COMMISSION IMPLEMENTING DECISION (EU) 2022/1516

of 8 September 2022

amending Implementing Decision (EU) 2021/1073 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic ([1]), and in particular Article 9(1) thereof,

Whereas:

(1) Regulation (EU) 2021/953 sets out the EU Digital COVID Certificate the purpose of which is to serve as a proof that a person has received a COVID-19 vaccine, a negative test result or has recovered from infection for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic.

(2) In order for the EU Digital COVID Certificate to be operational throughout the Union, the Commission adopted Implementing Decision (EU) 2021/1073 ([2]) laying down technical specifications and rules to populate, securely issue and verify EU Digital COVID Certificates, ensure the protection of personal data, lay down the common structure of the unique certificate identifier and issue a valid, secure and interoperable barcode.

(3) On 29 June 2022, the European Parliament and Council adopted Regulation (EU) 2022/1034 ([3]), which extends the period of application of Regulation (EU) 2021/953 on the EU Digital COVID Certificate until 30 June 2023. That extension ensures that the EU Digital COVID Certificate can continue to facilitate free movement during the COVID-19 pandemic, while pursuing a high level of public health protection. This is particularly relevant in the event that certain restrictions to free movement on grounds of public health are maintained or (re-)introduced, for example in response to the emergence and spread of new SARS-CoV-2 variants of concern.

(4) To enlarge the scope of COVID-19 diagnostic tests that may be used for the issuance of an EU Digital COVID Certificate, the definition of rapid antigen tests set out in Article 2, point 5, of Regulation (EU) 2021/953 was amended by Regulation (EU) 2022/1034 to include laboratory-based antigenic assays. It is now possible for Member States to issue test certificates and, following the adoption of Commission Delegated Regulation (EU) 2022/256 ([4]), certificates of recovery on the basis of the antigen tests included in the EU common list of COVID-19 antigen tests, as agreed, and regularly updated, by the Health Security Committee and as meeting the established criteria.

([1]) OJ L 211, 15.6.2021, p. 1.

([2]) Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 230, 30.6.2021, p. 32).

([3]) Regulation (EU) 2022/1034 of the European Parliament and of the Council of 29 June 2022 amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 173, 30.6.2022, p. 37).

([4]) Commission Delegated Regulation (EU) 2022/256 of 22 February 2022 amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery based on rapid antigen tests (OJ L 42, 23.2.2022, p. 4).

(5) Article 5(5) of Regulation (EU) 2021/953 was also amended by Regulation (EU) 2022/1034 in order to allow Member States to issue vaccination certificates to participants in clinical trials that have been approved by Member States' ethical committees and competent authorities, regardless of whether the participant received the COVID-19 vaccine candidate or, to avoid undermining the studies, the dose administered to the control group. Pursuant to Article 3(11) of Regulation (EU) 2021/953, where necessary, the Commission is to ask the Health Security Committee, ECDC or EMA to issue guidance on the acceptance of COVID-19 vaccines undergoing clinical trials in the Member States.

(6) In view of these amendments to Regulation (EU) 2021/953, in order to ensure the interoperability of the EU Digital COVID Certificate, the rules for populating the EU Digital COVID Certificate should be updated to reflect the possibility to use laboratory-based antigenic assays for test and recovery certificates and to issue vaccination certificates for participants in clinical trials.

(7) Implementing Decision (EU) 2021/1073 should therefore be amended accordingly.

(8) In the light of the need for rapid implementation of the amended technical specifications for the EU Digital COVID Certificate, this Decision should enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

(9) The measures provided for in this Decision are in accordance with the opinion of the Committee, established by Article 14 of Regulation (EU) 2021/953,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2021/1073 is amended as follows:

(1) Annex II is amended in accordance with Annex I to this Decision;

(2) Annex V is amended in accordance with Annex II to this Decision.

Article 2

This Decision shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 September 2022.

For the Council
The President
J. SÍKELA

ANNEX I

Annex II to Implementing Decision (EU) 2021/1073 is amended as follows:

(1) in the introductory section, the first sentence of the sixth paragraph shall be replaced by the following:

'As some value sets based on the coding systems provided for in this Annex, such as those for vaccine and antigen test coding, are changing often, they shall be published and regularly updated by the Commission with the support of the eHealth Network and the Health Security Committee.';

(2) in Section 3, the following paragraphs are added:

'If a country using the EU Digital COVID Certificate ("EU DCC") decides to issue vaccination certificates to clinical trial participants during ongoing clinical trials, the vaccine medicinal product shall be coded following the pattern

CT_*clinical-trial-identifier*

Where the clinical trial has been registered in the EU Clinical Trials Register (EU-CTR), the clinical trial identifier from this register shall be used. In other cases, identifiers from other registers (such as clinicaltrials.gov or Australian New Zealand Clinical Trials Registry) may be used.

The clinical trial identifier shall include a prefix allowing the identification of the clinical trial register (such as EUCTR for EU Clinical Trials Register, NCT for clinicaltrials.gov, ACTRN for Australian New Zealand Clinical Trials Registry).

Where the Commission has received guidance from the Health Security Committee, the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA) with regard to the acceptance of certificates issued for a COVID-19 vaccine undergoing clinical trials, the guidance shall be published either as part of the value sets document or separately.';

(3) in Section 4, the following paragraph is added:

'If a country using EU DCC decides to issue vaccination certificates to clinical trial participants during ongoing clinical trials, the vaccine marketing authorization holder or manufacturer shall be coded using the value designated to it in the value set, if available. In other cases, the vaccine marketing authorization holder or manufacturer shall be coded using the rule described under Section 3 Vaccine medicinal product (CT_*clinical-trial-identifier*).';

(4) in Section 7, the following paragraph is added:

'The code LP217198-3 (Rapid immunoassay) shall be used to indicate both rapid antigen tests and laboratory-based antigenic assays.';

(5) in Section 8, the first sentence of the second paragraph shall be replaced by the following:

'The content of the value set shall include the selection of antigen test as listed in the common and updated list of COVID-19 antigen tests, established on the basis of Council Recommendation 2021/C 24/01 and agreed by the Health Security Committee. The list is maintained by the JRC in the COVID-19 In Vitro Diagnostic Devices and Test Methods Database at: https://covid-19-diagnostics.jrc.ec.europa.eu/devices/hsc-common-recognition-rat'.

ANNEX II

Section 4 of Annex V to Implementing Decision (EU) 2021/1073 is amended as follows:

(1) in point 4.1, the table is amended as follows:

(a) in the third row (field 'v/mp', field name 'COVID-19 vaccine product'), the second sentence under the column 'Instructions' is replaced by the following:

'A coded value from the value set vaccine-medicinal-product.json or a coded value referring to a clinical trial and following the rule defined in Section 3 of Annex II.';

(b) in the fourth row (field 'v/ma', field name 'COVID-19 vaccine marketing authorisation holder or manufacturer'), the second sentence under the column 'Instructions' is replaced by the following:

'A coded value from the value set vaccine-mah-manf.json or a coded value referring to a clinical trial and following the rule defined in Section 4 of Annex II.';

(2) in point 4.2, the table is amended as follows:

(a) in the third row (field 't/nm', field name 'Test name (nucleic acid amplification tests only)'), the third paragraph under the column 'Instructions' is replaced by the following:

'For antigen test: the field shall not be used, as the name of the test is supplied indirectly through the test device identifier (t/ma).';

(b) the fourth row is replaced as follows:

'**t/ma**	Test device identifier (antigen tests only)	Antigen test device identifier from the JRC database. Value set (HSC common list): — All antigen tests in HSC common list (human readable). — https://covid-19-diagnostics.jrc.ec.europa.eu/devices/hsc-common-recognition-rat (machine-readable, values of the field id_device included on the list form the value set). In EU/EEA countries, issuers shall only issue certificates for tests belonging to the currently valid value set. The value set shall be updated every 24 hours. Values outside of the value set may be used in certificates issued by third countries, however the identifiers shall still be from the JRC database. The use of other identifiers such as those provided directly by test manufacturers is not permitted. Verifiers shall detect values not belonging to the up to date value set and display certificates bearing these as invalid. If an identifier is removed from the value set, certificates including it may be accepted for a maximum of 72 hours after the date of removal. The value set is distributed from the EUDCC Gateway. For antigen test: exactly 1 (one) non-empty field shall be provided. For NAAT: the field shall not be used, even if the NAA test identifier is available in the JRC database. Example: "ma": "344"(SD BIOSENSOR Inc, STANDARD F COVID-19 Ag FIA)';

(c) in the seventh row (field 't/tc', field name 'Testing centre or facility'), the third paragraph under the column 'Instructions' is replaced by the following:

'For antigen test: the field is optional. If provided, it shall not be empty.';

(3) in point 4.3, in the table, the second row (field 'r/fr'), the word 'NAAT' is deleted from the columns 'Field name' and 'Instructions'.