



Brussels, **XXX**
[...](2021) **XXX** draft

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UNTIL ADOPTION

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

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EXPLANATORY MEMORANDUM

CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The Commission is proposing to put in place a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the Member States (Digital Green Certificate).

To ensure a well-coordinated, predictable and transparent approach to the adoption of restrictions on freedom of movement, the Council adopted, on 13 October 2020, Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic¹. In line with point 17 of the Council Recommendation (EU) 2020/1475, Member States could require persons travelling from risk areas in another EU Member State to undergo quarantine/self-isolation and/or to undergo a test for SARS-CoV-2 infection prior to and/or after arrival.

To show compliance with the different requirements, travellers have been asked to provide various types of documentary evidence, such as medical certificates, test results, or declarations. The absence of standardised and secured formats has resulted in travellers experiencing problems in the acceptance of their documents, as well as reports of fraudulent or forged documents being presented². These issues, which can lead to unnecessary delays and obstacles, are likely to become even more prominent as more and more Europeans are being tested for and vaccinated against COVID-19 and receive documentary proof to this effect. The European Council has taken up this matter. In their statement, adopted following the informal video conferences on 25 and 26 February 2021³, the members of the European Council called for work to continue on a common approach to vaccination certificates.

There is consensus among Member States on the use of such certificates for medical purposes, such as to ensure proper follow-up between a first and second dose, as well as any necessary subsequent booster. Member States are working on developing vaccination certificates, often using information available in immunisation registries.

The Commission has been working with the Member States in the eHealth Network, a voluntary network connecting national authorities responsible for eHealth, on preparing the interoperability of vaccination certificates. On 27 January 2021, the eHealth Network adopted Guidelines on proof of vaccination for medical purposes⁴. These guidelines define the central interoperability elements, namely a minimum dataset for vaccination certificates, and a unique identifier.

Based on the technical work carried out so far, the Commission proposes, in its proposal for Regulation EU COM(2021)/xxx, to establish an EU-wide framework for the issuance, verification and acceptance of vaccination certificates within the EU as part of a “Digital Green Certificate”. At the same time, this framework should also cover other certificates issued during the COVID-19 pandemic, namely documents certifying a negative test result for SARS-CoV-2 infection as well as documents certifying that the person concerned has

¹ OJ L 337, 14.10.2020, p. 3.

² <https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates>

³ SN 2/21.

⁴ https://ec.europa.eu/health/sites/health/files/chealth/docs/vaccination-proof_interoperability_guidelines_en.pdf

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recovered from a previous infection with SARS-CoV-2. This allows persons who are not vaccinated or who have not yet had the opportunity to be vaccinated to benefit from such an interoperable framework as well, facilitating their [travel](#). While children, for example, cannot benefit from COVID-19 vaccination for the time being, they should be able to receive a test or recovery certificate, which could also be received by their parents on their behalf.

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This [proposal](#) has the objective of ensuring that the same framework applies to third-country nationals who are legally staying or legally residing on the territory of an EU Member State and who are entitled to travel to another Member State in accordance with Union law.

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Pursuant to Article 77(2)(c) of the Treaty on the Functioning of the European Union (TFEU), the Union shall develop policies setting out the conditions under which nationals of third countries shall have the freedom to travel within the Union for a short period. However, some of the measures adopted by Member States to limit the spread of the COVID-19 outbreak have had an impact on the freedom to travel within the Union of legally staying [or legally residing](#) third-country nationals. These measures have often consisted of restrictions on entry or other specific requirements applicable to cross-border travellers, such as the requirement to undergo quarantine or self-isolation or to be tested for COVID-19 infection prior to and/or after arrival.

Council Recommendation (EU) 2020/1475 which also addresses the situation of third-country nationals legally staying or legally residing in the Union, established a coordinated approach on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission, published by the European Centre for Disease Prevention and Control (ECDC)⁵, based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas.

On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen *acquis* to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475. To ensure interoperability between the different technical solutions for vaccination certificates being developed by the Member States, some of which have already started accepting proofs of vaccination to exempt travellers from certain restrictions, uniform conditions for the issuance, verification and acceptance of certificates on COVID-19 vaccination, tests and recovery are needed.

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The “Digital Green Certificate” framework to be established should lay out the format and content of certificates on COVID-19 vaccination, testing and recovery. The Commission also proposes that the “Digital Green Certificate” framework should ensure that these certificates can be issued in an interoperable format and be reliably verified when presented by the holder in other Member States, thereby facilitating [travel](#) within the [European Union](#).

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The certificates should contain only such personal data as is necessary. Given that the personal data includes sensitive medical data, a very high level of data protection should be ensured and data minimisation principles should be preserved. In particular, the “Digital

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⁵ <https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement>

Green Certificate” framework should not require the setting up and maintenance of a database at EU level, but should allow for the decentralised verification of digitally signed interoperable certificates.

The proposed Regulation (EU) 2021/XXX takes into account ongoing efforts at the international level, such as under the auspices of the World Health Organization (‘WHO’) and other specialized agencies of the United Nations, to establish specifications and guidance for using digital technologies for documenting vaccination status. Third countries should be encouraged to recognise the “Digital Green Certificate” when waiving restrictions on non-essential travel. In particular, this could include interoperability between technological systems established at global level and the systems established for the purpose of this Regulation to facilitate free movement.

- **Consistency with existing policy provisions in the policy area**

This proposal is without prejudice to the Schengen rules as regards the entry conditions for third country nationals. The proposed Regulation should not in any way be understood as encouraging or facilitating the reintroduction of border controls, which must remain a measure of last resort subject to the conditions set out in [Regulation \(EU\) 2016/399](#) (“the Schengen Borders Code”)⁶.

The proposal complements and builds upon other policy initiatives adopted during the COVID-19 pandemic in the field of free movement and travelling, such as Council Recommendation (EU) 2020/1475 and Council Recommendation (EU) 2020/912⁷. In particular, Council Recommendation (EU) 2020/1475 describes the general principles based on which Member States should coordinate their actions when adopting and applying measures to protect public health in response to the COVID-19 pandemic, and Council Recommendation (EU) 2020/912 lists the third-countries from where non-essential travel should be allowed, as well as the functions and needs for which essential travel is allowed irrespective of the third-country of origin.

- **Consistency with other Union policies**

This proposal is part of the set of EU measures to respond to the COVID-19 pandemic. It builds, in particular, on previous technical work carried out in the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council⁸ and the eHealth Network, a voluntary network connecting national authorities responsible for eHealth.

The proposal complements and builds upon policy initiatives adopted in the field of free movement during the COVID-19 pandemic, such as Council Recommendations 2020/1475 and 2021/119.

This proposal is consistent with the Union's policy on immigration of third country nationals.

⁶ [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 \(OJ L 77, 23.3.2016, p.1\).](#)

⁷ [Council Recommendation \(EU\) 2021/132 of 2 February 2021 amending Recommendation \(EU\) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction \(OJ L 41, 4.2.2021, p. 1–5\).](#)

⁸ [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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2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

Article 77(2)(c) TFEU stipulates that the Union shall set out the conditions under which nationals of [legally staying or legally residing](#) third countries shall have the freedom to travel within the Union for a short period. The ordinary legislative procedure applies.

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The proposal aims to facilitate the travel of third-country nationals within the EU during the COVID-19 pandemic by establishing a common framework for the issuance and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery. This should allow third-country nationals legally staying [or legally residing](#) in the EU to demonstrate that they fulfil public health requirements imposed, in compliance with Union law, by the Member State of destination. The proposal also aims to ensure that restrictions to the freedom to travel currently in place to limit the spread of COVID-19 can be lifted in a coordinated manner as more scientific evidence becomes available.

This proposal establishes neither an obligation nor a right to vaccination. Vaccination strategies are a national competence of the Member States.

• Subsidiarity

The objectives of this proposal, namely to facilitate travelling within the Union during the COVID-19 pandemic by establishing secure and interoperable certificates on the holder's vaccination, testing and recovery status cannot be sufficiently achieved by the Member States individually but can rather, by reason of the scale and effects of the action, be better achieved at Union level.

Absence of EU level action would likely result in Member States adopting different systems, resulting in [legally staying or legally residing](#) third-country nationals exercising their freedom to travel experiencing problems in terms of having the documents they have been issued recognised in other Member States. In particular, it is necessary to agree on the technical standards to be used to ensure interoperability, security and verifiability of the certificates being issued.

• Proportionality

EU action can add considerable value in addressing the challenges identified above and is the only way by which a converged and compatible framework can be achieved and maintained.

The adoption of unilateral or uncoordinated measures regarding COVID-19 health certificates may lead to measures that limit the possibility for [third country nationals who are entitled to travel within the Union, to engage in such travel.](#)

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The proposed Regulation should be suspended once the COVID-19 pandemic has been overcome, since as of that point, there is no justification to oblige third-country nationals to present any health documents when [travelling within the Union](#). At the same time, their applications should resume if the WHO declares another pandemic due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential.

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• Choice of the instrument

A Regulation ensures the direct, immediate and common implementation of EU law in all Member States.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

The proposal takes into account the discussions held at regular intervals with Member States, the technical exchanges taking place within the Health Security Committee and the eHealth Network, the information available on the evolving epidemiological situation and relevant available scientific evidence.

- **Collection and use of expertise**

The proposal builds on the technical exchanges taking place within the Health Security Committee and the eHealth Network, the information published by ECDC on the epidemiological situation related to the COVID-19 pandemic, and relevant available scientific evidence.

- **Impact assessment**

In view of the urgency, the Commission did not carry out any impact assessment.

- **Fundamental rights**

This proposal implies processing of personal data, including health data. There are potential impacts on individuals' fundamental rights, namely Article 7 of the Charter on the respect of private life and Article 8 on the right to the protection of personal data. Processing the personal data of individuals, including collection, access and use of personal data, affects the right to privacy and the right to protection of personal data under the Charter. Interference with these fundamental rights must be justified.

As regards the right to the protection of personal data including data security, Regulation (EU) 2016/679 of the European Parliament and of the Council⁹ applies. No derogation from the data protection regime of the Union is envisaged and clear rules, conditions and robust safeguards shall be implemented by Member States in line with the EU data protection rules as appropriate. The framework to be established by the proposed Regulation does not require the exchange of personal data between the Member States and the Commission or between the Member States themselves. The proposed Regulation does not establish a European database on vaccination, testing or recovery from COVID-19. For the purposes of the proposed Regulation, the personal data need only to be included in the certificate issued, which should be protected against falsification and tampering.

4. BUDGETARY IMPLICATIONS

The financing of actions supporting this initiative will be covered by the Legislative Financial Statement submitted with the proposal for Regulation (EU) 2021/XXX.

⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Not relevant.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 of the proposal describes the subject matter of the proposed Regulation.

Article 2 provides for an expedited entry into force of the Regulation.

Proposal for a

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on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2)(c) thereof,

Having regard to the proposal from the European Commission,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Under the Schengen *acquis*, 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 Member States during a period of 90 days in any 180-day period.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.
- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.
- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic¹⁰.
- (5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632¹¹ on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen *acquis* to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.

¹⁰ OJ L 337, 14.10.2020, p. 3.

¹¹ [Council Recommendation \(EU\) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area \(OJ L 366, 4.11.2020, p. 25\).](#)

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(6) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.

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(7) Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council¹². This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC of the European Parliament and the Council¹³, vaccines whose distribution has been temporarily authorised based on Article 5(2) of that Directive, or vaccines having received a WHO Emergency Use Listing. Regulation (EU) 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.

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(8) To facilitate travel within the territories of the Member States by third country nationals who are entitled to engage in such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) 2021/xxxx should apply also to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.

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(9) For certificates to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable.

(10) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions in response to the pandemic. Any need for verification of certificates established by Regulation (EU) 2021/xxxx cannot as such justify the

¹² 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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¹³ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

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reintroduction of border checks at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code)¹⁴.

- (11) In accordance with Articles 1 and 2 of Protocol No 22 on the 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 *acquis*, 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.
- (12) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC¹⁵; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.
- (13) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen *acquis* within the meaning of Article 3(2) of the 2003 Act of Accession, Article 4(2) of the 2005 Act of Accession and Article 4(2) of the 2011 Act of Accession.
- (14) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* 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 *acquis* which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC¹⁶.
- (15) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* 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 *acquis* 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/EC¹⁷.
- (16) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen *acquis* 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

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¹⁴ 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 (OJ L 77, 23.3.2016, p.1).

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 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).

¹⁷ 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).

development of the Schengen acquis 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/EU¹⁸,

HAVE ADOPTED THIS REGULATION:

Article 1

Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with [Union](#) law.

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Article 2

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 be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament
The President*

*For the Council
The President*

¹⁸ 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).