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10501/22

Interinstitutional File: 2022/0031(COD)

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COCON 42
COMIX 335
SCHENGEN 70
AVIATION 128
PHARM 114
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PE 74

#### **INFORMATION NOTE**

General Secretariat of the Council
Permanent Representatives Committee/Council
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic
- Outcome of the European Parliament's first reading
(Brussels, 22 to 23 June 2022)

### I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure<sup>1</sup>, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

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OJ C 145, 30.6.2007, p. 5.

In this context, the Chair of the <u>Committee on Civil Liberties</u>, <u>Justice and Home Affairs</u> (LIBE), Juan Fernando LOPEZ AGUILAR (S&D, ES), presented on behalf of the Committee a compromise amendment (amendment number 36) to the abovementioned proposal for a Regulation. This amendment had been agreed during the informal contacts referred to above. In addition, the ID group tabled 18 amendments (amendments number 18-35).

### II. VOTE

When it voted on 23 June 2022, the <u>plenary</u> adopted the compromise amendment (amendment number 36) to the abovementioned proposal for a Regulation. No other amendments were adopted. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto<sup>2</sup>.

The Parliament's position reflects what had been previously agreed between the institutions. The <u>Council</u> should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol " " indicates deleted text.

# P9\_TA(2022)0252

# EU Digital COVID Certificate - Union citizens \*\*\*I

European Parliament legislative resolution of 23 June 2022 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (COM(2022)0050 – C9-0031/2022 – 2022/0031(COD))

# (Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2022)0050),
- having regard to Article 294(2) and Article 21(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0031/2022),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the undertaking given by the Council representative by letter of 15 June 2022 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union;
- having regard to Rule 59 of its Rules of Procedure,
- having regard to the opinion of the Committee on Transport and Tourism,
- having regard to the position in the form of amendments of the Committee on the Environment,
   Public Health and Food Safety,
- having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs (A9-0138/2022),
- 1. Adopts its position at first reading hereinafter set out;
- 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
- 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

### P9 TC1-COD(2022)0031

Position of the European Parliament adopted at first reading on 23 June 2022 with a view to the adoption of Regulation (EU) 2022/... of the European Parliament and of the Council amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure<sup>3</sup>,

Position of the European Parliament of 23 June 2022.

### Whereas:

**(1)** Regulation (EU) 2021/953 of the European Parliament and of the Council<sup>4</sup> lays down the 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 also contributes 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.

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

- (2) According to Regulation (EU) 2021/953, test certificates are to be issued on the basis of two types of tests for SARS-CoV-2 infection, namely molecular nucleic acid amplification tests (NAAT tests), including those using reverse transcription polymerase chain reaction (RT-PCR), and rapid antigen tests, which rely on the 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.
- (3) Regulation (EU) 2021/953 does not cover laboratory-based antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays. From July 2021, the technical working group on COVID-19 diagnostic tests, which is responsible for preparing updates to the EU common list of COVID-19 antigen tests agreed by the Health Security Committee established pursuant to Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council<sup>5</sup>, has been reviewing the proposals put forward by Member States and manufacturers for COVID-19 laboratory-based antigenic assays. Those proposals have been assessed against the same criteria as those used for rapid antigen tests, and the Health Security Committee has established a list of the laboratory-based antigenic assays that meet those criteria.

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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).

**(4)** As a result of those developments and to enlarge the scope of the different types of diagnostic tests that may be used for the issuance of an EU Digital COVID Certificate, the definition of rapid antigen tests should be amended to include laboratory-based antigenic assays. It should thus be possible for Member States to issue test certificates and, following the adoption of Commission Delegated Regulation (EU) 2022/2566, certificates of recovery on the basis of the antigen tests included in the EU common list of COVID-19 antigen tests agreed, and regularly updated, by the Health Security Committee as meeting the established quality criteria. Given that Member States' COVID-19 testing strategies differ, the possibility for Member States to use antigen tests for the issuance of recovery certificates should thus remain optional, to be used in particular when there is a shortage of NAAT capacity due to a high number of infections in the area concerned or for another reason. Where sufficient NAAT capacity is available, Member States can continue to issue certificates of recovery only on the basis of NAAT tests, which are considered as the most reliable methodology for the testing of COVID-19 cases and contacts. Similarly, during periods in which there is an increase in SARS-CoV-2 infections, resulting in high demand for testing or a shortage of NAAT tests, Member States could have the possibility, temporarily, of issuing certificates of recovery based on antigen tests. When infections decrease, Member States can continue to issue certificates of recovery only on the basis of NAAT tests.

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<sup>6</sup> 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).

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

(6) In accordance with Article 5(1) of Regulation (EU) 2021/953, the Member State in which a COVID-19 vaccine was administered is to issue a vaccination certificate to the person concerned. Nevertheless, this should not be understood as preventing a Member State from issuing vaccination certificates referred to in point (a) of Article 3(1) of Regulation (EU) 2021/953 to persons who provide proof that they have been vaccinated in another Member State.

In particular in light of the emergence of new SARS-CoV-2 variants of concern, the **(7)** continued development and study of COVID-19 vaccines is a crucial factor in the fight against the COVID-19 pandemic. In that 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 therefore needs to be encouraged. Preventing participants in clinical trials from obtaining vaccination certificates could constitute a major disincentive to participating in such trials, delaying the conclusion of such trials and, more generally, having a negative impact on public health. In addition, the integrity of clinical trials, including in terms of data blinding and confidentiality, should be preserved to ensure the validity of their results. It should therefore be possible for Member States to issue vaccination certificates to participants in clinical trials that have been approved by Member States' ethical committees and competent authorities, regardless of whether the participant received the COVID-19 vaccine candidate or, to avoid undermining the studies, the dose administered to the control group.

(8) In addition, it is necessary to clarify that it should be possible for other Member States to accept vaccination certificates for COVID-19 vaccines undergoing clinical trials in order to waive restrictions to free movement put in place, in accordance with Union law, in response to the COVID-19 pandemic. The acceptance period of such vaccination certificates should not be longer than that of certificates issued based on COVID-19 vaccines that have been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>7</sup>. The acceptance period of such vaccination certificates can differ, depending on whether the vaccine was administered as part of the primary vaccination series or as a booster. Within that period, Member States can accept such vaccination certificates unless they have been revoked following the conclusion of the clinical trial, in particular where the COVID-19 vaccine is subsequently not granted a marketing authorisation or where the vaccination certificates were issued for a placebo administered to the control group as part of a blinded trial. In this regard, the issuance of vaccination certificates to participants in clinical trials for COVID-19 vaccines and the acceptance of those certificates is a *Member State competence.* If a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, vaccination certificates for that vaccine fall, from the date of the issuance of that marketing authorisation, 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 regard to the acceptance of certificates issued for a COVID-19 vaccine undergoing clinical trials that has not yet been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, which should take into account the ethical and scientific criteria necessary for carrying out clinical trials.

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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).

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

(10)In addition, 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 infections, rapidly replacing Delta and reaching an unprecedented intensity of community transmission across the Union. As noted by the ECDC in its Rapid Risk Assessment of 27 January 2022, Omicron infections appear less likely to lead to a severe clinical outcome requiring 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 ill 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.

- (11) After the peak in Omicron infections in early 2022, 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. As a result of the COVID-19 vaccines currently available, a significantly higher percentage of the population is also better protected from falling seriously ill and dying from COVID-19. 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 COVID-19 pandemic because of the emergence of new SARS-CoV-2 variants of concern cannot be ruled out. As also noted by the ECDC, significant uncertainties remain at this stage of the COVID-19 pandemic.
- pandemic, it cannot be excluded that Member States continue to require Union citizens and their family members exercising their right to free movement to present proof of COVID-19 vaccination, test result or recovery after 30 June 2022, the date on which Regulation (EU) 2021/953 is due to expire. It is thus important to avoid a situation in which, in the event that certain restrictions to free movement based on public health remain in place after 30 June 2022, Union citizens and their family members are deprived of the possibility of using their EU Digital COVID Certificates, which are an effective, secure and privacy-preserving way of proving COVID-19 vaccination, test result or recovery, where their possession is required by Member States in order to exercise their right to free movement.

- (13) In that context, Member States should require Union citizens and their family members exercising their right to free movement to present proof of COVID-19 vaccination, a test result or recovery, or should impose additional restrictions such as additional travel-related testing for SARS-CoV-2 infections or travel-related quarantine or self-isolation, only where such restrictions are non-discriminatory, and necessary and proportionate for the purpose of safeguarding public health based on the latest available scientific evidence, including epidemiological data published by the ECDC on the basis of Council Recommendation (EU) 2022/1078, and in line with the precautionary principle.
- (14) When imposing restrictions to free movement on grounds of public health, Member States should pay particular attention to the specificities of the outermost regions, exclaves and geographically isolated areas and the likely impact of such restrictions on cross-border regions, given the strong social and economic ties of those regions.
- (15) Any verification of the certificates making up the EU Digital COVID Certificate should not lead to further restrictions to the freedom of movement within the Union or to restrictions on travel within the Schengen area.

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).

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 a requirement to present EU Digital COVID Certificates, should be lifted as soon as the epidemiological situation allows, the extension of the period of application of Regulation (EU) 2021/953 should be limited to 12 months. In addition, the extension of the period of application of that Regulation should not be understood as requiring Member States, in particular those that lift domestic public health measures, to maintain or impose restrictions to free movement. 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 also be extended. It is necessary to ensure that the EU Digital COVID Certificate framework can adapt to new evidence regarding COVID-19 vaccination, reinfection after recovery, or testing and to scientific progress in containing the COVID-19 pandemic.

(17)By 31 December 2022, the Commission should submit a third report to the European Parliament and to the Council on the application of Regulation (EU) 2021/953. The report should contain, in particular, an overview of the information received pursuant to Article 11 of that Regulation regarding the restrictions to free movement put in place by the Member States to limit the spread of SARS-CoV-2, an overview describing all developments regarding domestic and international uses of the EU Digital COVID Certificate, any relevant updates regarding the assessment included in the second report, and an assessment of the appropriateness of the continued use of EU Digital COVID Certificates for the purposes of that Regulation, taking into account epidemiological developments and the latest available scientific evidence, and in the light of the principles of necessity and proportionality. When drawing up the report, the Commission should request guidance from the ECDC and the Health Security Committee. Without prejudice to the Commission's right of initiative, the report should be accompanied by a legislative proposal to shorten the period of application of Regulation (EU) 2021/953 taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic and any recommendations from the ECDC and the Health Security Committee to that effect.

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

- (19) Since the objective of this Regulation, namely to facilitate the exercise of the right to free movement within the Union during the COVID-19 pandemic by establishing a framework for the issuance, verification and acceptance of interoperable COVID-19 certificates on a person's COVID-19 vaccination, test result or recovery, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (20) In order to allow for its prompt and timely application to ensure the continuity of the EU Digital COVID Certificate, this Regulation should enter into force on the day of its publication in the Official Journal of the European Union.
- The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(1) and (2) of Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>9</sup> and delivered a joint opinion on *14 March* 2022<sup>10</sup>.

HAVE ADOPTED THIS REGULATION:

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Not yet published in the OJ.

### Article 1

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

- (1) in Article 2, point 5 is replaced by the following:
  - "(5) "antigen test" means one of the following categories of test which relies on the detection of viral proteins (antigens) to reveal the presence of SARS-CoV-2:
    - (a) rapid antigen tests, such as lateral flow immunoassays that give results in less than 30 minutes;
    - (b) laboratory-based antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays for the detection of antigens;";

- (2) Article 3 is amended as follows:
  - (a) paragraph 1 is amended as follows:
    - (i) in the first subparagraph, points (b) and (c) are replaced by the following:
      - "(b) a certificate confirming that the holder has been subject to a NAAT test, or an antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel in the Member State issuing the certificate and indicating the type of test, the date on which it was carried out and the result of the test (test certificate);
      - (c) a certificate confirming that, following a positive result of a NAAT test, or an antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, carried out by health professionals or by skilled testing personnel, the holder has recovered from a SARS-CoV-2 infection (certificate of recovery).";
    - (ii) the second subparagraph is replaced by the following:"The Commission shall publish the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, including any updates.";

- (b) paragraph 11 is replaced by the following:
  - "11. Where necessary, the Commission shall ask the Health Security Committee, the ECDC or EMA to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, in particular with regard to new SARS-CoV-2 variants of concern, and on the acceptance of COVID-19 vaccines undergoing clinical trials in the Member States.";
- (3) in Article 4, paragraph 2 is replaced by the following:
  - "2. The trust framework shall be based on a public key infrastructure and allow for the reliable and secure issuance and verification of the authenticity, validity and integrity of the certificates referred to in Article 3(1). The trust framework shall allow for the detection of fraud, in particular forgery. In addition, it shall enable the exchange of certificate revocation lists containing the unique certificate identifiers of revoked certificates. Such certificate revocation lists shall not contain any other personal data. The verification of the certificates referred to in Article 3(1) and, where applicable, certificate revocation lists shall not give rise to the issuer being notified of the verification.";
- (4) Article 5 is amended as follows:
  - (a) in paragraph 2, first subparagraph, point (b) is replaced by the following:
    - "(b) information about the COVID-19 vaccine and the number of doses administered to the holder, regardless of the Member State in which those doses were administered;";

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

"Member States may also issue vaccination certificates to persons participating in a COVID-19 vaccine clinical trial that has been approved by Member States' ethical committees and competent authorities, regardless whether the participant received the COVID-19 vaccine candidate or the dose administered to the control group. The information about the COVID-19 vaccine to be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex shall not undermine the integrity of the clinical trial.

Member States may accept vaccination certificates issued by other Member States in accordance with the fourth subparagraph in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2, unless their acceptance period has expired or they have been revoked following the conclusion of the clinical trial, in particular on the grounds that the COVID-19 vaccine was subsequently not granted a marketing authorisation or that the vaccination certificates were issued for a placebo administered to the control group as part of a blinded trial.";

- (5) in Article 6(2), point (b) is replaced by the following:
  - "(b) information about the NAAT test or antigen test to which the holder was subject;";
- (6) Article 7 is amended as follows:
  - (a) paragraph 1 is replaced by the following:
    - "1. Each Member State shall issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of a NAAT test carried out by health professionals or by skilled testing personnel.

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

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

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

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

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

- (7) in Article 10, paragraph 5 is replaced by the following:
  - "5. No certificate revocation lists that have been exchanged pursuant to Article 4(2) shall be retained after the end of the period of application of this Regulation.";
- (8) Article 11 is replaced by the following:

"Article 11

Restrictions to free movement and information exchange

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

- 2. Where a Member State imposes, in accordance with Union law, including the principles set out in paragraph 1 of this Article, additional restrictions on holders of the certificates referred to in Article 3(1), in particular as a result of a SARS-CoV-2 variant of concern or interest, it shall inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To that end, the Member State shall provide the following information:
  - a) the reasons for such restrictions, including all relevant epidemiological data and scientific evidence supporting those restrictions that are available and accessible at that stage;
  - (b) the scope of such restrictions, specifying which certificate holders are subject to or exempt from such restrictions;
  - (c) the date and duration of such restrictions.

- 2a. Where a Member State imposes restrictions in accordance with paragraphs 1 and 2, it shall pay particular attention to the likely impact of such restrictions on crossborder regions and to the specificities of outermost regions, exclaves and geographically isolated areas.
- 3. Member States shall inform the Commission and the other Member States of the issuance and the conditions of acceptance of the certificates referred to in Article 3(1), including the COVID-19 vaccines they accept pursuant to the second subparagraph of Article 5(5).
- 4. Member States shall provide the public with clear, comprehensive and timely information with regard to paragraphs 1, 2 and 3. As a general rule, Member States shall make that information publicly available 24 hours before new restrictions come into effect, taking into account that some flexibility is required for epidemiological emergencies. In addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner.

<sup>1. \*</sup> 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).";

- (9) in Article 12, paragraph 2 is replaced by the following:
  - "2. The power to adopt delegated acts referred to in Article 5(2), Article 6(2) and Article 7(1) and (2) shall be conferred on the Commission for a period of 24 months from 1 July 2021.";

- (10) Article 16 is amended as follows:
  - (a) in paragraph 2, the third subparagraph is deleted;
  - (b) the following paragraph is added:
    - "3. By 31 December 2022, the Commission shall submit a report to the European Parliament and to the Council on the application of this Regulation.

The report shall contain, in particular:

- (a) an overview of the information received pursuant to Article 11 regarding the restrictions to free movement put in place by the Member States to limit the spread of SARS-CoV-2;
  - 2. (b) an overview describing all the developments regarding the domestic and international uses of the certificates referred to in Article 3(1) and the adoption of implementing acts pursuant to Article 8(2) on COVID-19 certificates issued by third countries;
  - 3. (c) any relevant updates regarding the assessment, set out in the report submitted pursuant to paragraph 2 of this Article, of the impact of this Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccine, fundamental rights and non-discrimination, as well as the protection of personal data during the COVID-19 pandemic;

4.

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

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

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

- in Article 17, the second paragraph is replaced by the following: "It shall apply from 1 July 2021 to 30 June 2023.";
- in the Annex, point 2(i) is replaced by the following:
  - "(i) testing centre or facility (optional for antigen test);".

## Article 2

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

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

For the European Parliament
The President

For the Council

The President