



EUROPEAN COMMISSION

*Brussels, 20.08.2021
C(2021) 6292 final*

Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinions on the proposal for a Regulation 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 {COM(2021)130 final} and the proposal for a Regulation 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 {COM(2021)140 final}.

The proposals form part of a package of ambitious measures designed to ensure a gradual, safe and lasting reopening. The adoption of these proposals is thus a crucial part of this effort.

The freedom of movement is one of the EU citizen's most cherished rights. This is why it is crucial to have an EU level approach to issuing, verifying and accepting certificates issued across the EU, to help holders to exercise their right to free movement within the EU, as well as making it easier to wind down in a coordinated manner the COVID-19 restrictions put in place in compliance with EU law.

The Commission is pleased to announce that the European Parliament and the Council have reached an agreement on the Regulations to establish an EU Digital COVID Certificate. On this basis, the Regulations have been adopted on 14 June 2021 and entered into application on 1 July 2021. All EU Member States, EEA countries and Switzerland are already connected to the gateway built by the Commission which allows for the cross-border verification of the certificates.

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The Commission welcomes that the Senato della Repubblica has delivered positive opinions with regard to the Regulations and considers them as complying with the principle of subsidiarity. The Commission equally notes the Senato della Repubblica's comments and is pleased to have this opportunity to provide a number of clarifications regarding the Regulation. The Commission trusts that these will allay the Senato della Repubblica's concerns.

In response to the more technical comments in the Opinions, the Commission would like to refer to the attached annex.

The Commission hopes that the clarifications provided in this reply address the comments raised by the Senato della Repubblica and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Janusz Wojciechowski
Member of the Commission*

Annex

The Commission has carefully considered each of the issues raised by the Senato della Repubblica in its Opinion and is pleased to offer the following clarifications.

The Regulation does not affect the Member States' competence to decide on the most appropriate measures to safeguard public health, including for instance quarantine or testing requirements. Without prejudice to Member States' competence to impose restrictions on grounds of public health, the Parliament and the Council agreed that 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, taking into account, in particular, available scientific evidence, including epidemiological data published by the European Centre for Disease Control (ECDC).

Where a Member State requires, in accordance with Union law, holders of EU Digital COVID Certificate 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 is obliged to inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions.

On 14 June, the Council amended Council Recommendation (EU) 2020/1475 to make best use of the EU Digital COVID Certificate framework. As vaccination campaigns are speeding up all over the EU, the Recommendation intends to coordinate the gradual easing of free movement restrictions.

As regards the need for additional scientific evidence, the Regulation empowers the Commission to ask the Health Security Committee, the European Centre for Disease Control or the European Medicines Agency to issue guidance on the available scientific evidence on the effects of medical events documented in the EU Digital COVID Certificate, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and SARS-CoV-2 transmission, the situation of people having recovered from COVID-19, and the impacts of the new SARS-CoV-2 variants on people who have been vaccinated or already infected.

The Regulation also empowers the Commission to adapt it in light of newly emerging evidence. In particular, the Commission is empowered to enlarge the types of tests on the basis of which a certificate of recovery could be issued, by including, for example, rapid antigen tests or antibody tests. The Regulation is thus flexible enough to take into account new scientific evidence and guidance.

With respect to the acceptance of vaccination certificates, Member States will be under an obligation to accept vaccination certificates for COVID-19 vaccines that have been centrally authorised by the European Medicines Agency. Member States will also be able to accept certificates for vaccines that have been authorised at national level or by the WHO. In any event, Member States are of course not obliged to introduce restrictions to free movement.

The certificates contain an interoperable, digitally readable barcode with the relevant data relating to the certificates. The digital signature is created using the signer's cryptographic private key. The registration of the keys is done by trusted authorities (e.g. Ministries of Health) of the Member States.

The verifying Member State (country of destination) or the transport service provider, will check the validity and authenticity of the certificate by verifying who issued and signed it (e.g. a hospital, a test centre or a health authority). When the certificate will be checked, the QR code will be scanned and the signature verified. The QR code will contain a digital seal to make sure the certificate is authentic.

To allow for the cross-border verification of the certificates, the Commission has built a gateway. All EU Member States, EEA countries and Switzerland are already live connected to this gateway. The Commission has also supported Member States in developing software that authorities can use to check the QR codes. This framework ensures a reliable and secure issuance and verification of certificates. The framework thus prevents fraud and forgery.

Member States may also use the EU Digital COVID Certificate for domestic purposes, if the legal basis for the processing of such data for other purposes, including the related retention periods, is provided for in national law, which must comply with Union data protection law. Where the certificate is used for non-medical purposes, personal data accessed during the verification process are not to be retained, as provided for in this Regulation.

Where a Member State has adopted or adopts, on the basis of national law, a system of COVID-19 certificates for domestic purposes, it should ensure that EU Digital COVID Certificates can also be used and are also accepted for domestic purposes, in order to avoid that persons travelling to another Member State and using the EU Digital COVID Certificate are obliged to obtain an additional national COVID-19 certificate.

As regards the personal data to be included in the certificates, the Annex to the proposed Regulation contains the necessary key information, namely surname, forename and date of birth. This is the data that the Member State experts have identified as necessary for the reliable issuance and verification of the certificates.

The Regulation follows the data minimisation principle enshrined in the General Data Protection Regulation. The certificates should only contain the information necessary to facilitate citizens' free movement rights. For this reason, the Regulation does not establish a European database on vaccination, testing or recovery from COVID-19,

allowing instead for the decentralised verification of digitally signed interoperable certificates.

Furthermore, the Regulation does not create a legal basis for retaining personal data obtained from the certificate by the Member State of destination or by cross-border passenger transport services operators.

With regard to recovered persons who are asymptomatic, they may be issued with a recovery certificate if they have received a positive PCR test. Such a certificate should be issued from the eleventh day after the positive PCR test. If the asymptomatic person does not test positive, it will receive a negative test certificate. Both certificates facilitate to exercise free movement rights. The scientific evidence and level of standardisation currently does not allow for the issuance of recovery certificates based on antibody tests. The Commission, however, monitors the situation and may put forward a proposal to include antibody tests if scientific evidence becomes available.

To ensure the reliability of the test result, only the results of PCR tests and rapid antigen tests in the list established under Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) should be eligible for a test certificate under the Regulation. This list of rapid antigen test is regularly reviewed by the Member States' experts represented in the Health Security Committee.

The vaccination certificate will be issued after the administration of each dose and should clearly indicate whether the vaccination course has been completed. The amended Recommendation (EU) 2020/1475 states that fully vaccinated persons holding vaccination certificates in line with the EU Digital COVID Certificate should be exempted from travel-related testing or quarantine 14 days after having received the last dose. This should also cover recovered persons having received a single dose of a 2-dose vaccine.

The definition of the civil age below which there cannot be a requirement for a certificate of recovery falls under the competence of Member States. In any case, the update to Recommendation 2020/1475 states that children under 12 should be exempted from travel-related testing.

The Regulation does not mention a minimum validity period for the test and vaccination certificates. In particular, scientific evidence on the duration of the protection afforded by vaccination is evolving quickly. In the amendment of Recommendation (EU) 2020/1475, standard validity periods for travel-related PCR and rapid antigen tests have been taken up.

The Commission has also committed to mobilise additional EUR 100 million under the Emergency Support Instrument for the purchase of tests that qualify for the issuance of a test certificate pursuant to the Regulation.

The Regulation will be in force until 1 July 2022.