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2022/0031 (COD)

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WK 6632/2022 INIT

LIMITE

COVID-19

JAI

POLGEN

FRONT

FREMP

IPCR

VISA

MI

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TRANS

COCON

COMIX

SCHENGEN

AVIATION

PHARM

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WORKING DOCUMENT

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| From: | Presidency |
| To: | Ad hoc Working Party on the proposals for a Digital Covid Certificate |
| Subject: | EU Digital COVID Certificate amending Regulations - four-column table |

For the purpose of discussions at the meeting of the ad hoc Working Party on the proposals for a Digital Covid Certificate on 11 May, delegations will find in the Annex the four-column table on the above-mentioned proposals.

Delegations are invited to give their views on the compromise texts proposed by the Presidency in the fourth column.

WK 6632/2022 INIT

LIMITE

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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 proposal (5942/22) | European Parliament | Council mandate (7001/22) | Compromise text |
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| 1. | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, |
| 2. | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof, |
| 3. | Having regard to the proposal from the European Commission, | Having regard to the proposal from the European Commission, | Having regard to the proposal from the European Commission, | Having regard to the proposal from the European Commission, |
| 4. | After transmission of the draft legislative act to the national parliaments, | After transmission of the draft legislative act to the national parliaments, | After transmission of the draft legislative act to the national parliaments, | After transmission of the draft legislative act to the national parliaments, |
| 5. | Acting in accordance with the ordinary legislative procedure, | Acting in accordance with the ordinary legislative procedure, | Acting in accordance with the ordinary legislative procedure, | Acting in accordance with the ordinary legislative procedure, |
| 6. | Whereas: | Whereas: | Whereas: | Whereas: |
| 7. | (1) Regulation (EU) 2021/953 of the European Parliament and of the | (1) Regulation (EU) 2021/953 of the European Parliament and of the | (1) Regulation (EU) 2021/953 of the European Parliament and of | (1) Regulation (EU) 2021/953 of the European Parliament and of |

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| | Council ¹ 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. | Council ² 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. | the Council ³ 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. | the Council ⁴ 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. |
| 8. | (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 | (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 | (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 | (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 |

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 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).

³ 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).

⁴ 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).

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| | lateral flow immunoassay that gives results in less than 30 minutes, provided they are carried out by health professionals or by skilled testing personnel. However, Regulation (EU) 2021/953 does not cover antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays, which test for antigens in a laboratory setting. As of July 2021, the technical working group on COVID-19 diagnostic tests ⁵ , responsible for preparing updates to the common list of COVID-19 rapid antigen tests ⁶ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁷ , also reviews proposals put forward by Member States and manufacturers for COVID-19 laboratory-based antigenic assays. | of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes, provided they are carried out by health professionals or by skilled testing personnel. However, Regulation (EU) 2021/953 does not cover antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays, which test for antigens in a laboratory setting. As of July 2021, the technical working group on COVID-19 diagnostic tests ² , responsible for preparing updates to the common list of COVID-19 rapid antigen tests ³ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁴ , also reviews proposals put forward by Member States and manufacturers | of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes, provided they are carried out by health professionals or by skilled testing personnel. However, Regulation (EU) 2021/953 does not cover antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays, which test for antigens in a laboratory setting. As of July 2021, the technical working group on COVID-19 diagnostic tests ⁹ , responsible for preparing updates to the common list of COVID-19 rapid antigen tests ¹⁰ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ¹¹ , also reviews proposals put forward by Member States and | lateral flow immunoassay that gives results in less than 30 minutes, provided they are carried out by health professionals or by skilled testing personnel. However, Regulation (EU) 2021/953 does not cover antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays, which test for antigens in a laboratory setting. As of July 2021, the technical working group on COVID-19 diagnostic tests ¹³ , responsible for preparing updates to the common list of COVID-19 rapid antigen tests ¹⁴ agreed by the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ¹⁵ , also reviews proposals put forward by Member States and manufacturers for COVID-19 laboratory-based antigenic assays. |

⁵ https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

⁶ https://ec.europa.eu/health/system/files/2022-01/covid-19_rat_common-list_en.pdf

⁷ 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).

⁹ https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

¹⁰ https://ec.europa.eu/health/system/files/2022-01/covid-19_rat_common-list_en.pdf

¹¹ 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)

¹³ https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

¹⁴ https://ec.europa.eu/health/system/files/2022-01/covid-19_rat_common-list_en.pdf


¹⁵ 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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| | 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. | 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 <i>and, following the adoption of Commission Delegated Regulation (EU) 2022/256⁸, certificates of recovery</i> 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. <i>The use of antigen tests for the issuance of recovery certificates</i> | 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 <u>and, following the adoption of Commission Delegated Regulation (EU) 2022/256¹², certificates of recovery</u> 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. | 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 <u>and, following the adoption of Commission Delegated Regulation (EU) 2022/256¹⁶, certificates of recovery</u> 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. <i>In this context, it is necessary to take into account that COVID-19 testing strategies differ between Member</i> |

⁸ *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).*

¹² 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).

¹⁶ 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).

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| | | <p><i>pursuant to Delegated Regulation (EU) 2022/256 entails an increased risk of issuing recovery certificates based on false positive tests. The possibility for Member States to use antigen tests for the issuance of recovery certificates should remain optional, to be used in particular when the availability of NAAT tests is scarce due to a high number of infections in the area concerned or another reason. In particular, where sufficient NAAT capacity is available, Member States could continue to issue certificates of recovery only on the basis of NAAT tests, which are considered as the most reliable methodology for the testing of COVID-19 cases and contacts. Similarly, Member States could issue certificates of recovery based on antigen tests during periods of increased SARS-CoV-2 infections and a resulting high testing demand or shortage of NAAT capacity, and could return to issuing certificates of recovery only based on NAAT tests once infections decrease.</i></p> |  | <p>States. 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 thus 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.</p> |
| 9. | (3) In accordance with Article 5 of Regulation (EU) 2021/953, | (3) In accordance with Article 5 of Regulation (EU) 2021/953, | (3) In accordance with Article 5 of Regulation (EU) 2021/953, | EP to check |

| | COM proposal (5942/22) | European Parliament | Council mandate (7001/22) | Compromise text |
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| | <p>vaccination certificates issued by Member States are to contain the number of doses administered to the holder. It should be clarified in the text of the Regulation that this is intended to reflect all doses administered, in any Member State, not just those administered in the Member State issuing the certificate. Limiting the indication of previous doses to those received in the Member State issuing the certificate could lead to a divergence between the number actually administered and that indicated on the certificate, and could prevent holders from making use of their 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 valid EU Digital COVID Certificates, and a Member State should not require additional information or evidence from citizens holding such certificates, such as the batch number of previous doses. 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, vaccination certificates covered by an implementing act adopted pursuant to Articles 3(10) and 8(2) of Regulation</p> | <p>vaccination certificates issued by Member States are to contain the number of doses administered to the holder. It should be clarified in the text of the Regulation that this is intended to reflect all doses administered, in any Member State, not just those administered in the Member State issuing the certificate. Limiting the indication of previous doses to those received in the Member State issuing the certificate could lead to a divergence between the number actually administered and that indicated on the certificate, and could prevent holders from making use of their 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 valid EU Digital COVID Certificates, and a Member State should not require additional information or evidence from citizens holding such certificates, such as the batch number of previous doses. 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, vaccination certificates covered by an implementing act adopted pursuant to Articles 3(10) and 8(2) of Regulation</p> | <p>vaccination certificates issued by Member States are to contain the number of doses administered to the holder. It should be clarified in the text of the Regulation that this is intended to reflect all doses administered, in any Member State, not just those administered in the Member State issuing the certificate. Limiting the indication of previous doses to those received in the Member State issuing the certificate could lead to a divergence between the number actually administered and that indicated on the certificate, and could prevent holders from making use of their 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 valid EU Digital COVID Certificates, and a Member State should not require additional information or evidence from citizens holding such certificates, such as the batch number of previous doses. <u>A Member State may require a person to submit a valid proof of identity and a previous valid EU vaccination or recovery certificate.</u> In this context, the rules for accepting vaccination certificates issued by other Member States set out in Article 5(5) of Regulation</p> | |

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| | (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. According to 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. | (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. According to 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. | (EU) 2021/953 apply. In addition, vaccination 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. According to 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. | |
| 10. | | | <u>(3a) In accordance with Article 5(1) of Regulation (EU) 2021/953, each Member State is to issue vaccination certificates to persons to whom a COVID-19 vaccine has been administered. As also noted in Recital 23 of that Regulation, a vaccination certificate is thus to be issued by the Member State where the vaccination was administered. Nevertheless, this should not be understood as preventing a Member State from issuing vaccination certificates in the EU Digital COVID Certificate format</u> | EP to check |

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| | | | <u>to persons who provide proof of vaccination in another Member State.</u> | |
| 11. | <p>(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</p> | <p>(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</p> | <p>(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</p> | <p>(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 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. <u>The acceptance period validity 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 Council¹⁹, and may depend on whether the vaccine was administered as part of the primary vaccination series or as a booster vaccines approved by the European Medicines Agency (EMA). Within</u></p> |

¹⁹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union 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)

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| | <p>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 726/2004¹⁷, 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</p> | <p>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. <i>The validity period of such vaccination certificates should not be longer than that of the vaccination certificates issued for COVID-19 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.</i> If a</p> | <p>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 726/2004¹⁸, 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</p> | <p><i><u>this period, such vaccination certificates should be accepted unless they have been revoked following the conclusion of the clinical trial, for example because the COVID-19 vaccine is subsequently not granted a marketing authorisation, or because the certificates were issued for a placebo 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 States' competence.</u></i> If a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, vaccination certificates for that vaccine fall, as of that moment, within the scope of the first subparagraph of Article 5(5) of Regulation (EU) 2021/953. <i>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</i></p> |

¹⁷ 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).

¹⁸ 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).

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| | 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. | COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 ⁵ , vaccination certificates for that vaccine fall, as of that moment, within the scope of the first subparagraph of Article 5(5) of Regulation (EU) 2021/953. <i>Where a COVID-19 vaccine, having undergone clinical trials, is not granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, vaccination certificates issued for that clinically-trialled COVID-19 vaccine should no longer be valid.</i> 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. | 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. | <i>clinically-trialled COVID-19 vaccine should no longer be valid.</i> 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. |
| 12. | (5) Since the adoption of Regulation (EU) 2021/953, the | (5) Since the adoption of Regulation (EU) 2021/953, the | (5) Since the adoption of Regulation (EU) 2021/953, the | (5) Since the adoption of Regulation (EU) 2021/953, the |

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| | 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 States ²⁰ . 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. | 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 States ²¹ . 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. | 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 States ²² . 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. | 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 States ²³ . 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. |
| 13. | (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 | (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 | (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 | (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 |

²⁰ <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html>

²¹ <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html>

²² <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html>

²³ <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html>

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| | <p>‘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 2022²⁴, 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,</p> | <p>‘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 2022²⁵, 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,</p> | <p>‘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 2022²⁶, 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,</p> | <p>‘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 2022²⁷, 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,</p> |

²⁴ <https://www.ecdc.europa.eu/sites/default/files/documents/RRA-19th%20update-27-jan-2022.pdf>

²⁵ <https://www.ecdc.europa.eu/sites/default/files/documents/RRA-19th%20update-27-jan-2022.pdf>

²⁶ <https://www.ecdc.europa.eu/sites/default/files/documents/RRA-19th%20update-27-jan-2022.pdf>

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

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| | mainly through absence from work and education. | mainly through absence from work and education. | mainly through absence from work and education. | mainly through absence from work and education. |
| 14. | (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 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 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 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. |
| 15. | | <i>(7a) Overall, however, as Council Recommendation (EU) 2022/107²⁸ 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</i> | | <i>(7a) At the same time, as noted in Overall, however, as Recital 13 of Council Recommendation (EU) 2022/107 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 an this improving public</i> |

²⁸ 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).

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| | | <i>health environment, it is all the more important to enhance the protection of the right to free movement by setting out common principles on when Member States might activate restrictions for Union citizens travelling with a valid EU Digital COVID Certificate.</i> | | <i>health environment, it is all the more important to <u>facilitate enhance the protection of the right to free movement by underlining the setting out common principles on when Member States might impose limitations on this right on grounds of public health activate restrictions for Union citizens travelling with a valid certificate.</u></i> |
| 16. | (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 | (8) <i>It cannot therefore</i> 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, <i>where required by Member States to exercise their right to free movement</i> , 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 | (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 | (8) <i>In view of the remaining uncertainties regarding the further evolution of the pandemic, it cannot therefore</i> 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, <i>where required by Member States to exercise their right to free movement</i> , which are an effective, secure and privacy-preserving way of proving one's COVID-19 status, <i>where their possession is required by</i> |

| | COM proposal (5942/22) | European Parliament | Council mandate (7001/22) | Compromise text |
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| | <p>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.</p> | <p>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. <i>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.</i> 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. <i>Any need for Member States to verify EU Digital COVID Certificates should not provide a justification for the temporary introduction of controls at internal borders.</i> 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 <i>new evidence on the efficacy of COVID-</i></p> | <p>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.</p> | <p><u>Member States in order to exercise their right to free movement.</u> 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.</p> <p>(8a) <u>In this context, Member States should require</u> Union citizens exercising their right to free movement to present proof of COVID-19 vaccination, test or recovery <u>only where this is necessary and proportionate in light of the epidemiological situation and associated public health risk, as also outlined in the general principles in points 1 to 10 of Council Recommendation (EU) 2022/107.</u></p> <p>(8b) 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</p> |

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| | | <i>19 health technologies and to scientific progress in containing the COVID-19 pandemic.</i> | | 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 <u><i>new evidence regarding COVID-19 vaccination, reinfection after recovery, or and testing and to</i></u> scientific progress in containing the COVID-19 pandemic. |
| 17. | | <i>(8a) By 31 December 2022, the Commission should submit a report to the European Parliament and to the Council on the application of this Regulation. The report should contain, in particular, an overview of information received from Member States on restrictions to free movement, including of the restrictions applied by Member States, an assessment of the impact of this Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccine, the impact on fundamental rights and on the principle of non discrimination, as well as the impact on the protection of personal data during the COVID 19 pandemic. It should also assess any</i> | | <u><i>(8aa) By 1 February 2023, 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 pursuant to the present regulation, of the restrictions to free movement put in place by the Member States to limit the spread of SARS-CoV-2, of the international use of the EU Digital COVID Certificate, and an assessment of the necessity and proportionality of the continued use of the certificates referred to in Article 3(1) to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic, taking into account</i></u> |

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| | | <i>domestic uses by Member States of the EU Digital COVID Certificates for purposes other than freedom of movement, and whether they constitute obstacles to free movement. Furthermore, the report should include an assessment of the necessity and proportionality of using the EU Digital COVID Certificates in view of the pandemic situation and the latest available scientific evidence, taking account of the ECDC and the Health Security Committee opinions and recommendations, which should also be contained in the report. The report may be accompanied by a legislative proposal, in particular to shorten the period of application of this Regulation. The Commission is specifically invited to do so where the ECDC and Health Security Committee opinions and recommendations so allow.</i> | | <u><i>epidemiological developments and the latest available scientific evidence. For this purpose, the Commission's report should also contain opinions and recommendations from ECDC and the Health Security Committee, where available. The report could be accompanied by a legislative proposal 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 ECDC and the Health Security Committee.</i></u> |
| 18. | (9) The incorrect cross-reference in Article 13 of Regulation (EU) 2021/953 should be corrected. | (9) The incorrect cross-reference in Article 13 of Regulation (EU) 2021/953 should be corrected. | (9) — The incorrect cross-reference in Article 13 of Regulation (EU) 2021/953 should be corrected. | (9) — The incorrect cross-reference in Article 13 of Regulation (EU) 2021/953 should be corrected. |
| 19. | (10) Regulation (EU) 2021/953 should therefore be amended accordingly. | (10) Regulation (EU) 2021/953 should therefore be amended accordingly. | (10) Regulation (EU) 2021/953 should therefore be amended accordingly. | (10) Regulation (EU) 2021/953 should therefore be amended accordingly. |
| 20. | (11) Similarly, Regulation (EU) 2022/XXXX of the | (11) Similarly, Regulation (EU) 2022/XXXX of the | (11) Similarly, Regulation (EU) 2022/XXXX of the | (11) Similarly, Regulation (EU) 2022/XXXX of the |

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| | European Parliament and of the Council ²⁹ prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council ³⁰ , 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 Council ³¹ . | European Parliament and of the Council ³² prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council ³³ , 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 Council ³⁵ prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council ³⁶ , 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 Council ³⁸ prolongs the period of application of Regulation (EU) 2021/954 of the European Parliament and of the Council ³⁹ , 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 |

²⁹ Reference to be added.

³⁰ 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).

³¹ 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).

³² Reference to be added.

³³ 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).

³⁵ Reference to be added.

³⁶ 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).

³⁸ Reference to be added.

³⁹ 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).

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| | | European Parliament and of the Council ³⁴ . | European Parliament and of the Council ³⁷ . | European Parliament and of the Council ⁴⁰ . |
| 21. | (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 <i>Official Journal of the European Union</i> . | (12) <i>In order to allow for its prompt application</i> , this Regulation should enter into force on the third day following that of its publication in the Official Journal of the European Union. | (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 <i>Official Journal of the European Union</i> . | Council to check |
| 22. | (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 ⁴¹ , | (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 ⁴² , | (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 ⁴³ , | (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 ⁴⁴ , |
| 23. | HAVE ADOPTED THIS REGULATION: | HAVE ADOPTED THIS REGULATION: | HAVE ADOPTED THIS REGULATION: | HAVE ADOPTED THIS REGULATION: |
| 24. | <i>Article 1</i> | <i>Article 1</i> | <i>Article 1</i> | <i>Article 1</i> |

³⁴ 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).

³⁷ 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).

⁴⁰ 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).

⁴¹ Reference to be added.

⁴² **OJ**

⁴³ Reference to be added.

⁴⁴ **OJ**

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| 25. | Regulation (EU) 2021/953 is amended as follows: | Regulation (EU) 2021/953 is amended as follows: | Regulation (EU) 2021/953 is amended as follows: | Regulation (EU) 2021/953 is amended as follows: |
| 26. | (1) in Article 2, paragraph 5 is replaced by the following: | (1) in Article 2, paragraph 5 is replaced by the following: | (1) in Article 2, paragraph 5 is replaced by the following: | (1) in Article 2, paragraph 5 is replaced by the following: |
| 27. | “(5) “antigen test” means a test, of one of the following categories, that relies on detection of viral proteins (antigens) to reveal the presence of SARS-CoV-2: | “(5) “antigen test” means a test, of one of the following categories, that relies on detection of viral proteins (antigens) to reveal the presence of SARS-CoV-2: | “(5) “antigen test” means a test, of one of the following categories, that relies on detection of viral proteins (antigens) to reveal the presence of SARS-CoV-2: | “(5) “antigen test” means a test, of one of the following categories, that relies on detection of viral proteins (antigens) to reveal the presence of SARS-CoV-2: |
| 28. | (a) rapid antigen tests, such as lateral flow immunoassays that give results in less than 30 minutes, | (a) rapid antigen tests, such as lateral flow immunoassays that give results in less than 30 minutes, | (a) rapid antigen tests, such as lateral flow immunoassays that give results in less than 30 minutes, | (a) rapid antigen tests, such as lateral flow immunoassays that give results in less than 30 minutes, |
| 29. | (b) antigenic assays performed in a laboratory setting, such as enzyme-linked immunosorbent assays or automated immunoassays for detection of viral antigens;”; | (b) antigenic assays performed in a laboratory setting, such as enzyme-linked immunosorbent assays or automated immunoassays for detection of viral antigens;”; | (b) antigenic assays performed in a laboratory setting, such as enzyme-linked immunosorbent assays or automated immunoassays for detection of viral antigens;”; | (b) antigenic assays performed in a laboratory setting, such as enzyme-linked immunosorbent assays or automated immunoassays for detection of viral antigens;”; |
| 30. | (2) Article 3 is amended as follows: | (2) Article 3 is amended as follows: | (2) Article 3 is amended as follows: | (2) Article 3 is amended as follows: |
| 31. | (a) paragraph 1 is amended as follows: | (a) paragraph 1 is amended as follows: | (a) paragraph 1 is amended as follows: | (a) paragraph 1 is amended as follows: |
| 32. | (i) point (b) is replaced by the following: | (i) point (b) is replaced by the following: | (i) point (b) is replaced by the following: | (i) point (b) is replaced by the following: |
| 33. | “(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 | | “(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 | “(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 |

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| | 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);”; | | 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);”; | 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);”; |
| 34. | | <i>(ia) point (c) is replaced by the following:</i> | <u>(ii) point (c) is replaced by the following:</u> | <u>(ii) point (c) is replaced by the following:</u> |
| 35. | | “(c) a certificate confirming that, following a positive result of a NAAT test, or a rapid 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).” | <u>“(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).”;</u> | <u>“(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).”;</u> |
| 36. | (ii) the second subparagraph is replaced by the following: | (ii) the second subparagraph is replaced by the following: | (iii) the second subparagraph is replaced by the following: | (iii) the second subparagraph is replaced by the following: |
| 37. | “The Commission shall publish the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, including any updates.”; | “The Commission shall publish the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, including any updates.”; | “The Commission shall publish the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, including any updates.”; | “The Commission shall publish the EU common list of COVID-19 antigen tests agreed by the Health Security Committee, including any updates.”; |

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| 38. | (b) paragraph 11 is amended as follows: | (b) paragraph 11 is amended as follows: | (b) paragraph 11 is amended as follows: | (b) paragraph 11 is amended as follows: |
| 39. | “Where necessary, the Commission shall ask the Health Security Committee, 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.”; | “Where necessary, the Commission shall ask the Health Security Committee, 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.”; | “Where necessary, the Commission shall ask the Health Security Committee, 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.”; | “Where necessary, the Commission shall ask the Health Security Committee, 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.”; |
| 40. | | <i>(2a) in Article 4, paragraph 2 is replaced by the following:</i> | | Council to check |
| 41. | | “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 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 | | |

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| | | 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.” | | |
| 42. | (3) Article 5 is amended as follows: | (3) Article 5 is amended as follows: | (3) Article 5 is amended as follows: | (3) Article 5 is amended as follows: |
| 43. | (a) in paragraph 2, point (b) is replaced by the following: | (a) in paragraph 2, point (b) is replaced by the following: | (a) in paragraph 2, point (b) is replaced by the following: | (a) in paragraph 2, point (b) is replaced by the following: |
| 44. | “(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;”; | (b) information about the COVID-19 <i>vaccines</i> and the number of doses administered to the holder, regardless of the Member State in which they have been administered; | “(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;”; | EP to check |
| 45. | (b) in paragraph 5, the following subparagraph is added: | (b) in paragraph 5, the following subparagraph is added: | (b) in paragraph 5, the following subparagraphs is added: | (b) in paragraph 5, the following subparagraphs is added: |
| 46. | “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 | 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 | “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 | “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 |

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| | 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.”; | with the specific data fields set out in point 1 of the Annex shall not undermine the integrity of the clinical trial. <i>The validity period of such vaccination certificates shall not be longer than that of other vaccination certificates issued pursuant to this paragraph.</i> 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. <i>Where a COVID-19 vaccine undergoing clinical trials is subsequently granted a marketing authorisation pursuant to Regulation (EC) No 726/2004, the vaccination certificates issued in respect of that vaccine continue to be valid in accordance with the first subparagraph of this paragraph. Where a COVID-19 vaccine subsequently receives a negative evaluation of an application for marketing authorisation, or where no marketing authorisation is sought for that vaccine, the certificates issued on the basis of that vaccine shall no longer be valid.</i> ; | 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.”; | with the specific data fields set out in point 1 of the Annex shall not undermine the integrity of the clinical trial. <i>The validity period of such vaccination certificates shall not be longer than that of other vaccination certificates issued pursuant to this paragraph.</i> 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, <u><i>unless they have been revoked following the conclusion of the clinical trial.</i></u> <i>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.</i> |

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| 47. | (4) in Article 6(2), point (b) is replaced by the following: | (4) in Article 6(2), point (b) is replaced by the following: | (4) in Article 6(2), point (b) is replaced by the following: | (4) in Article 6(2), point (b) is replaced by the following: |
| 48. | “(b) information about the NAAT test or antigen test to which the holder was subject;”; | “(b) information about the NAAT test or antigen test to which the holder was subject;”; | “(b) information about the NAAT test or antigen test to which the holder was subject;”; | “(b) information about the NAAT test or antigen test to which the holder was subject;”; |
| 49. | (5) in Article 7, paragraph 4 is replaced by the following: | | (5) in Article 7 <u>is amended as follows:</u> | EP to check |
| 50. | | | <u>(a) paragraph 1 is replaced by the following:</u> | |
| 51. | | | <u>“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.</u> | |
| 52. | | <i>(-a) in Article 7(1), the second subparagraph is replaced by the following:</i> | | |
| 53. | | “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 <i>an</i> 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 | <u>A Member State may also issue, upon request, certificates of recovery referred to in point (c) of Article 3(1) following a positive result of an antigen test listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee carried out by</u> | |

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| | | personnel.” | <u>health professionals or by skilled testing personnel.</u> | |
| 54. | | <i>(-aa) In Article 7(1), the third subparagraph is replaced by the following:</i> | | |
| 55. | | “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 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.” | <u>Member States may issue certificates of recovery based on antigen tests carried out by health professionals or by skilled testing personnel on or after 1 October 2021, provided that the antigen test used was included in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee at the time the positive test result was produced.</u> | |
| 56. | | <i>(-ab) In Article 7(1), the fourth subparagraph is replaced by the following:</i> | | |
| 57. | | “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.” | <u>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.</u> | |
| 58. | | | <u>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</u> | |

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| | | | <u>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.”;</u> | |
| 59. | | (5) in Article 7, paragraph 4 is replaced by the following: | (b) paragraph 4 is replaced by the following: | (b) paragraph 4 is replaced by the following: |
| 60. | “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.”; | “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.”; | “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.”; | “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.”; |
| 61. | | <i>(5a) in Article 10, paragraph 5 is replaced by the following:</i> | | EP and Council to check |
| 62. | | “5. Any certificate revocation lists exchanged between Member | | |

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| | | States pursuant to Article 4(2) shall not be retained after the end of period of the application of this Regulation.”; | | |
| 63. | | <i>(5b) Article 11 is replaced by the following:</i> | | Political issue (Travel restrictions) |
| 64. | | “Article 11 | | |
| 65. | | Restrictions to free movement and information exchange | | |
| 66. | | 1. Without prejudice to Member States’ <i>exclusive</i> competence to impose restrictions <i>to free movement</i> 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 <i>introducing</i> restrictions <i>or obstacles to, or requirements for, the exercise of the right</i> to free movement, such as additional travel-related testing for SARS-CoV-2 infection or travel-related quarantine or self-isolation, unless they are <i>strictly</i> necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, also taking into account <i>fully the</i> available scientific evidence, including epidemiological | | 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, <i>also</i> taking into account available scientific evidence, including epidemiological data published by the ECDC on the basis of <i>Recommendation (EU) 2020/1475.</i> |

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| | | data published by the ECDC on the basis of Recommendation (EU) 2020/1475. | | |
| 67. | | <p>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)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:</p> | | <p>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:</p> <p>a) the reasons for such restrictions, <u>including all relevant epidemiological data and scientific evidence supporting those restrictions;</u></p> <p>(b) the scope of such restrictions, specifying which certificate holders are subject to or exempt from such restrictions;</p> |

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| | | | | (c) the date and duration of such restrictions. |
| 68. | | 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) 2022/107⁴⁵: | | |
| 69. | | (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; | | |
| 70. | | (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; | | |
| 71. | | (c) any such restrictions shall be lifted as soon as the | | |

⁴⁵ 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).”

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| | | <i>epidemiological situation, including in hospitals, allows it;</i> | | |
| 72. | | <i>(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;</i> | | |
| 73. | | <i>(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;</i> | | |
| 74. | | <i>(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;</i> | | |
| 75. | | <i>(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;</i> | | |

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| 76. | | <i>(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> | | <u><i>2a. Where a Member State requires other restrictions in application of §1 and 2, Member States shall pay particular attention to the specificities of cross-border regions, outermost regions, exclaves and geographically isolated areas and the likely impact of such a measure on the functioning of the cross-border regions, taking into account the strong social and economic ties between them.</i></u> |
| 77. | | <i>(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;</i> | | |
| 78. | | <i>(j) Member States shall regularly exchange information on all matters covered by the scope of this recommendation and inform citizens accordingly;</i> | | |
| 79. | | <i>(k) restrictions shall not take the form of prohibitions on the operation of certain transport services;</i> | | |
| 80. | | <i>Moreover, in such a situation, the Member State concerned shall inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To that end, the</i> | | |

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| | | <i>Member State shall provide the following information:</i> | | |
| 81. | | <i>(a) the reasons for such restrictions, including all relevant epidemiological data and scientific evidence supporting those restrictions;</i> | | |
| 82. | | <i>(b) the scope of such restrictions, specifying which certificate holders are subject to or exempt from such restrictions;</i> | | |
| 83. | | <i>(c) the date and duration of such restrictions.</i> | | |
| 84. | | 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). | | 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). |
| 85. | | 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 | | 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 |

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| | | addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner.; | | addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner. |
| 86. | (6) in Article 12, paragraph 2 is replaced by the following: | (6) in Article 12, paragraph 2 is replaced by the following: | (6) in Article 12, paragraph 2 is replaced by the following: | (6) in Article 12, paragraph 2 is replaced by the following: |
| 87. | “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.”; | “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.”; | “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.”; | “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.”; |
| 88. | (7) in Article 13, paragraph 2 is replaced by the following: | (7) in Article 13, paragraph 2 is replaced by the following: | (7) in Article 13, paragraph 2 is replaced by the following: | (7) in Article 13, paragraph 2 is replaced by the following: |
| 89. | “2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.”; | “2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.”; | “2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.”; | “2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.”; |
| 90. | | <u>(7a) Article 16 is replaced by the following:</u> | <u>(7a) Article 16 is replaced by the following:</u> | |
| 91. | | “Article 16 | | |

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| 92. | | Commission report | | |
| 93. | | 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: | | 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: |
| 94. | | (a) — the number of certificates issued pursuant to this Regulation; | | (a) the number of certificates issued pursuant to this Regulation; |
| 95. | | (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 | | (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 |
| 96. | | (c) — the information received pursuant to Article 11. | | (c) the information received pursuant to Article 11. |
| 97. | | | | 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. |
| 98. | | | | The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement, including on travel and |

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| | | | | 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. |
| 99. | | | | 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. |
| 100a) | | 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. | <u>“By 1 February 2023, the Commission shall submit a report to the European Parliament and to the Council on the application of this Regulation.</u>” | <u>3. By 1 February 2023, the Commission shall submit a report to the European Parliament and to the Council on the application of this Regulation.</u> |
| 100b) | | The report shall contain, in particular, <i>an overview of information received from Member States pursuant to Article 11, including of the restrictions applied by Member States</i> , 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, <i>the impact on fundamental rights and on the principle of non-discrimination, as well as</i> and the impact on the protection of personal data during | <u>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.</u> | <u>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.</u> |

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| | | the COVID-19 pandemic. <i>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 such uses constitute obstacles to free movement.</i> | | |
| 100c) | | <i>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.</i> | | |
| 100d) | | The report may be accompanied by a legislative proposal 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.” | <u>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.”;</u> | <u><i>The report may be accompanied by a legislative proposal 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 ECDC and the Health Security Committee.</i></u> |

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| 100. | (8) in Article 17, the second paragraph is replaced by the following: | (8) in Article 17, the second paragraph is replaced by the following: | (8) in Article 17, the second paragraph is replaced by the following: | (8) in Article 17, the second paragraph is replaced by the following: |
| 101. | “It shall apply from 1 July 2021 to 30 June 2023.”; | “It shall apply from 1 July 2021 to 30 June 2023.”; | “It shall apply from 1 July 2021 to 30 June 2023.”; | “It shall apply from 1 July 2021 to 30 June 2023.”; |
| 102. | (9) in the Annex, point 2(i) is replaced by the following: | (9) in the Annex, point 2(i) is replaced by the following: | (9) in the Annex, point 2(i) is replaced by the following: | (9) in the Annex, point 2(i) is replaced by the following: |
| 103. | “(i) testing centre or facility (optional for antigen test);”. | “(i) testing centre or facility (optional for antigen test);”. | “(i) testing centre or facility (optional for antigen test);”. | “(i) testing centre or facility (optional for antigen test);”. |
| 104. | <i>Article 3</i> | <i>Article 3</i> | <i>Article 3<u>2</u></i> | <i>Article 3<u>2</u></i> |
| 105. | This Regulation shall enter into force on the third day following that of its publication in the <i>Official Journal of the European Union</i> . | This Regulation shall enter into force on the third day following that of its publication in the <i>Official Journal of the European Union</i> . | This Regulation shall enter into force on the third day following that of its publication in the <i>Official Journal of the European Union</i> . | This Regulation shall enter into force on the third day following that of its publication in the <i>Official Journal of the European Union</i> . |
| 106. | This Regulation shall be binding in its entirety and directly applicable in all Member States. | This Regulation shall be binding in its entirety and directly applicable in all Member States. | This Regulation shall be binding in its entirety and directly applicable in all Member States. | This Regulation shall be binding in its entirety and directly applicable in all Member States. |

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2021/954 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
~~**amending Regulation (EU) 2021/954 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**~~

| | COM proposal (5943/22) | European Parliament | Council mandate (7001/22) | Compromise texte |
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| | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, |
| 1. | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2), point (c) thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2), point (c) thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2), point (c) thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2), point (c) thereof, |
| 2. | Having regard to the proposal from the European Commission, | Having regard to the proposal from the European Commission, | Having regard to the proposal from the European Commission, | Having regard to the proposal from the European Commission, |
| 3. | Acting in accordance with the ordinary legislative procedure, | Acting in accordance with the ordinary legislative procedure, | Acting in accordance with the ordinary legislative procedure, | Acting in accordance with the ordinary legislative procedure, |
| 4. | Whereas: | Whereas: | Whereas: | Whereas: |
| 5. | (1) Under the Schengen <i>acquis</i> , third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other | (1) Under the Schengen <i>acquis</i> , third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the | (1) Under the Schengen <i>acquis</i> , third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the | (1) Under the Schengen <i>acquis</i> , third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the |

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| | Member States during a period of 90 days in any 180-day period ¹ . | territories of all other Member States during a period of 90 days in any 180-day period ² . | territories of all other Member States during a period of 90 days in any 180-day period ³ . | territories of all other Member States during a period of 90 days in any 180-day period ⁴ . |
| 6. | (2) On 14 June 2021, the European Parliament and the Council adopted Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate ⁵ . That Regulation sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Regulation (EU) 2021/953 is accompanied by Regulation (EU) | (2) On 14 June 2021, the European Parliament and the Council adopted Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate ⁷ . That Regulation sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Regulation (EU) 2021/953 is accompanied by Regulation (EU) | (2) On 14 June 2021, the European Parliament and the Council adopted Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate ⁹ . That Regulation sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Regulation (EU) 2021/953 is accompanied by | (2) On 14 June 2021, the European Parliament and the Council adopted Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate ¹¹ . That Regulation sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Regulation (EU) 2021/953 is accompanied by |

¹ 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).

² 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).

³ 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).

⁴ 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).

⁵ 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).

⁷ 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).

⁹ 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).

¹¹ 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).

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| | 2021/954 of the European Parliament and of the Council ⁶ , which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State's territory and who are entitled to travel to other Member States in accordance with Union law. | 2021/954 of the European Parliament and of the Council ⁸ , which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State's territory and who are entitled to travel to other Member States in accordance with Union law. | Regulation (EU) 2021/954 of the European Parliament and of the Council ¹⁰ , which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State's territory and who are entitled to travel to other Member States in accordance with Union law. | Regulation (EU) 2021/954 of the European Parliament and of the Council ¹² , which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State's territory and who are entitled to travel to other Member States in accordance with Union law. |
| 7. | (3) Regulations (EU) 2021/953 and (EU) 2021/954 are due to expire on 30 June 2022. Nevertheless, the pandemic is still on-going and the recent outbreak of the 'Omicron' variant of concern continues to negatively impact travel within the Union. Consequently, the EU Digital COVID Certificate remains relevant and it is necessary to allow for its continued use. | (3) Regulations (EU) 2021/953 and (EU) 2021/954 are due to expire on 30 June 2022. Nevertheless, the pandemic is still on-going and the recent outbreak of the 'Omicron' variant of concern continues to negatively impact travel within the Union. Consequently, the EU Digital COVID Certificate remains relevant and it is necessary to allow for its continued use. | (3) Regulations (EU) 2021/953 and (EU) 2021/954 are due to expire on 30 June 2022. Nevertheless, the pandemic is still on-going and the recent outbreak of the 'Omicron' variant of concern continues to negatively impact travel within the Union. Consequently, the EU Digital COVID Certificate remains relevant and it is necessary to allow for its continued use. | (3) Regulations (EU) 2021/953 and (EU) 2021/954 are due to expire on 30 June 2022. Nevertheless, the pandemic is still on-going and the recent outbreak of the 'Omicron' variant of concern continues to negatively impact travel within the Union. Consequently, the EU Digital COVID Certificate remains relevant and it is necessary to allow for its continued use. |

⁶ 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).

⁸ 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) 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).

¹² 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).

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| 8. | (4) The application of Regulation (EU) 2021/953 is to be prolonged by 12 months. Since the objective of Regulation (EU) 2021/954 is to extend the application of Regulation (EU) 2021/953 to certain categories of third country nationals lawfully residing or staying in the Union, the duration of its application should be directly linked to that of Regulation (EU) 2021/953. Regulation (EU) 2021/954 should therefore be amended accordingly. | (4) The application of Regulation (EU) 2021/953 is to be prolonged by 12 months. Since the objective of Regulation (EU) 2021/954 is to extend the application of Regulation (EU) 2021/953 to certain categories of third country nationals lawfully residing or staying in the Union, the duration of its application should be directly linked to that of Regulation (EU) 2021/953. Regulation (EU) 2021/954 should therefore be amended accordingly. | (4) The application of Regulation (EU) 2021/953 is to be prolonged by 12 months. Since the objective of Regulation (EU) 2021/954 is to extend the application of Regulation (EU) 2021/953 to certain categories of third country nationals lawfully residing or staying in the Union, the duration of its application should be directly linked to that of Regulation (EU) 2021/953. Regulation (EU) 2021/954 should therefore be amended accordingly. | (4) The application of Regulation (EU) 2021/953 is to be prolonged by 12 months. Since the objective of Regulation (EU) 2021/954 is to extend the application of Regulation (EU) 2021/953 to certain categories of third country nationals lawfully residing or staying in the Union, the duration of its application should be directly linked to that of Regulation (EU) 2021/953. Regulation (EU) 2021/954 should therefore be amended accordingly. |
| 9. | (5) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/953 should not be considered to justify the temporary reintroduction of controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules as set out in Regulation (EU) 2016/399 of the European Parliament and of the Council (Schengen Borders Code). | (5) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/953 should not be considered to justify the temporary reintroduction of controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules as set out in Regulation (EU) 2016/399 of the European Parliament and of the Council (Schengen Borders Code). | (5) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/953 should not be considered to justify the temporary reintroduction of controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules as set out in Regulation (EU) 2016/399 of the European Parliament and of the Council (Schengen Borders Code). | (5) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/953 should not be considered to justify the temporary reintroduction of controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules as set out in Regulation (EU) 2016/399 of the European Parliament and of the Council (Schengen Borders Code). |
| 10. | (6) In accordance with Articles 1 and 2 of Protocol No 22 on the | (6) In accordance with Articles 1 and 2 of Protocol No 22 on the | (6) In accordance with Articles 1 and 2 of Protocol No 22 on the | (6) In accordance with Articles 1 and 2 of Protocol No 22 on the |

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| | position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen <i>acquis</i> , Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law. | position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen <i>acquis</i> , Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law. | position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen <i>acquis</i> , Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law. | position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen <i>acquis</i> , Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law. |
| 11. | (7) This Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ¹³ ; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. In order to allow Member States to accept, under the conditions set out in Regulation (EU) 2021/953, COVID-19 certificates issued by Ireland to third-country nationals legally staying or residing in its territory for the purposes of facilitating travel within | (7) This Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ¹⁴ ; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. In order to allow Member States to accept, under the conditions set out in Regulation (EU) 2021/953, COVID-19 certificates issued by Ireland to third-country nationals legally staying or residing in its territory for the purposes of facilitating travel within | (7) This Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ¹⁵ ; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. In order to allow Member States to accept, under the conditions set out in Regulation (EU) 2021/953, COVID-19 certificates issued by Ireland to third-country nationals legally staying or residing in its territory for the purposes of facilitating travel within | (7) This Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ¹⁶ ; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. In order to allow Member States to accept, under the conditions set out in Regulation (EU) 2021/953, COVID-19 certificates issued by Ireland to third-country nationals legally staying or residing in its territory for the purposes of facilitating travel within |

¹³ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

¹⁴ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

¹⁵ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

¹⁶ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

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| | the territories of the Member States, Ireland should issue those third-country nationals with COVID-19 certificates that comply with the requirements of the EU Digital COVID Certificate trust framework. Ireland and the other Member States should accept certificates issued to third-country nationals covered by this Regulation on a reciprocal basis. | the territories of the Member States, Ireland should issue those third-country nationals with COVID-19 certificates that comply with the requirements of the EU Digital COVID Certificate trust framework. Ireland and the other Member States should accept certificates issued to third-country nationals covered by this Regulation on a reciprocal basis. | the territories of the Member States, Ireland should issue those third-country nationals with COVID-19 certificates that comply with the requirements of the EU Digital COVID Certificate trust framework. Ireland and the other Member States should accept certificates issued to third-country nationals covered by this Regulation on a reciprocal basis. | the territories of the Member States, Ireland should issue those third-country nationals with COVID-19 certificates that comply with the requirements of the EU Digital COVID Certificate trust framework. Ireland and the other Member States should accept certificates issued to third-country nationals covered by this Regulation on a reciprocal basis. |
| 12. | (8) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen <i>acquis</i> within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. | (8) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen <i>acquis</i> within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. | (8) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen <i>acquis</i> within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. | (8) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen <i>acquis</i> within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. |
| 13. | (9) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to | (9) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to | (9) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to | (9) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to |

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| | in Article 1, point C, of Council Decision 1999/437/EC ¹⁷ . | in Article 1, point C, of Council Decision 1999/437/EC ¹⁸ . | in Article 1, point C, of Council Decision 1999/437/EC ¹⁹ . | in Article 1, point C, of Council Decision 1999/437/EC ²⁰ . |
| 14. | (10) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC ²¹ . | (10) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with | (10) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction | (10) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen <i>acquis</i> within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction |

¹⁷ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

¹⁸ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

¹⁹ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

²⁰ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

²¹ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

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| | | Article 3 of Council Decision 2008/146/EC ²² . | with Article 3 of Council Decision 2008/146/EC ²³ . | with Article 3 of Council Decision 2008/146/EC ²⁴ . |
| 15. | (11) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen <i>acquis</i> within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU ²⁵ . | (11) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen <i>acquis</i> within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1 point C, of Decision | (11) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen <i>acquis</i> within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction | (11) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen <i>acquis</i> within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen <i>acquis</i> which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction |

²² Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

²³ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

²⁴ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

²⁵ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

| | COM proposal (5943/22) | European Parliament | Council mandate (7001/22) | Compromise texte |
|-----|---|---|---|---|
| | | 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU ²⁶ . | with Article 3 of Decision 2011/350/EU ²⁷ . | with Article 3 of Decision 2011/350/EU ²⁸ . |
| 16. | (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 <i>Official Journal of the European Union</i> . | (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 <i>Official Journal of the European Union</i> . | (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 <i>Official Journal of the European Union</i> . | (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 <i>Official Journal of the European Union</i> . |
| 17. | (13) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the | (13) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the | (13) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European | (13) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European |

²⁶ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

²⁷ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

²⁸ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

| | COM proposal (5943/22) | European Parliament | Council mandate (7001/22) | Compromise texte |
|-----|---|---|--|---|
| | Council ²⁹ and delivered an opinion on [...], | Council ³⁰ and delivered an opinion on [...], | Parliament and of the Council ³¹ and delivered an opinion on [...], | Parliament and of the Council ³² and delivered an opinion on [...], |
| 18. | HAVE ADOPTED THIS REGULATION: | HAVE ADOPTED THIS REGULATION: | HAVE ADOPTED THIS REGULATION: | HAVE ADOPTED THIS REGULATION: |
| 19. | Article 1 | Article 1 | Article 1 | Article 1 |
| 20. | Article 3 of Regulation (EU) 2021/954 is replaced by the following: | Article 3 of Regulation (EU) 2021/954 is replaced by the following: | Article 3 of Regulation (EU) 2021/954 is replaced by the following: | Article 3 of Regulation (EU) 2021/954 is replaced by the following: |
| 21. | <i>‘Article 3</i> This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. | <i>‘Article 3</i> This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. | <i>‘Article 3</i> This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. | <i>‘Article 3</i> This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. |

²⁹ 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).

³⁰ 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).

³¹ 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).

³² 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).

| | COM proposal (5943/22) | European Parliament | Council mandate (7001/22) | Compromise texte |
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| 22. | It shall apply from 1 July 2021 for as long as Regulation (EU) 2021/953 is applicable.' | It shall apply from 1 July 2021 for as long as Regulation (EU) 2021/953 is applicable.' | It shall apply from 1 July 2021 for as long as Regulation (EU) 2021/953 is applicable.' | It shall apply from 1 July 2021 for as long as Regulation (EU) 2021/953 is applicable.' |
| 23. | Article 2 | Article 2 | Article 2 | Article 2 |
| 24. | This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. | This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. | This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. | This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union. |
| 25. | This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties. | This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties. | This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties. | This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties. |