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COVER NOTE

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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Delegations will find attached document COM(2021) 294 final.

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JAI.A



EUROPEAN COMMISSION

> Brussels, 31.5.2021 COM(2021) 294 final

2021/0138 (NLE)

Proposal for a

COUNCIL RECOMMENDATION

amending Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

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. The Council Recommendation 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)², 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.

Recommendation (EU) 2020/1475 seeks to ensure increased coordination among Member States considering the adoption of measures restricting free movement on grounds of public health in the context of the pandemic. When adopting and applying restrictions to free movement, Member States should respect EU law, in particular the principles of proportionality and non-discrimination. Recommendation (EU) 2020/1475 was later amended in view of a very high level of community transmission across the EU, possibly linked to the increased transmissibility of new SARS-CoV-2 variants of concern³.

After another peak of infections in early April, infection numbers have recently been decreasing across the EU. By the end of week 19 (16 May 2021), the 14-day cumulative case notification rate for the EU/EEA had fallen to 224 per 100 000 population, and had been decreasing for six weeks⁴. This decrease is despite a continuous increase in the testing rate. Similar decreases can be observed for hospital and intensive care unit occupancy by and new admissions of COVID-19 patients.

This improvement of the epidemiological situation is predominantly linked to an accelerating EU vaccination campaign. By 27 May 2021, the cumulative uptake of at least one vaccine dose among adults aged 18 years and above in the EU/EEA had reached 42.8%, and the cumulative uptake of full vaccination among adults aged 18 years and above had reached 18.9%. Importantly, the cumulative uptake of full vaccination had reached high levels among target groups, such as persons aged 80 years and above (63.5%) and healthcare workers $(64.2\%)^5$. By the end of May 2021, over 300 million doses of vaccines will have been delivered to Member States. Enough doses will be delivered to vaccinate 70% of the adult population in the EU by the end of July 2021.

¹ OJ L 337, 14.10.2020, p. 3.

² <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

³ Council Recommendation (EU) 2021/119 of 1 February 2021 amending Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (OJ L 36I, 2.2.2021, p. 1).

⁴ <u>https://covid19-surveillance-report.ecdc.europa.eu/archive-COVID19-reports/index.html</u>

⁵ <u>https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab</u>

In view of these welcome developments, Member States have started to gradually lift restrictions imposed to limit the spread of SARS-CoV-2, as regards both travel and other activities. To do so in a safe way, many Member States are making use of COVID-19 certificates, covering vaccination, test results and/or recovery.

On 20 May 2021, the European Parliament and the Council reached political agreement on the EU Digital COVID Certificate, a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic⁶. The political agreement on the two Regulations proposed by the Commission⁷ was later confirmed by Council's Permanent Representatives Committee⁸ and the Parliament's Committee on Civil Liberties, Justice and Home Affairs⁹. The EU Digital COVID Certificate, which will allow all persons living in the EU to obtain an interoperable COVID-19 certificate, aims to contribute to facilitating the gradual and coordinated lifting of restrictions to free movement put in place, in accordance with EU law, to limit the spread of SARS-CoV-2.

It is important that efforts are made to ensure a smooth rollout of the EU Digital COVID Certificate. For this purpose, the Commission recommends Member States to make use, to the maximum extent possible, of existing possibilities under national law to start issuing EU Digital COVID Certificate already before the entry into application of the Regulation based on the technical specifications developed by the Member States in the eHealth Network¹⁰. Where national law provides for the verification of COVID-19 certificates, holders of an EU Digital COVID Certificate could make use of them when travelling already before the entry into application of the Regulation. The Commission supports this process by launching the central part of the EU Digital COVID Certificate, the EU gateway storing the public keys needed for the verification of an EU Digital COVID Certificate. Given that no personal data is exchanged via the EU gateway, Member States could already make use of its functionality.

In view of the improving epidemiological situation, as well as the upcoming rollout of the EU Digital COVID Certificate, Recommendation (EU) 2020/1475 should be amended to coordinate this gradual lifting of free movement restrictions. On the one hand, holders of vaccination and recovery certificates travelling within the EU should in principle not be subject to additional restrictions, such as travel-related testing for SARS-CoV-2 infection or travel-related self-isolation or quarantine. On the other hand, the provisions on persons in the possession of a negative test result should be streamlined to limit complexity and confusion for travellers, thus boosting compliance with the measures imposed. For this purpose, the different measures that could be applied to travellers could be linked more closely with the

⁶ <u>https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2593</u>

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 facilitate free movement during the COVID-19 pandemic (Digital Green Certificate) (COM(2021) 130 final) and 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 or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate) (COM(2021) 140 final).

^{8 &}lt;u>https://www.consilium.europa.eu/en/press/press-releases/2021/05/21/covid-19-coreper-endorses-political-agreement-on-the-eu-digital-covid-certificate-to-facilitate-free-movement/</u>

 ^{9 &}lt;u>https://www.europarl.europa.eu/news/en/press-room/20210523IPR04606/civil-liberties-committee-endorses-eu-digital-covid-certificate</u>

¹⁰ Available at: <u>https://ec.europa.eu/health/ehealth/covid-19_en</u>

colour code of the place of departure. In particular, a standard validity period for tests for SARS-CoV-2 infection could simplify travel within the EU.

In addition, Recommendation 2020/1475 should be adapted to take into account the adoption of Council Recommendation (EU) 2021/816 amending Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction¹¹, including the increase of the threshold for the 14-day cumulative COVID-19 case notification rate from 25 to 75.

At the same time, it is necessary to remain vigilant regarding SARS-CoV-2 variants. ECDC regularly assesses new evidence on variants detected through epidemic intelligence, rulesbased genomic variant screening, or other scientific sources¹². This covers, in particular, 'variants of concern', for which clear evidence is available indicating a significant impact on transmissibility, severity and/or immunity that is likely to have an impact on the epidemiological situation in the EU/EEA. It also covers 'variants of interest', for which evidence is available on genomic properties, epidemiological evidence or in-vitro evidence that could imply a significant impact on transmissibility, severity and/or immunity, realistically having an impact on the epidemiological situation in the EU/EEA.

ECDC makes available a 'SARS-CoV-2 variants dashboard'¹³ to provide an overview of the proportion of variants of concern and variants of interest in the EU/EEA, together with sequencing volumes. This information should be taken into account by Member States when considering the introduction of restrictions to free movement. To obtain timely and accurate information on the emergence and circulation of SARS-CoV-2 variants of concern or interest, it is important that Member State meet ECDC's recommendations regarding sequencing volumes, which should meet a level of 10% or 500 sequences of SARS-CoV-2-positive cases sequenced, in line with the Communication from the Commission to the European Parliament, the European Council and the Council on a united front to beat COVID-19¹⁴.

As provided in the rules on the EU Digital COVID Certificate, Member States should be able to re-introduce restrictions on certificate holders, including holders of vaccination or recovery certificates, because, for example, the epidemiological situation in a Member State or in a region within a Member State deteriorates rapidly. This 'emergency brake' is intended, in particular, to prevent the spread of SARS-CoV-2 variants of concern or interest.

• Consistency with existing policy provisions in the policy area

This recommendation serves to facilitate the implementation of existing provisions related to restrictions of the freedom of movement on grounds of public health. In particular, it intends to facilitate the implementation of the EU Digital COVID Certificate.

• Consistency with other Union policies

This recommendation is in line with other Union policies, including those regarding public health and the absence of internal border controls.

¹¹ OJ L 182, 21.5.2021, p. 1.

¹² https://www.ecdc.europa.eu/en/covid-19/variants-concern

¹³ <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/variants-dashboard</u>

¹⁴ COM(2021) 35 final.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The Treaty on the Functioning of the European Union (TFEU), and in particular Articles 21(2), 168(6) and 292.

• Subsidiarity (for non-exclusive competence)

Article 292 TFEU enables the Council to adopt recommendations. According to this provision, the Council shall act on a proposal from the Commission in all cases where the Treaties provide that it shall adopt acts on a proposal from the Commission.

This applies in the current situation, as a consistent approach is necessary to avoid further disruptions caused by unilateral and not sufficiently coordinated measures restricting free movement within the Union. Article 21(1) TFEU stipulates that every citizen of the Union shall have the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. If action by the Union should prove necessary to attain this objective, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, may adopt provisions with a view to facilitating the exercise of these rights.

Pursuant to Article 168(6), the Council, on a proposal from the Commission, may also adopt recommendations for the purposes of ensuring a high level of human health protection in the definition and implementation of all Union policies and activities.

Proportionality

The adoption of unilateral or uncoordinated measures is likely to lead to restrictions on free movement that are inconsistent and fragmented, resulting in uncertainty for Union citizens when exercising their EU rights. The proposal does not go beyond what is necessary and proportionate for achieving the intended objective.

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

• Ex-post evaluations/fitness checks of existing legislation

n.a.

Stakeholder consultations

The proposal takes into account the discussions held at regular intervals with Member States since the first temporary restrictions were implemented, the information available on the evolving epidemiological situation and relevant available scientific evidence.

Impact assessment

n.a.

• Fundamental rights

Freedom of movement is a fundamental right enshrined in Article 45 of the Charter of Fundamental Rights of the European Union. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general

interest recognised by the Union or the need to protect the rights and freedom of others. Article 21 of the Charter prohibits restriction on ground of nationality within the scope of application of the Treaties.

Any limitations to the freedom of movement within the Union justified on grounds of public health must be necessary, proportionate and based on objective and non-discriminatory criteria. They must be suitable for securing the attainment of the objective that they pursue; and not go beyond what is necessary in order to attain that objective.

4. **BUDGETARY IMPLICATIONS**

None.

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(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2), Article 168(6) and Article 292, first and second sentence thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) 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 pandemic¹. Recommendation (EU) 2020/1475 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 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.
- (2) Using the criteria and thresholds established in Recommendation (EU) 2020/1475, the European Centre for Disease Prevention and Control has been publishing, once a week, a map of Member States, broken down by regions, in order to support Member States' decision-making².
- (3) As provided for in recital 15 of Recommendation (EU) 2020/1475, the Commission, supported by European Centre for Disease Prevention and Control, should, in view of the evolving epidemiological situation, regularly assess the criteria, data needs and thresholds outlined in this Recommendation, including whether other criteria should be considered or the thresholds adapted, and transmit its findings to the Council for its consideration, together with a proposal to amend the Recommendation.
- (4) Following such a proposal from the Commission, the Council adopted, on 1 February 2021, Council Recommendation (EU) 2021/119 amending Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic³ in view of a very high level of community transmission

¹ OJ L 337, 14.10.2020, p. 3.

Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>
OLL 26L 2 2 2021 p. 1

OJ L 36I, 2.2.2021, p. 1.

across the Union, possibly linked to the increased transmissibility of the new SARS-CoV-2 variants of concern.

- Member States may, in accordance with Union law, limit the fundamental right of free (5) movement on grounds of public health. Any restrictions to the free movement of persons within the Union that are put in place to limit the spread of SARS-CoV-2 should be based on specific and limited public interest grounds, namely the protection of public health. It is necessary for such limitations to be applied in accordance with the general principles of Union law, in particular proportionality and nondiscrimination. Any measures taken should therefore be strictly limited in scope and time, in line with the efforts to restore free movement within the Union, and should not extend beyond what is strictly necessary to safeguard public health. Furthermore, such measures should be consistent with measures taken by the Union to ensure the seamless free movement of goods and essential services across the internal market, including the free movement of medical supplies and medical and healthcare personnel through the "green lane" border crossings referred to in the Commission communication of 23 March 2020 on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services⁴.
- (6) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, the European Parliament and the Council have agreed, on 20 May 2021, to establish the EU Digital COVID Certificate, a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, testing and recovery. The EU Digital COVID Certificate should contribute to facilitating the gradual and coordinated lifting of restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2. Facilitating freedom of movement is one of the key preconditions for starting an economic recovery.
- (7) On 20 May 2021, the Council adopted Council Recommendation (EU) 2021/816 amending Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction⁵, recommending that Member States ease the restrictions on non-essential travel to the EU, in particular for those third-country nationals who have received the last recommended dose of a COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council⁶. In addition, Member States have the possibility to allow non-essential travel to the EU of third-country nationals who have received the last recommended dose of a COVID-19 vaccine that has completed the WHO emergency use listing process⁷. Recommendation (EU) 2021/816 also increased the thresholds for the 14-day cumulative COVID-19 case notification rate used to determine the list of non-EU countries from where non-essential travel should be permitted. At the same time, to limit the risk of SARS-CoV-2 variants of concern or interest entering the EU,

⁴ OJ C 96I, 24.3.2020, p. 1.

⁵ OJ L 182, 21.5.2021, p. 1

⁶ 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).

⁷ <u>https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process</u>

Recommendation (EU) 2021/816 provides for an 'emergency brake' mechanism, allowing Member States to act quickly and in a coordinated manner to temporarily limit to a strict minimum all travel from affected third countries. Recommendation 2020/1475 should be adapted to take into account these developments, including the change to the threshold for the case notification rate.

- (8) In its conclusions of 25 May 2021⁸, the European Council stated that efforts to ensure a coordinated approach should continue ahead of the summer. In that context, the European Council welcomed the agreement reached on the EU Digital COVID Certificate and called for its rapid implementation. As a next step, with a view to facilitating free movement in the EU, the European Council called for the revision by mid-June of Recommendation (EU) 2020/1475. The European Council also welcomed the adoption of Recommendation (EU) 2021/816.
- (9) The *[EU Digital COVID Certificate Regulation]* will start applying as of 1 July 2021. As of this date, vaccinated, tested or recovered persons will have a right to obtain an EU Digital COVID certificate, including when they have been vaccinated before the date of application of the *[EU Digital COVID Certificate Regulation]*, even if as part of a clinical trial. Recommendation 2020/1475 should therefore be adapted to make best use of the EU Digital COVID Certificate framework. In particular, EU Digital COVID Certificates ensure safe issuance, verification and acceptance of interoperable vaccination, test and recovery certificates, and certificates issued in line with the *[EU Digital COVID Certificate Regulation]* should thus be the primary tool to be used in the context of travel within the EU.
- (10) The [EU Digital COVID Certificate Regulation] provides for a phasing-in period of six weeks, to give Member States which are unable to issue certificates in a format that complies with this Regulation from its date of application the possibility to continue issuing certificates which are not yet in compliance with the [EU Digital COVID Certificate Regulation]. During the phasing-in period, such certificates, as well as certificates issued before the date of application of the [EU Digital COVID Certificate Regulation], are to be accepted by all Member States provided that they contain the necessary data. For the purposes of Recommendation 2020/1475, such certificates should thus also be considered as issued in line with the [EU Digital COVID Certificate Regulation].
- (11) In addition, persons not in the possession of an EU Digital COVID Certificate, in particular because they have been vaccinated before the date of application of the *[EU Digital COVID Certificate Regulation]*, should be given every reasonable opportunity to prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State to holders of such certificates.
- (12) Efforts should be made to ensure a smooth rollout of the EU Digital COVID Certificate. For this purpose, Member States should make use, to the maximum extent possible, of existing possibilities under national law regarding the issuance of COVID-19 certificates to start issuing certificates in a format that is consistent with the *[EU Digital COVID Certificate Regulation]* already before its entry into application, based on the technical specifications developed by the Member States in the eHealth Network⁹. Where national law provides for the verification of COVID-19 certificates,

⁸ EUCO 5/21.

⁹ Available at: <u>https://ec.europa.eu/health/ehealth/covid-19_en</u>

holders of an EU Digital COVID Certificate could already make use of them when travelling. The Commission supports this process by launching the central part of the EU Digital COVID Certificate, the EU gateway storing the public keys needed for the verification of an EU Digital COVID Certificate. Given that no personal data is exchanged via the EU gateway, Member States could make use of its functionality already in advance of the entry into application of the *[EU Digital COVID Certificate Regulation]*.

- (13) Predominantly linked to significant increases in vaccination uptake across the Union, there is a strong and continuous downward trend in the 14-day cumulative COVID-19 case notification rate in the EU/EEA area. The cumulative uptake as of 27 May 2021 of at least one vaccine dose among adults aged 18 years and above has reached 42.8%, and the cumulative uptake of full vaccination among adults aged 18 years and above has reached 18.9%. Importantly, the cumulative uptake of full vaccination has reached high levels among priority groups such as persons aged 80 years and above and healthcare workers¹⁰. When considering whether to apply restrictions, Member States should take into account the level of protection provided by the increases in vaccination uptake, notably among target groups.
- (14) In view of these positive developments, Member States have started to gradually lift restrictions imposed to limit the spread of SARS-CoV-2, as regards both travel and other activities. To do so in a safe way, many Member States are making use of COVID-19 certificates, covering vaccination, test results and/or recovery. To coordinate the efforts towards a gradual lifting of restrictions to free movement put in place, in accordance with Union law, to limit the spread of SARS-CoV-2, Recommendation (EU) 2020/1475 should be adapted. Taking into account the differences in the epidemiological situation between the areas classified in the different colours established by Recommendation (EU) 2020/1475, and to provide more clarity and certainty to persons travelling within the Union, the restrictions that could be applied by Member States, based their own decision-making processes, should be further clarified.
- (15) In view of the low infection rates in areas classified as 'orange', no quarantine or selfisolation should be imposed on persons travelling from such areas. Member States could, however, require such travellers to undergo a test for SARS-CoV-2 infection, or offer tests upon arrival.
- (16) To simplify travel within the Union, standard validity periods for tests for SARS-CoV-2 infection should be established, also taking into account the upcoming rollout of the interoperable EU Digital COVID Certificate. Most Member States already provide that the sampling required for a molecular nucleic acid amplification test (NAAT) must, in order to be eligible, be carried out not more than 72 hours prior to arrival. A shorter validity period of not more than 48 hours is justified for rapid antigen tests listed in Annex I of the common list of COVID-19 rapid antigen tests agreed by the Health Security Committee¹¹, where such tests are accepted by a Member State for the purposes of travel. In both cases, the tests should have been carried out by health professionals or by skilled testing personnel.
- ¹⁰ <u>https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab</u>
- ¹¹ Available at: <u>https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf</u>

- (17) As noted in the *[EU Digital COVID Certificate Regulation]*, Member States are encouraged to ensure affordable and widely available testing possibilities to facilitate the exercise of the right to free movement, taking into account that not the entire population has had the opportunity to be vaccinated yet. The use of rapid antigen tests would serve to facilitate the issuance of test result certificates on an affordable basis. The Commission has also declared that it would mobilise EUR 100 million to support Member States in providing affordable tests.
- (18) Persons travelling from areas classified as 'red' could still be required to undergo quarantine or self-isolation, unless they are in the possession of a test certificate falling within the standard validity periods. Persons not in the possession of such a test certificate could be required to undergo a test for SARS-CoV-2 infection upon arrival and, where necessary, to quarantine or self-isolate until a negative test result is obtained.
- (19) Mandatory quarantine or self-isolation imposed on persons arriving from other Member States constitutes a significant restriction to free movement. It should be imposed only where absolutely necessary to protect public health, for example because the person concerned arrives from an area classified as 'red' without a test for SARS-CoV-2 infection, because the person concerned arrives from an area classified as 'dark red', or where a high prevalence of SARS-CoV-2 variants of concern or interest have been reported. Persons undergoing travel-related quarantine or self-isolation in such situations should be able to shorten its duration if a negative test result is obtained five to seven days after arrival, unless the traveller develops symptoms of COVID-19.
- (20)SARS-CoV-2 variants remain a cause for concern and should be taken into account by Member States in the context of restrictions to free movement in response to the COVID-19 pandemic. The European Centre for Disease Prevention and Control regularly assesses new evidence on variants detected through epidemic intelligence, rules-based genomic variant screening, or other scientific sources¹². This covers, in particular, variants of concern, for which clear evidence is available indicating a significant impact on transmissibility, severity and/or immunity that is likely to have an impact on the epidemiological situation in the EU/EEA, and variants of interest, for which evidence is available on genomic properties, epidemiological evidence or invitro evidence that could imply a significant impact on transmissibility, severity and/or immunity, realistically having an impact on the epidemiological situation in the EU/EEA. To provide an overview of the proportion of variants of concern and variants of interest in the EU/EEA together with sequencing volumes, the European Centre for Disease Prevention and Control makes available a 'SARS-CoV-2 variants dashboard'13. To obtain timely and accurate information on the emergence and circulation of SARS-CoV-2 variants of concern or interest, the European Centre for Disease Prevention and Control recommends that Member States' sequencing volumes should meet a recommended level of at least 10% or 500 sequences of SARS-CoV-2positive cases sequenced per week, as was also noted in the Communication from the Commission to the European Parliament, the European Council and the Council on a united front to beat COVID-19¹⁴. Insufficient sequencing volume results in poor ability to detect circulating variants of concern before they have an impact on the overall epidemiological situation.

¹² <u>https://www.ecdc.europa.eu/en/covid-19/variants-concern</u>

¹³ <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/variants-dashboard</u>

¹⁴ COM(2021) 35 final.

- (21) It is thus appropriate to continue to strongly discourage all non-essential travel to and from areas classified as 'dark red', to and from areas with a high prevalence of SARS-CoV-2 variants of concern or interest, especially variants that increase transmissibility, disease severity or affect vaccine efficacy, and to and from areas with an unknown prevalence due to insufficient sequencing volume.
- (22) Persons who are vaccinated and persons who have recovered from COVID-19 in the previous six months seem to have a reduced risk of infecting people with SARS-CoV-2, according to current and still evolving scientific evidence. The free movement of persons who, according to sound scientific evidence, do not pose a significant risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective of protecting public health. Where the epidemiological situation allows, such persons should not be subject to additional restrictions to free movement linked to the COVID-19 pandemic, such as travel-related testing for SARS-CoV-2 infection or travel-related self-isolation or quarantine, unless such additional restrictions are, according to the latest available scientific evidence, in line with the precautionary principle, necessary and proportionate for the purpose of safeguarding public health, and non-discriminatory.
- Many Member States already exempt or are planning to exempt vaccinated persons (23)from restrictions to free movement within the Union, and the upcoming rollout of the interoperable EU Digital COVID Certificate will make it easier for travellers to prove that they have been vaccinated. According to interim guidance on the benefits of full vaccination against COVID-19 for transmission and implications for nonpharmaceutical interventions published by the European Centre for Disease Prevention and Control on 21 April 2021¹⁵, requirements for testing and quarantine of travellers, where implemented, can be waived or modified for fully vaccinated individuals as long as there is no or very low level of circulation of variants of concern or interest in the community in the country of origin. This is because the likelihood that a fully vaccinated traveller will pose a risk for onward transmission of COVID-19 is assessed as very low, unless increased by factors such as high prevalence of variants of concern or interest. As a result, individuals who are fully vaccinated with a COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 should not be subject to additional travel-related testing for SARS-CoV-2 infection or travel-related self-isolation or quarantine when moving within the Union. At the same time, in the current epidemiological situation in the EU/EEA, in public spaces and in large gatherings, including during travel, non-pharmaceutical interventions such as physical distancing, the wearing of facemasks and hand and respiratory hygiene should be maintained irrespective of the vaccination status of the individual.
- (24) To simplify travel within the Union, a common understanding of the conditions under which vaccinated persons should be exempted from travel restrictions should be established. Vaccinated persons should be exempted from restrictions once at least 14 days have passed since full vaccination. Persons who have received the second dose in a 2-dose COVID-19 vaccine series and persons who have received a single dose vaccine should be considered as fully vaccinated.

¹⁵ Available at: <u>https://www.ecdc.europa.eu/sites/default/files/documents/Interim-guidance-benefits-of-full-vaccination-against-COVID-19-for-transmission-and-implications-for-non-pharmaceutical-interventions.pdf</u>

- (25)To achieve rapid vaccination rollout, some Member States have put in place policies to vaccinate as many people in the groups at high risk of severe COVID-19 as possible. Another recommendation is that only one dose of vaccine (in a two-dose schedule) should be given to individuals who have previously been infected with SARS-CoV-2. According to a report from the European Centre for Disease Prevention and Control of 6 May 2021, nine out of 23 responding EU/EEA countries are recommending a single dose for those previously infected (for vaccines that have a two-dose schedule)¹⁶. There is emerging evidence that for those individuals who have been previously infected with SARS-CoV-2, a single dose of Comirnaty and COVID-19 Vaccine Moderna (mRNA vaccines) elicits similar or higher antibody, B-cell and T-cell responses when compared to individuals that have not previously been infected. In addition, some studies have reported that a single vaccine dose in previously infected individuals appears to generate similar antibody, B-cell and T-cell responses to those found in non-infected individuals who have received two vaccine doses. There is also emerging evidence of higher antibody levels after one dose of the Vaxzevria vaccine in previously infected individuals compared to one dose in non-previously infected individuals and a single dose in previously infected individuals appears to generate similar antibody responses to those found in non-infected individuals who received two doses of vaccine. Without prejudice to Member States' competence to set their vaccination strategies, a person having received a single dose of a 2-dose COVID-19 vaccine that has been granted a marketing authorisation pursuant to Regulation (EC) No 726/2004 after having previously been infected with SARS-CoV-2 should also be considered, in a travel context, as fully vaccinated, where it is indicated in the vaccination certificate that the vaccination course has been completed following the administration of one dose.
- (26) Member States could also lift restrictions in other settings. In accordance with the first sub-paragraph of Article 5(5) of *[EU Digital COVID Certificate Regulation]*, where Member States accept proof of vaccination in order to waive restrictions to free movement also in other situations, for example after the first dose in a 2-dose series, they should also accept, under the same conditions, vaccination certificates for a COVID-19 vaccine covered by the first sub-paragraph of Article 5(5) of that Regulation. Member States should also be able to accept, for the same purpose, vaccination certificates issued for a COVID-19 vaccine covered by the second sub-paragraph of Article 5(5) of *[EU Digital COVID Certificate Regulation]*.
- (27) Accumulating evidence supports recommending that people who have recovered from laboratory-confirmed COVID-19 do not need additional travel-related testing for SARS-CoV-2 infection or travel-related self-isolation or quarantine at least within the first 180 days of the first positive NAAT test, provided that non-pharmaceutical interventions such as physical distancing, the wearing of face masks and hand and respiratory hygiene are maintained. As a result, many Member States already exempt or are planning to exempt recovered persons from restrictions to free movement within the Union, and the upcoming rollout of the interoperable EU Digital COVID Certificate will make it easier for travellers to prove that they have recovered after a positive NAAT test for SARS-CoV-2 infection.
- (28) In line with the precautionary approach, an 'emergency brake' mechanism should be established, according to which Member States should again require holders of

¹⁶ Available at: <u>https://www.ecdc.europa.eu/en/publications-data/overview-implementation-covid-19-vaccination-strategies-and-vaccine-deployment</u>

vaccination certificates or certificates of recovery to undergo a test for SARS-CoV-2 infection and/or quarantine/self-isolation if the epidemiological situation in a Member State or in a region within a Member State deteriorates rapidly, resulting in a classification as 'dark red' pursuant to point 10, or if a high prevalence of SARS-CoV-2 variants of concern or interest that increase transmissibility or disease severity or affect vaccine efficacy has been reported. Article 11(2) of *[EU Digital COVID Certificate Regulation]* provides that in such situations, the Member State concerned is to inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To ensure coordination, in particular where restrictions are imposed due to a new SARS-CoV-2 variants of concern or interest, the Council, in close cooperation with the Commission, should, on the basis of such information, be tasked to review the situation in a coordinated manner.

- (29) To ensure unity of travelling families, minors accompanying their parent or parents should not be required to undergo travel-related quarantine/self-isolation where no such requirement is imposed on the parent or parents, for example because they are in the possession of a vaccination certificate or a certificate of recovery. In addition, children under the age of 6 years should be exempt from the requirement to undergo travel-related tests for SARS-CoV-2 infection.
- (30)Contact tracing is a central pillar of the fight against the spread of the virus, especially in connection with the emergence of new variants. At the same time, effective and timely contact tracing is more challenging when it needs to be performed across borders and for high volumes of passengers travelling close to each other. To address this, Member States should consider requiring persons entering their territory through collective transport modes with pre-assigned seat or cabin to submit Passenger Locator Forms (PLF) in accordance with data protection requirements, in particular when they are tested only upon arrival. For this purpose, a common Digital Passenger Locator Form¹⁷ has been developed by the EU Healthy Gateways for possible use by Member States. Member States should be encouraged to join the PLF Exchange Platform, which is part of the Early Warning and Response System, to enhance their crossborder contact tracing capabilities for all transport modes. The PLF exchange platform will enable the secure, timely and effective exchange of data between the competent authorities of the Member States, by enabling them to transmit information from their existing national digital PLF systems and relevant epidemiological information to other competent authorities in an interoperable and automatic manner. For this purpose, the Commission adopted, on 27 May 2021, Commission Implementing Decision amending Implementing Decision (EU) 2017/253 as regards alerts triggered by serious cross-border threats to health and for the contact tracing of passengers identified through Passenger Locator Forms¹⁸.
- (31) Member States should be encouraged to publish relevant information also in a machine-readable format in order to facilitate the processing by stakeholders, such as transport operators cross-border passenger transport services operators.
- (32) In view of the evolving epidemiological situation and further progress in terms of vaccination uptake, and as more relevant scientific evidence becomes available, including on the need for repeated immunisation to provide protection against

¹⁷ <u>https://www.euplf.eu/en/home/index.html</u>

¹⁸ C(2021) 3921.

emerging variants or the need to receive booster doses at regular intervals, the Commission, supported by the European Centre for Disease Prevention and Control, should continue to regularly assess the criteria, data needs and thresholds outlined in this Recommendation, including whether other criteria should be considered or the thresholds adapted, and transmit its findings to the Council for its consideration, together with a proposal to amend the Recommendation, where necessary,

HAS ADOPTED THIS RECOMMENDATION:

Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic is amended as follows:

1. In point 8, letter (c) is replaced by the following:

"(c) the 'testing rate', that is, the number of tests for COVID-19 infection per 100 000 population carried out during the last week;".

2. In point 8, the following letter (d) is added:

"(d) the prevalence of SARS-CoV-2 variants of concern or interest as reported by the European Centre for Disease Prevention and Control, taking into account sequencing volume and their level of transmission in the EU/EEA area.".

3. In point 10, letters (b) and (c) are replaced by the following:

"(b) orange, if the 14-day cumulative COVID-19 case notification rate is less than 75 but the test positivity rate of tests for COVID-19 infection is 4% or more, or, if the 14-day cumulative COVID-19 case notification rate ranges from 25 to 150 but the test positivity rate of tests for COVID-19 infection is less than 4%;

(c) red, if the 14-day cumulative COVID-19 case notification rate ranges from 75 to 150 and the test positivity rate of tests for COVID-19 infection is 4% or more, or if the 14-day cumulative COVID-19 case notification rate is more than 150 but less than 500;".

4. In point 13, letters (b), (c) and (d) are replaced by the following:

"(b) Member States could take into account additional criteria and trends, including vaccination uptake. To this end, the European Centre for Disease Prevention and Control will provide data on the population size, the hospitalisation rate, the rate of ICU admission and the mortality rate, if available, on a weekly basis;

(c) Member States should take into account the epidemiological situation in their own territory, including the prevalence of SARS-CoV-2 variants of concern or interest, vaccination uptake, testing policies, the number of tests performed and test positivity rates, and other epidemiological indicators;

(d) Member States should take into account testing strategies and pay particular attention to the situation of areas with high testing rates.".

- 5. In point 13, letter (e) is deleted.
- 6. The following point 13a is inserted:

"By derogation from points 12, 15 and 16, Member States should take into account the prevalence of SARS-CoV-2 variants of concern or interest, especially variants that increase transmissibility or disease severity or affect vaccine efficacy, as well as sequencing volume and their level of transmission in the EU/EEA area, regardless how the area concerned is classified. For this purpose, Member States should make use of the data published by the European Centre for Disease Prevention and Control on variants of concern or interest in the EU/EEA¹⁹. To obtain timely and accurate information on the emergence and circulation of SARS-CoV-2 variants of concern or interest, Member States should meet the sequencing volumes of at least 10% or 500 sequences of SARS-CoV-2-positive cases sequenced per week recommended by the European Centre for Disease Prevention and Control.".

7. Point 16a is replaced by the following:

"Member States should strongly discourage all non-essential travel to and from areas classified as 'dark red' pursuant to point 10.

Member States should also strongly discourage all non-essential travel to and from areas with a high prevalence of SARS-CoV-2 variants of concern or interest and to and from areas with an unknown prevalence due to insufficient sequencing volume.

At the same time, Member States should seek to avoid disruptions to essential travel, to keep transport flows moving in line with the 'Green Lanes' system as well as avoid disruptions to supply chains and the movement of workers and self-employed persons travelling for professional or business reasons."

8. Point 17 is replaced by the following:

"Member States should in principle not refuse the entry of persons travelling from other Member States.

Member States that consider necessary to introduce restrictions to free movement on grounds of public health, based on their own decision-making processes, could require persons travelling from an area classified as 'orange' pursuant to point 10 to be in the possession of a test certificate issued in line with *[EU Digital COVID Certificate Regulation]* indicating a negative test result obtained

- not more than 72 hours before arrival, in case of molecular nucleic acid amplification test (NAAT); or
- not more than 48 hours before arrival, in case of a rapid antigen tests (RAT).

Persons not in the possession of such a test certificate could be required to undergo a test after arrival.

Member States that consider necessary to introduce restrictions to free movement on grounds of public health, based on their own decision-making processes, could require persons travelling from an area classified as 'red' or 'grey' pursuant to point 10 to undergo quarantine/self-isolation as recommended by the Health Security Committee²⁰ unless they are in the possession of a test certificate issued in line with *[EU Digital COVID Certificate Regulation]*, indicating a negative test result obtained

 not more than 72 hours before arrival, in case of molecular nucleic acid amplification test (NAAT); or

¹⁹ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/variants-dashboard</u>

Recommendations for a common EU approach regarding isolation for COVID-19 patients and quarantine for contacts and travellers, agreed by the Health Security Committee on 11 January 2021, <u>https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/hsc_quarantine-isolation_recomm_en.pdf</u>

 not more than 48 hours before arrival, in case of a rapid antigen tests (RAT).

Quarantine/self-isolation imposed on persons not in the possession of such a test certificate should be lifted when a negative test result is obtained after arrival, unless the traveller develops symptoms of COVID-19.

Member States should strengthen coordination efforts on the length of quarantine/self-isolation and substitution possibilities. Wherever possible and in accordance with strategies decided by Member States, the development of testing should be encouraged.

The test for SARS-CoV-2 infection required pursuant to this point could be either a molecular nucleic acid amplification test (NAAT) or a rapid antigen test listed in Annex I of the common list of COVID-19 rapid antigen tests agreed by the Health Security Committee²¹, as determined by the Member State of destination. Member States should offer affordable and widely available testing possibilities, while ensuring that doing so does not detract from the provision of essential public health services, in particular in terms of laboratory capacity.".

9. The following point 17aa is inserted:

"By derogation from points 17 and 17a and without prejudice to point 17ac, holders of vaccination certificates issued in line with *[EU Digital COVID Certificate Regulation]* for a COVID-19 vaccine covered by the first sub-paragraph of Article 5(5) of that Regulation according to which at least 14 days have passed since full vaccination should not be subject to additional restrictions to free movement, such as additional travel-related testing for SARS-CoV-2 infection or travel-related self-isolation or quarantine. For the purpose of this Recommendation, full vaccination should be understood as:

- (a) having received the second dose in a 2-dose series;
- (b) having received a single-dose vaccine;
- (c) having received a single dose of a 2-dose vaccine after having previously been infected with SARS-CoV-2.".
- 10. The following point 17ab is inserted:

"By derogation from points 17 and 17a and without prejudice to point 17ac, holders of certificates of a recovery issued in line with *[EU Digital COVID Certificate Regulation]* indicating that less than 180 days have passed since the date of the first positive test result should be not be subject to additional restrictions to free movement, such as additional travel-related testing for SARS-CoV-2 infection or travel-related self-isolation or quarantine.".

11. The following point 17ac is inserted:

"If the epidemiological situation in a Member State or in a region within a Member State deteriorates rapidly, resulting in a classification as 'dark red' pursuant to point 10, or if a high prevalence of SARS-CoV-2 variants of concern or interest that increase transmissibility, disease severity or affect vaccine efficacy has been reported, Member States should require holders of vaccination certificates or

²¹ Available at: <u>https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf</u>

certificates of recovery to undergo a test for SARS-CoV-2 infection and/or quarantine/self-isolation.

Based on information provided to the Commission and the Member States pursuant to Article 11 of the *[EU Digital COVID Certificate Regulation]*, and in particular where restrictions are imposed due to a new SARS-CoV-2 variants of concern or interest, the Council, in close cooperation with the Commission, should review the situation in a coordinated manner.".

- 12. Point 18 is deleted.
- 13. Point 19a is replaced by the following:

"Pursuant to point 17a, and subject to the exemptions in points 17aa and 17ab, travellers with an essential function or need travelling from a 'dark red' area should fulfil testing requirements and undergo quarantine/self-isolation, provided that this does not have a disproportionate impact on the exercise of their function or need.

By way of derogation, transport workers and transport service providers pursuant to point 19(b) should in principle not be required to undergo a test for COVID-19 infection in line with points 17(b) and 17a. Where a Member State requires transport workers and transport service providers to undergo a test for COVID-19 infection, rapid antigen tests should be used and the exemptions in points 17aa and 17ab should apply, and this should not lead to transport disruptions. Should transport or supply chain disruptions occur, Member States should lift or repeal any such systematic testing requirements immediately in order to preserve the functioning of the 'Green Lanes'. Transport workers and transport service providers should not be required to undergo quarantine in line with points 17(a) and 17a while exercising this essential function.".

14. Point 19b is replaced by the following:

"In addition to the exemptions in point 19a, Member States should not require persons living in border regions and travelling across the border on a daily or frequent basis for the purposes of work, business, education, family, medical care or caregiving to undergo a test or quarantine/self-isolation, in particular persons exercising critical functions or essential for critical infrastructure. If a testing requirement on cross-border travel is introduced in these regions, the frequency and type of tests on such persons should be proportionate and should allow for the exemptions set out in points 17aa and 17ab. If the epidemiological situation on both sides of the border is comparable, no travel-related testing requirement should be imposed. Persons who claim that their situation falls within the scope of this point could be required to provide documentary evidence or submit a declaration to this effect.".

15. The following point 19c is inserted:

"Minors accompanying their parent or parents should not be required to undergo travel-related quarantine/self-isolation where no such requirement is imposed on the parent or parents, for example due to the exemptions in point 17aa and 17ab. In addition, children under the age of 6 years should be exempt from the requirement to undergo travel-related tests for SARS-CoV-2 infection.".

16. Point 20 is replaced by the following:

"Member States should consider requiring persons travelling to their territory by means of collective transport modes with pre-assigned seat or cabin to submit Passenger Locator Forms (PLF) in accordance with data protection requirements. For this purpose, Member States are encouraged to make use of the common Digital Passenger Locator Form developed by the EU Healthy Gateways²². Member States should join the PLF Exchange Platform to enhance their cross-border contact tracing capabilities for all transport modes.".

17. Point 23 is replaced by the following:

"If a person develops symptoms upon arrival at the destination, testing, diagnosis, isolation and contact tracing should take place in accordance with the local practice, and entry should not be refused. Information on cases detected on arrival should be immediately shared with the public health authorities of the countries the person concerned has resided in during the previous 14 days for contact tracing purposes, using, where applicable, the PLF Exchange Platform, or otherwise the Early Warning and Response System."

18. Point 25 is replaced by the following:

"In line with Article 11 of *[EU Digital COVID Certificate Regulation]*, Member States should provide relevant stakeholders and the general public with clear, comprehensive and timely information about any restrictions to free movement, any accompanying requirements (for example which specific tests for SARS-CoV-2 infection qualify for the waiving of restrictions, or the need to submit passenger locator forms), as well as the measures applied to travellers travelling from risk areas as early as possible before new measures come into effect. As a general rule, this information should be published 24 hours before the measures come into effect, taking into account that some flexibility is required for epidemiological emergencies. The information should also be published in a machine-readable format.

This information should also be made available on the 'Re-open EU' web platform, which should contain the map published regularly by the European Centre for Disease Prevention and Control pursuant to points 10 and 11.

The substance of the measures, their geographical scope and the categories of persons to whom they apply should be clearly described.".

19. After point 25, the following heading is inserted:

"Rollout of the EU Digital COVID Certificate".

20. The following point 25a is inserted:

"The rollout of the EU Digital COVID Certificate should start as soon as possible, based on the technical specifications developed by the Member States in the eHealth Network²³.

Before the entry into application of the [EU Digital COVID Certificate Regulation], references to certificates issued in line with the Regulation should also cover certificates issued in another format.".

²² <u>https://www.euplf.eu/en/home/index.html</u>

²³ Available at: <u>https://ec.europa.eu/health/ehealth/covid-19_en</u>

Done at Brussels,

For the Council The President