt to *new evidence on the efficacy of COVID-19 technologies and* scientific progress in containing the COVID-19 pandemic.

Or. en

Amendment 30

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

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

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. *The use of EU Digital COVID Certificates should be proportionate to the epidemiological situation and associated public health risk.* 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

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.

should be limited to 12 months ***and subject to a mid-term evaluation after six months, with a possibility of repeal of that Regulation on the basis of a recommendation of the ECDC and the Health Security Committee.*** In addition, the extension of that Regulation should not be understood as requiring ***or encouraging*** Member States, in particular those that lift domestic public health measures, to maintain or impose free movement restrictions. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union delegated to the Commission pursuant to Regulation (EU) 2021/953 should be equally extended. It is necessary to ensure that the EU Digital COVID Certificate system can adapt to ***new evidence on the efficacy of COVID-19 health technologies and to*** scientific progress in containing the COVID-19 pandemic.

Or. en

Amendment 31

Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest

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

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.*

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, the extension of the application of Regulation (EU) 2021/953 should be limited to **3** months. In addition, Member States *should* lift domestic measures *that restrict freedoms*. It is necessary to ensure that the EU Digital COVID Certificate system *is a tool to be used only in exceptional circumstances and is not to be used permanently.*

Or. fr

Amendment 32

Juan Fernando López Aguilar, Sylvie Guillaume, Birgit Sippel

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

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.

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. ***Any need for Member States to verify EU Digital COVID certificates should not provide a justification for 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.

Or. en

Amendment 33
Tudor Ciuhodaru

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

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.

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 ***a*** 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 ***until 30 June 2022***. 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.

Or. ro

Amendment 34

Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

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 containing the COVID-19 pandemic.

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. 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.

Or. en

Amendment 35

Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) On 25 January 2022, the Council adopted Recommendation (EU) 2022/107^{1a}, moving from a ‘region-based’ approach to a ‘person-based’ approach. That Recommendation provides that a person who has a valid EU Digital COVID Certificate should in principle not be subject to additional travel restrictions, such as tests or quarantine, regardless of their place of departure in the Union. Persons who are not in possession of a valid EU Digital COVID Certificate could be required to undergo a test prior to or no later than 24 hours after arrival. However, Member States do not respect that Recommendation, leading to unpredictable, unclear and difficult situations for Union citizens travelling with a valid certificate. Therefore, the Commission should establish a European COVID Barometer by way of delegated act, laying down clear and harmonised Union-wide criteria for the activation of restrictions by Member States in each stage of the barometer. That tool should offer clarity and predictability to Union citizens, as it would be clear which additional travel restrictions are allowed to be in place during each stage of the barometer. It would also lead to a higher level of compliance with COVID-19 related-measures.

^{1a} Council Recommendation (EU) 2022/107 of 25 January 2022 on a coordinated approach to facilitate safe free movement during the COVID-19 pandemic and replacing Recommendation (EU) 2020/1475 (OJ L 18, 27.1.2022, p. 110).

Or. en

Amendment 36

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) The EU Digital COVID Certificate has been conceived only as a tool to facilitate free movement within the Union during the COVID-19 pandemic, taking into account the principles of proportionality and non-discrimination. However, in contravention of the objective of Regulation (EU) 2021/953, the EU Digital COVID Certificate has been used by many national, regional and local authorities in the Member States, as well as by the Union institutions, to impose restrictions for internal and domestic purposes. Without prejudice to Member States' competence to introduce national restrictions on grounds of public health this Regulation and the EU Digital COVID Certificate should not be intended as a tool for Member States to impose unjustified, disproportionate or discriminatory restrictions for domestic purposes.

Or. en

Amendment 37

Tineke Strik

Proposal for a regulation

Recital 8 c (new)

Text proposed by the Commission

Amendment

(8c) This Regulation does not provide a legal basis for the use or maintaining of the infrastructure for EU Digital COVID

Certificates beyond the purpose of facilitating the exercise of the right to free movement. Any further use should have a legal basis in national law and should be strictly limited to what is necessary and proportionate for epidemiological purposes. Because such use includes processing of health-related personal data, it requires a legal basis in national law that meets the conditions provided for in Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council^{1a}. The use of the certificates or maintaining of such infrastructure should not be possible after the expiry of this Regulation.

^{1a} Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Or. en

Amendment 38
Cornelia Ernst

Proposal for a regulation
Recital 8 d (new)

Text proposed by the Commission

Amendment

(8d) In light of the above it is necessary to continuously evaluate which measures remain effective, necessary and proportionate as regards the purpose of the fight against the COVID-19 pandemic.

Or. en

Amendment 39

Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

Proposal for a regulation

Recital 8 e (new)

Text proposed by the Commission

Amendment

(8e) Since the application of Regulation (EU) 2021/953, a large number of Member States have adopted temporary domestic measures obliging Union citizens to present a COVID-19 certificate for access to public transport, restaurants, hotels, bars, cultural institutions, sport facilities, and other spaces. Although those Member States have ensured that the EU Digital COVID Certificate is also accepted for such domestic measures, those domestic measures have led to considerable confusion among Union citizens that are willing to make use of such facilities during their stay in another Member State, and have therefore become a major obstacle to the freedom of movement of Union citizens from other Member States. Member States should therefore only adopt such domestic measures on the basis of the European COVID Barometer. This will offer clarity and predictability to Union citizens, as it would be clear which domestic measures are allowed to be in place during each stage of the barometer. It would also lead to a higher level of compliance with COVID-19 related measures.

Or. en

Amendment 40

Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

Proposal for a regulation

Recital 8 f (new)

Text proposed by the Commission

Amendment

(8f) By 31 December 2022, the Commission should submit a report to the European Parliament and Council on the application of this Regulation, including an assessment on the necessity to maintain, shorten or extend the period of application of this Regulation, taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic.

Or. en

Amendment 41
Tudor Ciuhodaru

Proposal for a regulation
Recital 11

Text proposed by the Commission

Amendment

(11) Similarly, Regulation (EU) 2022/XXXX of the European Parliament and of the Council⁸ prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council⁹, which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in the Schengen area without controls at internal borders and applies as a matter of Schengen acquis, without prejudice to the specific rules on the crossing of internal borders set out in Regulation (EU) 2016/399 of the European Parliament and of the Council¹⁰.

(11) Similarly, Regulation (EU) 2022/XXXX of the European Parliament and of the Council⁸ **does not** prolong the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council⁹, which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in the Schengen area without controls at internal borders and applies as a matter of Schengen acquis, without prejudice to the specific rules on the crossing of internal borders set out in Regulation (EU) 2016/399 of the European Parliament and of the Council¹⁰.

⁸ Reference to be added.

⁸ Reference to be added.

⁹ Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of

⁹ Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of

interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

¹⁰ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).

interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

¹⁰ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).

Or. ro

Amendment 42
Jeroen Lenaers

Proposal for a regulation
Recital 12

Text proposed by the Commission

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

Amendment

deleted

Or. en

Amendment 43
Cornelia Ernst

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission

(12a) Despite the Commission's commitment, in the Interinstitutional Agreement on Better Law-Making^{1a}, to

Amendment

perform an impact assessment when proposing new legislation, the Commission has failed to do so for Regulation (EU) 2021/953. Whereas an impact assessment would have provided substantiation as to the impact of the measures being adopted as well as to the effectiveness of already existing less intrusive measures as well as a more thorough assessment of the impact on fundamental rights, including on the right to data protection.

^{1a} *OJ L 123, 12.5.2016, p. 1*

Or. en

Amendment 44
Jeroen Lenaers

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered a joint opinion on ~~XXXX~~¹¹,

¹¹ *Reference to be added.*

Amendment

(13) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered a joint opinion on **14 March 2022**¹¹,

¹¹ *OJ*

Or. en

Amendment 45
Tudor Ciuhodaru

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

Text proposed by the Commission

Amendment

(ba) antibody detection tests, including serological tests for SARS-CoV-2 antibodies, carried out by authorised personnel,

Or. ro

Amendment 46
Tudor Ciuhodaru

Proposal for a regulation

Article 1 – paragraph 1 – point 2 – point a – point i

Regulation (EU) 2021/953

Article 3 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

(b) a certificate confirming that the holder has been subject to a NAAT test, an antigen test, **an antibody test, or a serological test for antibodies against SARS-CoV-2**, listed in the EU common list of COVID-19 antigen tests **or antibody tests, including serological tests for antibodies against SARS-CoV-2**, agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel in the Member State issuing the certificate and indicating the type of test, the date on which it was carried out and the result of the test (test certificate);

Or. ro

Amendment 47
Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest

Proposal for a regulation

Article premier – paragraph 1 – point 2 – point a – point i

Regulation (EU) 2021/953

Article 3 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 48
Tudor Ciuhodaru

Proposal for a regulation

Article 1 – paragraph 1 – point 2 – point a a (new)

Regulation (EU) 2021/953

Article 3 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) In paragraph 1, point (ba) is added:

“(ba) antibody tests, including serological tests for antibodies against SARS-CoV-2, conducted by authorised personnel;”

Or. ro

Amendment 49

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

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

(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).

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, ***or an antibody test listed in the EU common list of COVID-19 antibody 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

(Regulation (EU) 2021/953)

Amendment 50
Tudor Ciuhodaru

Proposal for a regulation

Article 1 – paragraph 1 – point 2 – point a – point ii

Regulation (EU) 2021/953

Article 3 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

Amendment

The Commission shall publish the EU common list of COVID-19 antigen tests ***and antibody tests, including serological tests for antibodies against SARS-CoV-2,*** agreed by the Health Security Committee, including any updates;

Or. ro

Amendment 51
Cornelia Ernst

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* support 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.”

Or. en

Amendment 52

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

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 53
Tineke Strik

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. ***Validity of such vaccination certificate issued by a Member State shall not be longer than that of the vaccination certificates issued pursuant to the second subparagraph of this paragraph. A certificate provided according to this criteria, 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 this paragraph. 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 marketing authorisation, validity of the certificate shall be discontinued.;

Or. en

Amendment 54

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

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 of such vaccination certificates, issued by Member States, shall not be longer than that of the vaccination certificates issued pursuant to the second subparagraph of this paragraph. 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 this paragraph. 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.***

Or. en

Amendment 55

Juan Fernando López Aguilar, Birgit Sippel

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

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***

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.;

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 marketing authorisation, or when no marketing authorisation is sought for that vaccine, the certificates issued on the basis of that vaccine shall no longer be valid.;***

Or. en

Amendment 56
Tudor Ciuhodaru

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

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. 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.;

the Annex shall not undermine the integrity of the clinical trial. Member States may accept vaccination certificates *or antibody tests, including serological tests for antibodies against SARS-CoV-2*, 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.;

Or. ro

Amendment 57
Cornelia Ernst

Proposal for a regulation
Article 1 – paragraph 1 – point 3 – point b
Regulation (EU) 2021/593
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 *shall* 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.;

Or. en

Amendment 58
Balázs Hidvéghi

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – point b a (new)

Regulation (EU) 2021/953

Article 5 – paragraph 5 – subparagraph 3 b (new)

Text proposed by the Commission

Amendment

(ba) in paragraph 5, the following subparagraph is added:

“By derogation from the second subparagraph, Member States shall accept vaccination certificates issued by other Member States in accordance with this Regulation for a COVID-19 vaccine which has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC if the vaccine was administered before 31 December 2021 and has been followed by a booster COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004.”;

Or. en

Amendment 59
Tudor Ciuhodaru

Proposal for a regulation

Article 1 – paragraph 1 – point 4 – point a (new)

Regulation (EU) 2021/953

Article 6 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(a) in Article 6(2), the following point (ba) is added:

“(ba) antibody tests, including serological tests for antibodies against SARS-CoV-2, carried out by authorised personnel”;

Amendment 60

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Nicolaus Fest, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation**Article 1 – paragraph 1 – point 5 – point –a (new)**

Regulation (EU) 2021/953

Article 7 – paragraph 1

Present text

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

A Member State may also issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of 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.

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

(-a) In Article 7, paragraph 1 is replaced by the following:

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

A Member State may also issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of 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.

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.

A Member State may also issue certificates of recovery referred to in point (c) of Article 3(1) following a positive result of an antibody test carried out by health professionals or by skilled testing

personnel, provided that the antibody test used was included in the EU common list of COVID-19 antibody tests agreed by the Health Security Committee at the time the positive test result was produced.

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

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

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

Or. en

Justification

Switzerland had been issuing certificates of recovery, valid 90 days, also following a positive result of an antibody test, provided that such a test would correspond to WHO standards, be certified with the CE marking and be performed by a laboratory certified by Swissmedic (see <https://www.admin.ch/gov/fr/accueil/documentation/communiqués.msg-id-85714.html>). It is logical that people with natural immunity acquired through antibodies coverage are eligible for a certificate of recovery.

Amendment 61 **Maria Grapi**

Proposal for a regulation

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

Regulation (EU) 2021/953

Article 7 – paragraph 1

Present text

(1) Each Member State shall issue, upon request, certificates of recovery

Amendment

(-aa) Article 7, paragraph (1) is replaced by the following:

“(1) Each Member State shall issue, upon request, certificates of recovery

referred to in point (c) of Article 3(1) following a positive result of *a NAAT test carried out by health professionals or by skilled testing personnel.*

referred to in point (c) of Article 3(1) following a positive result of *an antigen test, or an antibody test, including a serological test for antibodies against SARS-CoV-2, or based on any other scientifically validated method. Citizens who have recovered from the illness no longer need to be vaccinated.*”

Or. ro

Amendment 62
Tudor Ciuhodaru

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

Text proposed by the Commission

Amendment

(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.

deleted

Or. ro

Amendment 63
Maria Grapi

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), 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, ***so that holders of medical laboratory results can show that they have natural immunity or have recovered from the illness, and, consequently, the recovery certificates shall be valid indefinitely.*** 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.

Or. ro

Amendment 64

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

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

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

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.;

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.;

Or. en

Amendment 65
Cornelia Ernst

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* pursuant to Article 4(2) shall not be retained after the end of period of the application of this Regulation.

Amendment

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

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

Or. en

Amendment 66
Tineke Strik

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

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.

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 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:*

(a) *the reasons for such restrictions;*

(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, Member States shall refrain from *introducing* restrictions *or additional requirements to the exercise of the right to free* movement, *including the requirement to present the EU Digital COVID Certificates*, unless they are *strictly* necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, taking *fully* into account available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.

2. Where a Member State, *in view of the pandemic situation, introduces measures limiting free movement, it shall refrain from imposing additional travel restrictions or further restrictive measures for holders of certificates referred to in Article 3.*

deleted

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

deleted

(c) the date and duration of such restrictions.

deleted

3. Where a Member State requires, by way of exception, and only where strictly necessary and proportionate for public health reasons based on the latest available scientific evidence, 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, in full compliance with Union law and avoiding direct or indirect discrimination, as a result, for instance, of a SARS-CoV-2 variant of concern or interest, it shall inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To that end, the Member State shall provide the following information:

(a) the reasons for such restrictions, including all relevant epidemiological data and scientific evidence supporting 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,

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.

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.”;

Or. en

Amendment 67

Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

Proposal for a regulation

Article 1 – paragraph 1 – point 5 c (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

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

“Article 11

Restrictions to free movement and information exchange

deleted

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 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:

(a) the reasons for such restrictions; *deleted*

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

(c) the date and duration of such restrictions. *deleted*

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). *deleted*

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. *deleted*

The Member States shall only adopt additional travel restrictions for holders of valid certificates referred to in Article 3(1) on basis of a European COVID Barometer. This barometer shall set clear and harmonised criteria for the activation of restrictions in each stage of the barometer and offer clarity and predictability to the holders of such valid certificates.

By ...[one month after the date of the entry into force of this Regulation] and on the basis of available scientific evidence, including epidemiological data published by the ECDC, the Commission shall adopt a delegated act establishing the European COVID Barometer.”;

Or. en

Amendment 68

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Nicolaus Fest, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

Article 1 – paragraph 1 – point 5 d (new)

Regulation (EU) 2021/953

Article 11 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

(5d) In Article 11, the following paragraph is added:

“4a. Member States shall not make use of the EU Digital COVID Certificate as a tool to implement domestic restrictions.”;

Or. en

Amendment 69

Sophia in 't Veld, Lucia  uriř Nicholsonov a, Michal řimečka, Jan-Christoph Oetjen

Proposal for a regulation

Article 1 – paragraph 1 – point 5 b (new)

Regulation (EU) 2021/953
Article 11 a (new)

Text proposed by the Commission

Amendment

(5b) Article 11a is added:

“Article 11a

Use of the European Digital COVID certificate for domestic measures

Where a Member State requires the use of COVID-19 certificates for domestic measures, it shall ensure that certificates making up the EU Digital COVID Certificate can also be used and are also accepted. Member States shall only adopt such domestic measures on the basis of the European COVID Barometer.”;

Or. en

Amendment 70

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Nicolaus Fest, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2021/953

Article 12 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

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

Or. en

Amendment 71

Tudor Ciuhodaru

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EU) 2021/953
Article 12 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. ro

Amendment 72
Tineke Strik

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

Present text

Amendment

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

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

“Article 16

Commission report

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.**

deleted

deleted

accessibility of such tests; and

(c) the information received pursuant to Article 11.

deleted

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.

deleted

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 contain, in particular, an assessment of the ***necessity, proportionality and*** impact of this Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccine, ***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 use by Member States of the EU Digital COVID Certificates for purposes other than freedom of movement, and shall put those in relation to the use for purposes under this Regulation.***

The assessment shall be accompanied by an opinion and recommendation of the ECDC and of the Health Security Committee regarding the necessity and proportionality of maintaining the application of the EU Digital COVID Certificates in view of the pandemic situation and the latest available scientific evidence.

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 ***might*** be accompanied by legislative proposal ***to shorten the period of application of this Regulation or to repeal this Regulation.***”;

Or. en

Amendment 73
Jeroen Lenaers

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

Present text

Amendment

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.

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

“Article 16

Commission report

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.**“;

deleted

deleted

deleted

deleted

The report shall contain, in particular, an assessment of the impact of the Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccine **as well as an overview of the restrictions applied by Member States pursuant to Article 11**, 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.

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

In case the epidemiological situation so permits, the Commission shall, after having consulted the Health Security Committee and the ECDC, put forward a proposal to shorten the period of application of this Regulation already at an earlier stage.

Or. en

Amendment 74

Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

Proposal for a regulation

Article 1 – paragraph 1 – point 7 c (new)

Regulation (EU) 2021/953

Article 16

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

Amendment

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

“Article 16

Commission report

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.***

deleted

deleted

accessibility of such tests; and

(c) the information received pursuant to Article 11.

deleted

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.

deleted

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 contain, in particular, an assessment of the impact of the Regulation on the facilitation of free movement, including on travel and tourism, and the acceptance of the different types of vaccine, fundamental rights and non-discrimination, as well as on the protection of personal data during the COVID-19 pandemic.

The report *may* be accompanied by **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 **shall** be accompanied by **an assessment on the necessity to maintain, shorten or** extend the application of this Regulation, taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic.”;

Or. en

Amendment 75

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

Proposal for a regulation

Article 1 – paragraph 1 – point 7 d (new)

Regulation (EU) 2021/953

Article 16 – paragraph 2

Present text

Amendment

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.

(7d) 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 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.*

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 Health Security Committee to either repeal this Regulation after the initial six months extension or* to extend the period of application of this Regulation *up to 12 months;*"

Or. en

Amendment 76

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Nicolaus Fest, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

Article 1 – paragraph 1 – point 7 e (new)

Regulation (EU) 2021/953

Article 16 – paragraph 3 (new)

Text proposed by the Commission

Amendment

(7e) in Article 16, the following paragraph is added:

“3. By 30 June 2022, the Commission shall submit a report to the Parliament and to the Council on the application of this Regulation. 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 fundamental rights and on the principles of proportionality and of non-discrimination, as well as on potential abuses. The report shall also assess impacts on facilitation of free

movement, including on travel and tourism, the acceptance of the different types of vaccine, and any impact on the protection of personal data.”

Or. en

Amendment 77

Annalisa Tardino, Tom Vandendriessche, Virginie Joron, Jaak Madison, Jean-Paul Garraud, H el ene Laporte

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2021/953

Article 17 – paragraph 2

Text proposed by the Commission

Amendment

deleted

‘It shall apply from 1 July 2021 to 30 June 2023.’

Or. en

Amendment 78

Pascal Canfin

on behalf of the Committee on the Environment, Public Health and Food Safety

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2021/953

Article 17 – paragraph 2

Text proposed by the Commission

Amendment

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

It shall apply from 1 July 2021 to 30 June 2023, *with a possibility of its repeal after six months pursuant to the evaluation and recommendation of the ECDC and the Health Security Committee;*

Or. en

Amendment 79
Cornelia Ernst

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EU) 2021/593
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, ***or until the WHO has declared that the COVID-19 pandemic has ended, whichever is earlier.***;

Or. en

Amendment 80
Tineke Strik

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, ***without prejudice to Article 16.***;

Or. en

Amendment 81
Sophia in 't Veld, Lucia Ďuriš Nicholsonová, Michal Šimečka, Jan-Christoph Oetjen

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 ***28 February*** 2023.;

Amendment 82
Jean-Paul Garraud, H el ene Laporte, Nicolaus Fest

Proposal for a regulation
Article premier – 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
2022.;

Or. fr

Amendment 83
Tudor Ciuhodaru

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
2022.

Or. ro

Amendment 84
Tudor Ciuhodaru

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EU) 2021/953
Annex – point 2 – point i

Text proposed by the Commission

(i) testing centre or facility (optional

Amendment

(i) testing centre or facility (optional

for antigen test);.

for antigen *tests or antibody tests, including serological tests for antibodies against SARS-CoV-2, carried out by authorised personnel*);.

Or. ro

Amendment 85
Maria Grapi

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission

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

Amendment

This Regulation shall *apply only when there is scientific evidence of the existence of the pandemic.*

Or. ro