

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

COMPROMISE 1 - Article 3(1)(c) EU Digital COVID Certificate and Article 7(1) Recovery Certificate and Recital 2

AMs covered: AM 3, AM 4, AM 5, AM 6 (Rapporteur)

Article 3

EU Digital COVID Certificate

1. The EU Digital COVID Certificate framework shall allow for the issuance, cross-border verification and acceptance of any of the following certificates:
 - (b) a certificate confirming that the holder has been subject to a NAAT test, or an rapid antigen test listed in the EU common and updated list of COVID 19 rapid antigen tests established on agreed by the basis of the Council Recommendation of 21 January 2021 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 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).

(covers Rapporteur AM 3)

Article 7

Recovery Certificate

1. Each Member State shall issue, upon request, the certificates of recovery referred to in point (c) of Article 3(1).

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

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 which 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.

(covers Rapporteur AMs 4, 5 and 6)

Recitals

AMs covered: AM 1 (Rapporteur), AM 13 (Greens), AM 14 (ENVI), AM 15 (EPP)

- (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.
- (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

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

² 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).

may be used as the basis for the issuance of an EU Digital COVID Certificate, the definition for rapid antigen tests should be adapted to include laboratory-based antigenic assays. It should thus be possible for Member States to issue test certificates **and, following the adoption of Commission Delegated Regulation (EU) 2022/256^{4a}, certificates of recovery** on the basis of the antigen tests included in the EU common list agreed, and regularly updated, by the Health Security Committee as meeting the established quality criteria. **The use of antigen tests for the issuance of recovery certificates pursuant to Commission Delegated Regulation (EU) 2022/256 entails an increased risk of issuing recovery certificates based on false positive tests. The possibility for Member States to use antigen tests for the issuance of recovery certificates should remain optional, to be used in particular when the availability of NAAT tests is scarce due to a high number of infections in the area concerned or another reason. In particular, where sufficient NAAT capacity is available, Member States could continue to issue certificates of recovery only on the basis of NAAT tests, which are considered as the most reliable methodology for the testing of COVID-19 cases and contacts. Similarly, Member States could issue certificates of recovery based on antigen tests during periods of increased SARS-CoV-2 infections and a resulting high testing demand or shortage of NAAT capacity, and could return to issuing certificates of recovery only based on NAAT tests once infections decrease.**

(covers AM 1 Rapporteur, AM 13 Greens, AM 14 ENVI, AM 15 EPP)

[footnote 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).*]

COMPROMISE 2 - Article 4 Trust framework for the EU Digital COVID Certificate and Article 10 Protection of personal data

AMs covered: AM 51 (Left), AM 65 (Left)

Article 4

Trust framework for the EU Digital COVID Certificate

1. The Commission and the Member States shall set up and maintain a trust framework for the EU Digital COVID Certificate.
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~~ **shall enable** 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.

3. The trust framework shall seek to ensure interoperability with technological systems established at international level.

(covers AM 51 Left)

Article 10

Protection of personal data

1. Regulation (EU) 2016/679 shall apply to the processing of personal data carried out when implementing this Regulation.
2. For the purpose of this Regulation, the personal data contained in the certificates issued pursuant to this Regulation shall be processed only for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic. After the end of period of the application of this Regulation, no further processing shall occur.
3. The personal data included in the certificates referred to in Article 3(1) shall be processed by the competent authorities of the Member State of destination or transit, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, only to verify and confirm the holder's vaccination, test result or recovery. To that end, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.
4. The personal data processed for the purpose of issuing the certificates referred to in Article 3(1), including the issuance of a new certificate, shall not be retained by the issuer longer than is strictly necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.
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. (AM 65 Left)

(covers AM 65 Left)

Annex – point 2 – point i

- (i) testing centre or facility (optional for antigen test);.

<i>COMPROMISE 3 - Article 5 Vaccination certificate and Recital 4</i>
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AMs covered: AM 52 (ENVI), AM 53 (Greens), AM 54 (ENVI), AM 55 (Rapporteur)

Article 5

Vaccination certificate

1. Each Member State shall, automatically or upon request by the persons concerned, issue the vaccination certificates referred to in point (a) of Article 3(1) to persons to

whom a COVID-19 vaccine has been administered. Those persons shall be informed of their right to a vaccination certificate.

2. The vaccination certificate shall contain the following categories of personal data:
 - (a) the identity of the holder;
 - (b) information about the COVID-19 vaccines and the number of doses administered to the holder, regardless of the Member State in which they have been administered; (*covers AM 52 ENVI*)
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 12 to amend point 1 of the Annex by modifying or removing data fields, or by adding data fields falling under the categories of personal data referred to in points (b) and (c) of the first subparagraph of this paragraph, where such an amendment is necessary to verify and confirm the authenticity, validity and integrity of the vaccination certificate, in the case of scientific progress in containing the COVID-19 pandemic, or to ensure interoperability with international standards.

3. The vaccination certificate shall be issued in a secure and interoperable format in accordance with Article 3(2) after the administration of each dose and shall clearly indicate whether or not the vaccination course has been completed.
4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 13 shall apply to delegated acts adopted pursuant to this Article.
5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2, they shall also accept, under the same conditions, vaccination certificates issued by other Member States in accordance with this Regulation for a COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004.

Member States may also accept, for the same purpose, vaccination certificates issued by other Member States in accordance with this Regulation for a COVID-19 vaccine that has been granted a marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine the distribution of which has been temporarily authorised pursuant to Article 5(2) of that Directive, or a COVID-19 vaccine that has completed the WHO emergency use listing procedure.

Where Member States accept vaccination certificates for a COVID-19 vaccine referred to in the second subparagraph, they shall also accept, under the same conditions, vaccination certificates issued by other Member States in accordance with this Regulation for the same COVID-19 vaccine.

Member States may also issue vaccination certificates referred to in point (a) of Article 3(1) to persons participating in clinical trials that concern a COVID-19 vaccine and that have been approved by Member States' ethical committees and competent authorities, regardless whether they have been administered the vaccine candidate or the dose administered to the control group. The information about the COVID-19 vaccine to be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex shall not undermine the integrity of the clinical trial. **The validity period of such vaccination certificates shall not be longer than that of other vaccination certificates issued pursuant to this paragraph.** Member States may accept vaccination certificates issued by other Member States in accordance with this paragraph in order to waive restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2. **Where a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, the vaccination certificates issued in respect of that vaccine continue to be valid in accordance with the first subparagraph of this paragraph. Where a COVID-19 vaccine subsequently receives a negative evaluation of an application for marketing authorisation, or when no marketing authorisation is sought for that vaccine, the certificates issued on the basis of that vaccine shall no longer be valid.**

(covers AMs 53 Greens, 54 ENVI, 55 Rapporteur)

Recitals

AMs covered: AM 2 (Rapporteur); AM 19 (ENVI); AM 20 (Greens)

- (4) In particular in light of the emergence of new SARS-CoV-2 variants of concern, the continued development and study of COVID-19 vaccines is a crucial aspect in the fight against the COVID-19 pandemic. In this context, it is important to facilitate the participation of volunteers in clinical trials, that is, studies performed to investigate the safety or efficacy of a medicine, such as a COVID-19 vaccine. Clinical research plays a fundamental role in the development of vaccines, and voluntary participation in clinical trials should therefore be encouraged. Depriving volunteers from access to EU Digital COVID Certificates could constitute a major disincentive to participate, delaying the conclusion of clinical trials and negatively impacting public health more generally. In addition, the integrity of clinical trials, including in terms of data blinding and confidentiality, should be preserved to ensure the validity of their results. It should thus be clarified that Member States may issue EU Digital COVID Certificates to

participants in clinical trials that have been approved by Member States' ethical committees and competent authorities, regardless whether they have received the COVID-19 vaccine candidate or, to avoid undermining the studies, the dose administered to the control group. In addition, it should be clarified that other Member States may accept vaccination certificates for COVID-19 vaccines undergoing clinical trials in order to waive restrictions to free movement put in place, in accordance with Union law, in response to the COVID-19 pandemic. **The validity of such vaccination certificates should not be longer than that of the certificates issued based on vaccines 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 the acceptance of those 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. **Where a COVID-19 vaccine, having undergone clinical trials, is not granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, certificates issued for that clinically-trialled COVID-19 vaccine should no longer be valid.** [AM 2 Rapporteur; AM 19 ENVI; AM 20 Greens] 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.

COMPROMISE 4 - Article 11 Restrictions to free movement and information exchange and Recitals 7a and 8

AMs covered: AM 66 (Greens), AM 67 (Renew)

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, ~~where Member States accept vaccination certificates, test certificates indicating a negative result or certificates of recovery,~~ they shall refrain from ~~introducing imposing additional~~ **restrictions or obstacles to, or requirements for, the exercise of the right** to free movement, ~~such as additional travel-related testing for SARS-CoV-2 infection or travel-related quarantine or self-isolation,~~ unless they are **strictly** necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, ~~also~~ taking into account **fully the** available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.

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).

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

3. Without prejudice to paragraph 2, where a Member State, nevertheless, introduces additional travel restrictions or restrictions limiting free movement applicable to holders of the certificates referred to in Article 3(1), it may do so only in accordance with the following principles as laid down in Council Recommendation (EU) 2022/107⁶:

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

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

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

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

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

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

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

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

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

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

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

Moreover, in such a situation, the Member State concerned 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, **including all relevant epidemiological data and scientific evidence supporting those restrictions;**
- (b) the scope of such restrictions, specifying which certificate holders are subject to or exempt from such restrictions;
- (c) the date and duration of such restrictions.

4. Member States shall inform the Commission and the other Member States of the issuance and the conditions of acceptance of the certificates referred to in Article 3(1), including the COVID-19 vaccines they accept pursuant to the second subparagraph of Article 5(5).

5. Member States shall provide the public with clear, comprehensive and timely information with regard to paragraphs 2 and 3. As a general rule, Member States shall make that information publicly available 24 hours before new restrictions come into effect, taking into account that some flexibility is required for epidemiological emergencies. In addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner.

(covers AM 66 Greens and AM 67 Renew)

Recitals

AMs covered: AM 29 (Greens), AM 30 (ENVI), AM 32 (S&D), AM 35 (Renew)

(7a) Overall, however, as Council Recommendation (EU) 2022/107 of 25 January 2022 makes clear, in its recital 13, “... a significantly higher percentage of the population is ... better protected from falling seriously ill and dying from COVID-19 as a result of the currently available COVID-19 vaccines”. In this improving public health environment, it is all the more important to enhance the protection of the right to free movement by setting out common principles on when Member States might activate restrictions for Union citizens travelling with a valid certificate.

(8) ~~As a result, it~~ cannot **therefore be excluded that Member States continue to require Union citizens exercising their right to free movement to present proof of COVID-19 vaccination, test or recovery beyond 30 June 2022, the date when Regulation (EU) 2021/953 is set to expire. It is thus important to avoid that, in the event that certain restrictions to free movement based on public health are still in place after 30 June 2022, Union citizens and their family members are deprived of the possibility to make use of their EU Digital COVID Certificates, **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. 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. **Nevertheless, the use of EU Digital Covid Certificates should be required only where this is strictly necessary and proportionate in light of the epidemiological situation and associated public health risk.** 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 introduction of internal border controls.** 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.

(covers AM 29 Greens, AM 30 ENVI, AM 32 S&D, AM 35 Renew)

COMPROMISE 5 - Article 16 Commission report and recital 8a

AMs covered: AM 7 (Rapporteur), AM 72 (Greens), AM 73 (EPP), AM 74 (Renew), AM 75 (ENVI)

Article 12

Exercise of the delegation

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.

Article 16

Commission reports

- ~~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.~~

1. By 31 ~~March~~ 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 overview of information received from Member States pursuant to Article 11, including of the restrictions applied by Member States**, an assessment of the impact of this Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccine, **the impact on fundamental rights and on the principle of non-discrimination, as well as and the impact** on the protection of personal data during the COVID-19 pandemic. **It shall also assess any domestic uses by Member States of the EU Digital COVID Certificates for purposes other than freedom of movement, and whether they constitute obstacles to free movement.**

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

The report may be accompanied by a 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,~~ **shorten the period of application of this Regulation. The Commission is specifically invited to do so where the ECDC and Health Security Committee opinions and recommendations so allow.**

(covers AM 7 Rapporteur, AM 72 Greens, AM 73 EPP, AM 74 Renew, AM 75 ENVI)

Article 17

Entry into force

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

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

Recitals

AMs covered: AM 26 (EPP), AM 29 (Greens), AM 30 (ENVI), AM 40 (Renew), AM 44 (EPP)

(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 States⁷. Increasing vaccine uptake remains a crucial objective in the fight against the pandemic, given the increased protection against hospitalisation and severe disease afforded by vaccination, and thus plays an important role in ensuring that restrictions to the free movement of persons can be lifted.

- (6) On the other hand, the spread of the SARS-CoV-2 variant of concern ‘Delta’ in the second half of 2021 caused an increase in the number of infections, hospitalisation and deaths, requiring Member States to adopt strict public health measures in an effort to protect healthcare system capacity. In early 2022, the SARS-CoV-2 variant of concern ‘Omicron’ caused sharp increases in the number of COVID-19 cases, rapidly replacing Delta and reaching an unprecedented intensity of community transmission across the Union. As noted by ECDC in its Rapid Risk Assessment of 27 January 2022⁸, Omicron infections appear less likely to lead to a severe clinical outcome that requires hospitalisation or admission to intensive care units. Although the reduction in severity is partially due to inherent characteristics of the virus, results from vaccine effectiveness studies have shown that vaccination plays a significant role in preventing severe clinical outcomes from Omicron infection, with effectiveness against severe illness increasing significantly among people having received three vaccine doses. Furthermore, given the very high levels of community transmission, leading to many people being sick at the same time, Member States are likely to undergo a period of substantial pressure on their healthcare systems and on the functioning of the society as a whole, mainly through absence from work and education.
- (7) After a peak in Omicron cases, a high proportion of the population is expected to enjoy, at least for a certain period, protection from COVID-19 either due to vaccination or prior infection, or both. However, it is not possible to predict the impact of a possible increase in infections in the second half of 2022. In addition, the possibility of a worsening of the pandemic situation because of the emergence of new SARS-CoV-2 variants of concern cannot be ruled out. As also noted by ECDC, significant uncertainties remain at this stage of the COVID-19 pandemic.

(8a) By 31 March December 2022, the Commission should submit a report to the European Parliament and to the Council on the application of this Regulation. The report should contain, in particular, an overview of information received from Member States on restrictions to free movement, including of the restrictions applied by Member States, an assessment of the impact of this Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccine, the impact on fundamental rights and on the principle of non discrimination, as well as the impact on the protection of personal data during the COVID 19 pandemic. It should also assess any domestic uses by Member States of the EU Digital COVID Certificates for purposes other than freedom of movement, and whether they constitute obstacles to free movement.

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

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

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

a legislative proposal, in particular to shorten the period of application of this Regulation. The Commission is specifically invited to do so where the ECDC and Health Security Committee opinions and recommendations so allow.

- (11) Similarly, Regulation (EU) 2022/XXXX of the European Parliament and of the Council⁹ prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council¹⁰, 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 Council¹¹.
- (12) **In order to allow for its prompt application**~~Given the urgency of the situation related to the COVID-19 pandemic~~, this Regulation should enter into force on the third day following that of its publication in the *Official Journal of the European Union*.
- (13) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered a joint opinion on **14 March 2022**¹²,

(covers AM 26 EPP, AM 29 Greens, AM 30 ENVI, AM 40 Renew)

⁹ Reference to be added.

¹⁰ Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID 19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID 19 pandemic (OJ L 211, 15.6.2021, p. 24).

¹¹ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).

¹² Reference to be added.