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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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⁽¹⁾ Text with EEA relevance.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2021/1068 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 24 June 2021

amending Regulation (EU) 2016/1628 as regards its transitional provisions for certain machinery fitted with engines in the power ranges greater than or equal to 56 kW and less than 130 kW, and greater than or equal to 300 kW, in order to address the impact of the COVID-19 crisis

(Text with EEA relevance)

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 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Regulation (EU) 2016/1628 of the European Parliament and of the Council ⁽³⁾ lays down requirements relating to emission limits for gaseous and particulate pollutants and EU type-approval procedures for various categories of engines for non-road mobile machinery.
- (2) The dates applicable to the new emission limit values, referred to as 'Stage V' in Regulation (EU) 2016/1628, are set out in order to provide manufacturers with clear and comprehensive information and an appropriate period of time for the transition to Stage V, whilst at the same time substantially reducing the administrative burden for approval authorities.
- (3) Due to the COVID-19 outbreak and the associated supply chain and production disruptions, non-road mobile machinery manufacturers, referred to as 'original equipment manufacturers' or 'OEMs' in Regulation (EU) 2016/1628, had difficulties meeting the deadlines of 30 June 2020 and 31 December 2020 set out in that Regulation for the production and the placing on the market of machinery fitted with certain categories of engines that comply with less stringent emission limit values than those of Stage V. Therefore, Regulation (EU) 2016/1628 was amended by Regulation (EU) 2020/1040 of the European Parliament and of the Council ⁽⁴⁾ in order to prolong those deadlines by 12 months.

⁽¹⁾ Opinion of 9 June 2021 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 10 June 2021 (not yet published in the Official Journal) and decision of the Council of 18 June 2021.

⁽³⁾ Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

⁽⁴⁾ Regulation (EU) 2020/1040 of the European Parliament and of the Council of 15 July 2020 amending Regulation (EU) 2016/1628 as regards its transitional provisions in order to address the impact of the COVID-19 crisis (OJ L 231, 17.7.2020, p. 1).

- (4) Since the continued supply chain and production disruptions caused by the COVID-19 pandemic still lead to delays in the production and the placing on the market of machinery fitted with other categories of engines (namely, engines in the power ranges greater than or equal to 56 kW and less than 130 kW, and greater than or equal to 300 kW) that comply with less stringent emission limit values than those of Stage V, it is very likely that OEMs will not be able to meet the deadlines of 30 June 2021 and 31 December 2021 set out in Regulation (EU) 2016/1628 for the production and the placing on the market of the machinery fitted with those engines without those manufacturers sustaining serious economic damage.
- (5) Given the current circumstances, and in order to ensure the smooth functioning of the internal market, to provide legal certainty and to avoid potential market disruption, it is necessary to prolong the transitional provisions of Regulation (EU) 2016/1628 for those categories of engines.
- (6) Given that the prolongation of the transitional provisions will have no environmental impact, as the transition engines concerned have already been produced, the extension of the relevant periods should be six months for the production of the machinery fitted with those engines and nine months for the placing on the market of the machinery fitted with those engines.
- (7) Since the objective of this Regulation, namely to prolong certain transitional provisions of Regulation (EU) 2016/1628, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ('TEU'). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (8) In view of the urgency entailed by the exceptional circumstances caused by the COVID-19 pandemic, it is considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.
- (9) Regulation (EU) 2016/1628 should therefore be amended accordingly.
- (10) In view of the fact that the transition period provided for in Regulation (EU) 2016/1628 for certain engine sub-categories is to expire on 31 December 2021 and that OEMs have until 30 June 2021 to produce non-road mobile machinery fitted with transition engines of those sub-categories, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

Article 1

Article 58 of Regulation (EU) 2016/1628 is amended as follows:

- (1) in paragraph 5, the following subparagraph is added:

'For engines of all sub-categories for which the date set out in Annex III for the placing on the market of Stage V engines is 1 January 2020, except for the engines referred to in the second and third subparagraphs, the transition period shall be extended by nine months and the 18-month period referred to in the first subparagraph shall be extended by six months.';

- (2) in paragraph 7, the following point is added:

'(e) 33 months from the applicable date for the placing on the market of engines set out in Annex III, in the case set out in the sixth subparagraph of paragraph 5.';

Article 2

This Regulation shall enter into force on the day 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, 24 June 2021.

For the European Parliament
The President
D. M. SASSOLI

For the Council
The President
A. P. ZACARIAS

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the entry into force of the Agreement on civil aviation safety between the European Union and Japan

The Agreement on civil aviation safety between the European Union and Japan signed in Brussels on 22 June 2020, entered into force on 30 June 2021, in accordance with Article 20(1) of the Agreement, as the last notification was deposited on 30 June 2021.

REGULATIONS

COUNCIL REGULATION (EU) 2021/1069

of 28 June 2021

amending Regulation (EU) 2020/1579 as regards certain fishing opportunities in the Baltic Sea, and amending Regulation (EU) 2021/92 as regards certain fishing opportunities for 2021 in Union and non-Union waters

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Council Regulation (EU) 2020/1579 ⁽¹⁾ fixes for 2021 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea. On 28 May 2021, the International Council for the Exploration of the Sea (ICES) published a revised scientific catch advice for herring in the Gulf of Bothnia for 2021. The advice updates the catch figure and upgrades the advice to category 1 maximum sustainable yield (MSY) advice. The fishing opportunities for herring in the Gulf of Bothnia should be adjusted accordingly, and therefore Regulation (EU) 2020/1579 should be amended accordingly.
- (2) Council Regulation (EU) 2021/92 ⁽²⁾ fixes for 2021 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in Union waters and, for Union vessels, in certain non-Union waters.
- (3) According to the ICES advice of 13 April 2021, catches of sprat (*Sprattus sprattus*) in ICES division 3a (Kattegat/Skagerrak) and ICES subarea 4 (North Sea) should be no more than 106 715 tonnes for the period from 1 July 2021 to 30 June 2022. The fishing opportunities for sprat for that period should therefore be set at 87 186 tonnes in Union waters of ICES division 2a and ICES subarea 4, and at 19 529 tonnes in ICES division 3a, in line with the maximum sustainable yield.
- (4) Regulation (EU) 2021/92 set at zero the total allowable catch (TAC) for anchovy (*Engraulis encrasicolus*) in ICES subareas 9 and 10 and Union waters of the Fishery Committee for the Eastern Central Atlantic 34.1.1 for the period from 1 July 2021 to 30 June 2022, pending the scientific advice for that period. ICES will issue its advice for that stock at the end of June 2021. In order to ensure that fishing activity may continue until the TAC is set on the basis of the latest scientific advice, a provisional TAC of 5 744 tonnes, based on the catches in the third quarter of 2020, should be established.
- (5) The numbers in point 6 of Annex VI to Regulation (EU) 2021/92 should be amended in order to reflect agreements concluded between some Member States to temporarily transfer between themselves, exclusively for year 2021, certain amounts of bluefin tuna farming input and capacity. Those changes have been notified to the International Commission for the Conservation of Atlantic Tunas (ICCAT) through an amended Union farming plan and do not affect the total farming capacity and input capacity of the Union in the ICCAT Convention Area.

⁽¹⁾ Council Regulation (EU) 2020/1579 of 29 October 2020 fixing for 2021 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea and amending Regulation (EU) 2020/123 as regards certain fishing opportunities in other waters (OJ L 362, 30.10.2020, p. 3).

⁽²⁾ Council Regulation (EU) 2021/92 of 28 January 2021 fixing for 2021 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters (OJ L 31, 29.1.2021, p. 31).

- (6) The catch limits provided for in Regulation (EU) 2020/1579 apply from 1 January 2021. The provisions introduced by this amending Regulation concerning catch limits for herring in the Gulf of Bothnia should therefore also apply from that date. Such retroactive application is without prejudice to the principles of legal certainty and protection of legitimate expectations, as the fishing opportunities concerned have not yet been exhausted.
- (7) This Regulation should enter into force on the day after its publication in order to enable the fishing season for sprat and anchovy to start on time on 1 July 2021,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment of Regulation (EU) 2020/1579

Regulation (EU) 2020/1579 is amended as set out in Part A of the Annex to this Regulation.

Article 2

Amendment of Regulation (EU) 2021/92

Regulation (EU) 2021/92 is amended as set out in Parts B and C of the Annex to this Regulation.

Article 3

Entry into force and application

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

Article 1 shall apply from 1 January 2021.

Article 2 shall apply from 1 July 2021.

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

Done at Luxembourg, 28 June 2021.

For the Council
The President
M. do C. ANTUNES

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ANNEX

PART A

In the Annex to Regulation (EU) 2020/1579, the fishing opportunities table for herring in ICES subdivisions 30-31 is replaced by the following:

'Species:	Herring <i>Clupea harengus</i>	Zone:	Subdivisions 30-31 (HER/30/31.)
Finland	96 321	Analytical TAC'	
Sweden	21 164		
Union	117 485		
TAC	117 485		

PART B

Annex IA to Regulation (EU) 2021/92 is amended as follows:

(1) the fishing opportunities table for sprat and associated by-catches in Union waters of ICES division 3a is replaced by the following:

'Species:	Sprat and associated by-catches <i>Sprattus</i>	Zone:	3a (SPR/03A.)
Denmark	13 086 ⁽¹⁾ ⁽²⁾	Analytical TAC	
Germany	27 ⁽¹⁾ ⁽²⁾		
Sweden	4 951 ⁽¹⁾ ⁽²⁾		
Union	18 064 ⁽¹⁾ ⁽²⁾		
TAC	19 529 ⁽²⁾		

(¹) Up to 5 % of the quota may consist of by-catches of whiting and haddock (OTH/*03A.). By-catches of whiting and haddock counted against the quota pursuant to this provision and by-catches of species counted against the quota pursuant to Article 15(8) of Regulation (EU) No 1380/2013 shall, together, not exceed 9 % of the quota.

(²) This quota may only be fished from 1 July 2021 to 30 June 2022. Transfers of this quota may be effected to United Kingdom and Union waters of 2a and 4. However, such transfers shall be notified in advance to the Commission and to the United Kingdom.'

(2) the fishing opportunities table for sprat and associated by-catches in United Kingdom and Union waters of ICES subarea 4 and United Kingdom waters of ICES division 2a is replaced by the following:

'Species:	Sprat and associated by-catches <i>Sprattus</i>	Zone:	United Kingdom and Union waters of 4; United Kingdom waters of 2a (SPR/2AC4-C)
Belgium	993 ⁽¹⁾ ⁽²⁾	Analytical TAC	
Denmark	78 553 ⁽¹⁾ ⁽²⁾		
Germany	993 ⁽¹⁾ ⁽²⁾		
France	993 ⁽¹⁾ ⁽²⁾		

The Netherlands	993	(¹) (²)
Sweden	1 330	(¹) (²) (³)
Union	83 855	(¹) (²)
Norway	0	(¹)
Faroe Islands	0	(¹) (⁴)
United Kingdom	3 331	(¹)
TAC	87 186	(¹)

(¹) The quota may only be fished from 1 July 2021 to 30 June 2022.

(²) Up to 2 % of the quota may consist of by-catches of whiting (OTH/*2AC4C). By-catches of whiting counted against the quota pursuant to this provision and by-catches of species counted against the quota pursuant to Article 15(8) of Regulation (EU) No 1380/2013 shall, together, not exceed 9 % of the quota.

(³) Including sandeel.

(⁴) May contain up to 4 % of by-catch of herring.'

(3) the table for fishing opportunities for anchovy in ICES subareas 9 and 10 and Union waters of CECAF division 34.1.1 is replaced by the following:

'Species:	Anchovy <i>Engraulis encrasicolus</i>	Zone:	9 and 10; Union waters of CECAF 34.1.1 (ANE/9/3411)
Spain	2 747	(¹)	Precautionary TAC
Portugal	2 997	(¹)	
Union	5 744	(¹)	
TAC	5 744	(¹)	

(¹) The quota may only be fished from 1 July 2021 to 30 September 2021.'

PART C

In Annex VI to Regulation (EU) 2021/92, point 6 is replaced by the following:

'6. Maximum bluefin tuna farming capacity and fattening capacity for each Member State and maximum input of wild caught bluefin tuna that each Member State may allocate to its farms in the eastern Atlantic and Mediterranean.

Table A

Maximum bluefin tuna farming capacity and fattening capacity		
	Number of farms	Capacity (in tonnes)
Spain	10	11 852
Italy	13	9 564
Greece	2	2 100
Cyprus	3	3 000
Croatia	7	7 880
Malta	6	14 511

Table B (1)

Maximum input of wild caught bluefin tuna (in tonnes)	
Spain	6 850
Italy	1 739,5
Greece	785
Cyprus	2 195
Croatia	2 947
Malta	10 260,5
Portugal	350

(1) The farming capacity of Portugal of 500 tonnes is covered by the unused capacity of the Union set out in table A.1.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1070**of 28 June 2021****laying down special control measures for a limited period of time related to infection with lumpy skin disease virus****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 71(3) thereof,

Whereas:

- (1) Infection with lumpy skin disease virus, caused by the lumpy skin disease virus (LSDV), is a vector-borne disease of cattle and Asian water buffalo that can cause substantial economic losses, reduce milk yield, cause severe emaciation, permanent damage to hides, several secondary complications, chronic debility, and incur movement or trade bans. It is on the list of notifiable diseases of the World Organisation for Animal Health (OIE) ⁽²⁾.
- (2) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases. Infection with lumpy skin disease virus is listed in Annex II to Regulation (EU) 2016/429, and accordingly it is a listed disease for the purposes of that Regulation, and it is subject to the disease prevention and control rules laid down therein. In addition, infection with LSDV is listed in the Annex to Commission Implementing Regulation (EU) 2018/1882 ⁽³⁾ as a category A, D and E disease.
- (3) Commission Delegated Regulation (EU) 2020/687 ⁽⁴⁾ supplements the rules for the control of category A, B and C diseases laid down in Regulation (EU) 2016/429, including disease control measures against infection with LSDV. Regulation (EU) 2016/429, Implementing Regulation (EU) 2018/1882 and Delegated Regulation (EU) 2020/687 all apply from 21 April 2021.
- (4) Previously, Commission Implementing Decision (EU) 2016/2008 ⁽⁵⁾ laid down rules on animal health control measures in relation to infection with LSDV in the Member States or parts thereof listed in Annex I thereto, including the minimum requirements for vaccination programmes against infection with LSDV submitted by the Member States to the Commission for approval. Bulgaria and Greece are concerned by such listing. Implementing Decision (EU) 2016/2008 ceased to apply on 20 April 2021, and the rules laid down in this Regulation should replace those laid down in that Implementing Decision.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ OIE – Listed diseases, infections and infestations in force in 2021. OIE - Terrestrial Animal Health Code, Twenty-eighth edition, 2019, ISBN 978-92-95108-85-1 (<https://www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2021/>).

⁽³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

⁽⁵⁾ Commission Implementing Decision (EU) 2016/2008 of 15 November 2016 concerning animal health control measures relating to lumpy skin disease in certain Member States (OJ L 310, 17.11.2016, p.51).

- (5) Since 2017, no outbreaks of infection with LSDV have been reported in Europe, but that disease is still present in Anatolia, Turkey, and in Russia, as well as in eastern Asia affecting Bangladesh, China and India. Therefore, the spread of that disease represents a potential risk for the agricultural sector in the Union.
- (6) Apart from Bulgaria and Greece, Croatia and a considerable number of neighbouring third countries, such as Bosnia and Herzegovina, Kosovo ⁽⁶⁾, Montenegro, North Macedonia, Serbia and Turkey have notified to the Commission that vaccination against infection with LSDV has been included in their disease control policy. Most of those third countries have now stopped vaccination and are maintaining surveillance measures.
- (7) The epidemiological situation in Eastern Europe and in neighbouring regions suggests that a certain risk of disease re-introduction or re-emergence, in high-risk areas where vaccination against infection with LSDV has ceased, may still exist.
- (8) Based on the available epidemiological information to date, the results of surveillance for infection with LSDV and vaccination against that disease, it is appropriate that vaccination against infection with LSDV should at least continue in the high-risk areas of Bulgaria and Greece. In addition, in all Member States or parts thereof where vaccination against that disease has been reduced or completely ceased, systematic surveillance, both active and passive, should continue.
- (9) According to the scientific report of the European Food Safety Authority (EFSA) on infection with LSDV, approved on 30 January 2020 ⁽⁷⁾ (the EFSA Report), a homologous vaccine should be used to reduce the risk of the further spread of infection with LSDV to south-eastern Europe. After vaccination has stopped, in the case of the re-emergence of that disease, a contingency plan and vaccine stockpiling, even on a regional basis, would be needed in order to react quickly with emergency vaccination.
- (10) The general disease control measures laid down in Regulation (EU) 2016/429, and the supplementing rules laid down in Delegated Regulation (EU) 2020/687, do not cover all necessary aspects of vaccination against infection with LSDV. It is therefore appropriate to lay down uniform implementing rules at Union level in this Regulation to cover special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation of that disease in the Union and in neighbouring third countries. The control measures laid down in this Regulation should take account of the experience gained in the application of Implementing Decision (EU) 2016/2008, as well as international standards set out in Chapter 11.9 'Infection with lumpy skin disease virus' of the Terrestrial Animal Health Code of the OIE (OIE Code) ⁽⁸⁾.
- (11) The rules laid down in this Regulation should provide for a regionalisation approach, and apply in tandem with the disease control measures laid down in Delegated Regulation (EU) 2020/687. In addition, this Regulation should list the restricted zones of Member States carrying out preventive vaccination plans with live attenuated vaccines where there are no outbreaks of infection with LSDV (restricted zone I); and areas with outbreaks of infection with LSDV (restricted zone II). The areas included in restricted zone I or in restricted zone II should be listed in Annex I to this Regulation taking account of the information provided by the competent authorities of the Member States affected by that disease.
- (12) Vaccinated bovine animals and products from those bovine animals may represent a risk for the spread of infection with LSDV. Therefore, this Regulation should provide for certain prohibitions and specific conditions on movements of consignments of bovine animals or different types of products from the restricted zones listed in Annex I to this Regulation. In order to avoid unnecessary disturbances for trade, certain derogations from those prohibitions and specific conditions should be laid down. Those derogations and specific conditions should take account of the principles of the OIE Code as regards risk mitigation measures against infection with LSDV, as well as the rules for the prevention and control of animal diseases laid down in Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/687.

⁽⁶⁾ This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

⁽⁷⁾ EFSA Journal 2020; 18(2):6010.

⁽⁸⁾ OIE – Terrestrial animal health code (2019). OIE - Terrestrial Animal Health Code, Twenty-eighth edition, 2019, ISBN 978-92-95108-85-1 (www.oie.int/en/standard-setting/terrestrial-code/access-online/).

- (13) In terms of the risk of the spread of infection with LSDV, different commodities pose different levels of risk. As indicated in the EFSA Report, the movement of live bovine animals, bovine semen and raw hides and skins from infected bovine animals pose a higher level of risk in terms of exposure and consequences than other products such as milk and dairy products, treated hides and skins or fresh meat, meat preparations and meat products originating from bovine animals. However, scientific or experimental evidence on their role in transmitting lumpy skin virus is not yet sufficient. The transmission of lumpy skin disease virus through semen, ova and embryos of animals of the bovine species cannot be excluded. Milk and dairy products, as well as colostrum, may represent a risk for the spread of lumpy skin disease virus only when destined for feeding to animals of the susceptible species.
- (14) Therefore, certain protective measures should be provided for those commodities based on the EFSA Report and the relevant most updated standards and recommendations from the OIE.
- (15) Movements of consignments of animals for immediate slaughter pose a lower level of risk for the spread of animal diseases than other types of movements of animals provided that risk mitigation measures are in place. It is therefore appropriate that the Member States should be permitted exceptionally to grant derogations from certain prohibitions laid down in this Regulation for movements of consignments of bovine animals, from restricted zones I and II, for immediate slaughter to a slaughterhouse located outside of restricted zones I and II in the same Member State.
- (16) The derogations for movements of consignments of certain bovine animals from a restricted zones I or II to another restricted zones I or II of another Member State with a similar disease status are justified where specific risk mitigating measures are applied. This requires the establishment of a safe channelling procedure under the strict control of the competent authorities of the Member State of origin, passage and destination.
- (17) Article 143 of Regulation (EU) 2016/429 provides that animal health certificates are to accompany the movements of animals, including bovine animals. Where derogations from the prohibition on movements of consignments of bovine animals from restricted zones I and II are applied to consignments of bovine animals intended for intra-Union movements, those animal health certificates should include a reference to this Regulation, to ensure that adequate and accurate health information is provided in those animal health certificates.
- (18) Where this Regulation provides for derogations from prohibitions on movements of consignments of germinal products from restricted zones I and II, the accompanying animal health certificates should include a reference to this Regulation, so as to ensure adequate and accurate health information in accordance with this Regulation and Commission Delegated Regulation (EU) 2020/686 ⁽⁹⁾.
- (19) The transport of bovine animals and animal by-products from those animals from restricted zones I and II should be carried out under animal welfare and biosecurity measures to avoid the spread of infection with LSDV.
- (20) Delegated Regulation (EU) 2020/687 applies from 21 April 2021. Accordingly, in the interest of legal certainty, this Regulation should enter into force as a matter of urgency.
- (21) This Regulation should apply for a period until 21 April 2023, taking into account the Union's experience in the control of infection with LSDV, the current epidemiological situation of that disease in Member States and neighbouring third countries and any future rules on vaccination laid down pursuant to Article 47 of Regulation (EU) 2016/429.
- (22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁹⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL RULES

Article 1

Subject matter and scope

This Regulation lays down special disease control measures against infection with the lumpy skin disease virus (LSDV) to be applied for a limited period of time by Member States in areas of their territory where:

- (a) an outbreak of that disease has been confirmed;
- (b) an outbreak of that disease has not been confirmed, but they decide to carry out vaccination against that disease in accordance with the rules laid down in this Regulation.

The special disease control measures laid down in this Regulation apply to bovine animals and by-products and germinal products obtained from such bovine animals, and are in addition to the disease control measures applicable to the protection, surveillance and further restricted zones established by the competent authority of a Member State following an outbreak of infection with LSDV, in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Delegated Regulation (EU) 2020/687 shall apply.

In addition, the following definitions shall also apply:

- (1) 'bovine animal' means an animal of the species of ungulates belonging to the genera Bison, Bos (including the subgenera Bos, Bibos, Novibos, Poephagus) and Bubalus (including the subgenus Anoa) and the offspring of crossings of those species;
- (2) 'restricted zone I' means a part of the territory of a Member State with a precise geographical delimitation:
 - (a) located outside an area where an outbreak of infection with LSDV has been confirmed;
 - (b) where vaccination against infection with LSDV is carried out in accordance with Article 3(2);
 - (c) listed or not in Part I of Annex I;
 - (d) subject to special disease control rules provided for in Articles 3 to 6;
- (3) 'restricted zone II' means a part of the territory of a Member State with a precise geographical delimitation:
 - (a) which includes an area where an outbreak of infection with LSDV has been confirmed;
 - (b) where vaccination against infection with LSDV is carried out in accordance with Article 3(1);
 - (c) listed or not in Part II of Annex I;
 - (d) subject to special disease control rules provided for in Article 3 to 6.

CHAPTER II

SPECIAL DISEASE CONTROL MEASURES AGAINST INFECTION WITH LSDV

SECTION 1

Establishment of restricted zones and vaccination against infection with LSDV*Article 3***Establishment of restricted zones I and II**

1. In the event of confirmation of an outbreak of infection with LSDV in bovine animals, the competent authority shall:
 - (a) establish a restricted zone II:
 - (i) covering at least the areas included in the protection, surveillance and further restricted zones established after the confirmation of that disease in accordance with Article 21 of Delegated Regulation (EU) 2020/687;
 - (ii) in accordance with the criteria laid down in Article 64 (1) of Regulation (EU) 2016/429;
 - (b) implement a vaccination against that disease in the restricted zone II referred to in point (a) as follows:
 - (i) in accordance with the rules for vaccination plans set out in Annex II;
 - (ii) under the control of the competent authority;
 - (iii) prioritising the use of homologous live attenuated vaccines;
 - (iv) vaccinating all bovine animals and their offsprings kept in the zone where vaccination is carried out, independently of their sex, age and gestational or productive status in accordance with the instructions of the manufacturer.

However, where a only one outbreak of infection with LSDV in kept bovine animals has been confirmed in an area of a Member State where that disease was not present before that outbreak, and where the measures carried out in accordance with Delegated Regulation (EU) 2020/687 prove to be effective in controlling the spreading of the disease, the competent authority may decide not to establish a restricted zone II.

2. The competent authority may establish a restricted zone I in areas where the presence of an outbreak of infection with LSDV has not been confirmed in order to prevent its spread, in accordance with the criteria laid down in Article 64(1) of Regulation (EU) 2016/429. In that restricted zone I, the competent authority shall carry out vaccination against that disease in accordance with paragraph 1, point (b), of this Article.
3. The competent authority of the Member States applying vaccination against infection with LSDV shall provide the information listed in Annex II, Part III of this Regulation to the Commission and the other Member States before starting the vaccination and the vaccination plan referred to in paragraph 1(b), point (i).

*Article 4***Prohibitions of movements in restricted zones I and II**

1. The competent authority shall prohibit movements of the following consignments in restricted zones II:
 - (a) bovine animals;
 - (b) germinal products from bovine animals;
 - (c) unprocessed animal by-products from bovine animals including milk, colostrum, dairy products and colostrum-based products intended for animal feed.

2. The competent authority shall prohibit movements of the following consignments in restricted zones I:
 - (a) bovine animals;
 - (b) germinal products from bovine animals;
 - (c) unprocessed animal by-products from bovine animals other than milk, colostrum, dairy products and colostrum-based products intended for animal feed.
3. By way of derogations from the prohibitions provided for in paragraphs 1 and 2, the competent authority may authorise the movements provided for in Chapter III in accordance with the conditions provided therein.

SECTION 2

Inclusion of a restricted zones I and II in Annex I

Article 5

Inclusion of restricted zone II in Annex I, Part II

Where, for epidemiological reasons, an area of a Member State covered totally or partially by a restricted zone II established in accordance with Article 3(1) is included in Part II of Annex I, the competent authority shall immediately:

- (a) adapt the boundaries of the initial restricted zone II to ensure that it corresponds to the restricted zone II described in that Annex;
- (b) extend the vaccination provided for in Article 3(1), point (b), and the prohibitions provided for in Article 4(1) to the restricted zone II described in that Annex.

Article 6

Inclusion of restricted zone I in Annex I, Part I

1. Where, for epidemiological reasons, an area of a Member State where an outbreak of infection with LSDV has not been confirmed is included in Part I of Annex I to this Regulation in accordance with the criteria laid down in Article 64(1) of Regulation (EU) 2016/429, the competent authority shall:

- (a) carry out vaccination in accordance with Article 3(1), point (b), in the restricted zone I described in that Annex;
- (b) implement the prohibitions provided for in Article 4(2) in the restricted zone I described in that Annex.

2. Where the competent authority decides to establish a restricted zone I in accordance with Article 3(2) that restricted zone shall be included in Part I of Annex I.

CHAPTER III

CONDITIONS FOR MOVEMENTS WITHIN AND FROM AREAS WHERE SPECIAL DISEASE CONTROL MEASURES AGAINST INFECTION WITH LUMPY SKIN DISEASE VIRUS ARE APPLIED

SECTION 1

Derogations from the prohibitions on movements of consignments of bovine animals from restricted zones I and II*Article 7***Derogations from the prohibition on movements of consignments of bovine animals from restricted zone I**

By way of derogations from the prohibition provided for in Article 4(2), point (a), the competent authority may authorise movements of consignments of bovine animals from establishments located in restricted zone I to:

- (a) a restricted zones I or II of the same or another Member State provided that all of the following conditions are fulfilled:
- (i) the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date;
 - (ii) all the other bovine animals kept in the same establishment of origin as the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on the date of dispatch;
 - (iii) the bovine animals in the consignment must have been kept in their establishment of origin since birth or for a continuous period of at least 28 days prior to the date of dispatch; and
 - (iv) the competent authority shall carry out:
 - a clinical examination, with favourable results, of all bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
 - if necessary, a laboratory examination, with favourable results, of bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
- (b) any destination – including areas outside restricted zones, other restricted zones I or restricted zones II – in the same Member State or in other Member States, if, in addition to the conditions laid down in point (a)(ii), (iii) and (iv) of this Article, all of the following conditions are fulfilled:
- (i) the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on the date of dispatch;
 - (ii) within a radius of at least 20 km around the establishment of origin of such consignments, there have been no outbreaks of infection with LSDV during a period of at least three months prior to the date of dispatch; and
 - (iii) all bovine animals kept in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against infection with LSDV at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within their maternal immunity;

- (c) any destination – including areas outside restricted zones, other restricted zones I or restricted zones II – in other Member States or territories in third countries, if, in addition to the conditions laid down in point (a) of this Article, the following conditions are fulfilled:
- (i) the animals must comply with any animal health guarantee, based on the favourable outcome of a risk assessment of measures against the spread of infection with LSDV required by the competent authority of the Member State of origin and approved by the competent authority of the Member States of destination and passage, prior to the date of dispatch;
 - (ii) there must have been no confirmed outbreaks of infection with LSDV within a radius of at least 20 km around the establishment of origin of such consignments for a period of at least three months prior to the date of dispatch; and
 - (iii) all bovine animals kept in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against infection with LSDV at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within their maternal immunity.

Article 8

Derogations from the prohibitions of movements of consignments of bovine animals from restricted zone II

By way of derogations from the prohibition provided for in Article 4(1), point (a), the competent authority may authorise movements of consignments of bovine animals from establishments located in restricted zone II to:

- (a) any destination, including areas outside restricted zones, restricted zones I, other restricted zones II in the same Member State and other Member States, provided that all of the following conditions are fulfilled:
- (i) the bovine animals in the consignment must comply with any animal health guarantee, based on the favourable outcome of a risk assessment of measures against the spread of infection with LSDV required by the competent authority of the Member State of origin and agreed with the competent authority of the Member States of destination or passage, prior to the date of dispatch;
 - (ii) the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date;
 - (iii) all other bovine animals kept in the same establishment of origin as the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on that date;
 - (iv) the competent authority shall carry out:
 - a clinical examination, with favourable results, of all bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
 - if necessary, a laboratory examination, with favourable results, of bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
 - (v) the bovine animals must have been resident since birth, or for a period of at least 28 days prior to the date of dispatch, in an establishment where, within a radius of at least 20 km, no outbreak of infection with LSDV has been confirmed during the three months prior to the date of dispatch;

- (vi) all bovine animals in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against infection with LSDV, in accordance with the rules for vaccination plans set out in Annex II, at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer or within their maternal immunity;
- (b) any destination located within another restricted zone II of the same Member State, provided that all of the following conditions are fulfilled:
 - (i) all other bovine animals kept in the establishment of origin of such consignments must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on that date; and
 - (ii) the bovine animals must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or are unvaccinated offspring less than four months old, born to dams vaccinated at least 28 days prior to parturition that remained within the immunity period according to the vaccine manufacturer on the date of parturition, and may be moved to another establishment.

Article 9

Specific conditions for authorising movements of consignments of bovine animals from restricted zones I and II to a slaughterhouse outside of those zones, located in the territory of the same Member State for the purpose of immediate slaughter

By way of derogations from the prohibitions provided for in Article 4(2), point (a), and Article 4(1), point (a), of this Regulation, the competent authority of the Member State may authorise movements of consignments of bovine animals from restricted zones I and II to a slaughterhouse outside of those zones, located in the territory of the same Member State, provided that the bovine animals are moved for the purpose of immediate slaughter in compliance with the general conditions laid down in Article 28(2) to (5) and Article 28(7) of Delegated Regulation (EU) 2020/687.

Article 10

Derogations from the prohibition on the movements of consignments of semen, ova and embryos of bovine animals from the restricted zones I and II

1. By way of derogations from the prohibition provided for in Article 4(2), point (b), the competent authority of a Member State may authorise movements of consignments of semen, ova and embryos of bovine animals, from approved germinal product establishments or other establishments located in restricted zone I to:

- (a) restricted zones I or II of the same Member State provided that all of the following conditions are fulfilled:
 - (i) the donor animals were either:
 - vaccinated and revaccinated against infection with LSDV according to the manufacturer's instructions of the vaccine used, and the first vaccination must have been administered at least 60 days prior to the date of collection of the semen, ova or embryo; or
 - subjected to a serological test to detect specific antibodies against the LSDV on the day of the collection and at least 28 days after the period of collection as regards semen or on the day of collection as regards embryos and ova, with negative results;
 - (ii) the donor animals were kept, during the 60 days prior to the date of collection of the semen, ova or embryos, in an artificial insemination centre or other appropriate establishment where, within a radius of at least 20 km, no outbreak of infection with LSDV has been confirmed during the three months prior to the date of collection of the semen, ova or embryos;

- (iii) the donor animals were clinically checked 28 days prior to the date of collection, as well as throughout the entire collection period, and did not show any clinical symptoms of infection with LSDV;
- (b) any destination located in another restricted zone I or II of another Member State, provided that, in addition to the conditions laid down in point (a), all of the following conditions are fulfilled:
 - (i) the donor animals were subjected to a LSDV detection by polymerase chain reaction (PCR) conducted on blood samples collected at the commencement of collection of the semen, ova or embryo and at least every 14 days thereafter during the semen collection period or on the day of collection for embryos and ova, with negative results;
 - (ii) the semen was subjected to a LSDV detection by PCR with negative results;
- (c) any destination located in the same or another Member State or, in case of restricted zone I, to a third country provided that, in addition to the conditions laid down in point (a), the donor animals comply with any other appropriate animal health guarantees, based on a positive outcome of a risk assessment of the impact of such dispatch and of the measures against the spread of infection with LSDV, required by the competent authority of the Member State of the establishment of origin and approved by the competent authorities of the Member States of the places of passage and of destination, prior to the dispatch of such semen, ova or embryos.

2. By way of derogations from the prohibition provided for in Article 4(1), point (b), the competent authority may authorise movements of consignments of semen, ova and embryos of bovine animals, from approved germinal product establishments or other establishments located in restricted zone II to any destination located in another restricted zone II of the same Member State.

Article 11

Derogations from the prohibition on the movements of unprocessed animal by-products from bovine animals from restricted zones I

By way of derogation from the prohibition provided for in Article 4(2), point (c), the competent authority of a Member State may authorise movements of consignments of unprocessed animal by-products from bovine animals from establishments located in restricted zone I to:

- (a) any destination located in the same Member State or to any destination located in restricted zones I or II in another Member State;
- (b) in the case of consignments of hides and skins, any destination located in any area of the same or another Member State or third country provided that one of the following conditions are fulfilled:
 - (i) the treated hides and skins have been subjected to one of the treatments referred to in point 28(b) to (e) of Annex I to Commission Regulation (EU) No 142/2011⁽¹⁰⁾; or
 - (ii) the treated hides and skin have been subjected to one of the treatments set out in Section XIV, Chapter I, point (4)(b)(ii), of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council⁽¹¹⁾, and have undergone all precautions to avoid recontamination with pathogenic agents after treatment.

⁽¹⁰⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

⁽¹¹⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

*Article 12***Derogation from the prohibition on the movements of consignments of unprocessed animal by-products from bovine animals from restricted zones II**

By way of derogation from the prohibition provided for in Article 4(1), point (c), the competent authority of a Member State may authorise movements of consignments of unprocessed animal by-products from bovine animals from establishments located in restricted zone II to:

- (a) in the case of unprocessed animal by-products other than hides and skins, any destination located in the same Member State or any destination located in restricted zones I or II of another Member State provided that the unprocessed animal by-products are dispatched under the official supervision of the competent authorities for processing or disposal in a plant approved in accordance with Article 24 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽¹²⁾;
- (b) in the case of hides and skins of bovine animals:
 - (i) any destination located in restricted zone II of the same or another Member State provided that they are untreated raw hides and skins destined for human consumption or untreated hides and skins dispatched under the official supervision of the competent authorities for processing or disposal in an approved plant;
 - (ii) any destination located in the same or another Member State provided that the conditions laid down in Article 11, point (b), are fulfilled;
- (c) in the case of colostrum, milk and dairy products, any destination located in any area of the same or another Member State provided that they have been subjected to a risk-mitigating treatment for infection with LSDV, as set out in Annex VII to Delegated Regulation (EU) 2020/687.

SECTION 2

Obligations on operators with regard to animal health certificates*Article 13***Operators' obligations with regard to animal health certificates for movements of consignments of bovine animals from restricted zones I and II outside of those zones**

Operators shall only move consignments of bovine animals from restricted zones I and II outside of those zones within the same Member State or to another Member State in the cases covered by Articles 7, 8 and 9 of this Regulation if the animals to be moved are accompanied by the animal health certificate provided for in Article 73 of Commission Delegated Regulation (EU) 2020/688 ⁽¹³⁾ that contains at least one of the following attestations of compliance with the requirements provided for in this Regulation:

- (a) 'Bovine animals from restricted zone I in compliance with the special control measures against infection with LSDV laid down in Article 7 of Commission Implementing Regulation (EU) 2021/1070.;
- (b) 'Bovine animals from restricted zone II in compliance with the special control measures against infection with LSDV laid down in Article 8 of Commission Implementing Regulation (EU) 2021/1070.;
- (c) 'Bovine animals from a restricted zone I or II in compliance with the special control measures against infection with LSDV laid down in Article 9 of Commission Implementing Regulation (EU) 2021/1070.'

⁽¹²⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁽¹³⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

However, in the case of movements of the consignments referred to in the first paragraph of this Article within the same Member State, the competent authority may decide that an animal health certificate does not have to be issued as referred to in Article 143(2), second subparagraph, of Regulation (EU) 2016/429.

Article 14

Operators' obligations with regard to animal health certificates for movements of consignments of germinal products obtained from bovine animals from establishments located in restricted zones I and II outside of those zones

Operators shall only move consignments of germinal products obtained from bovine animals from restricted zones I and II outside of those zones within the same Member State or to another Member State in accordance with Article 10 of this Regulation, if those consignments are accompanied by an animal health certificate as referred to in Article 161(4) of Regulation (EU) 2016/429 that contains at least one of the following attestations of compliance with the requirements provided for in this Regulation:

- (a) 'Germinal products (semen, ova and/or embryos, indicate as appropriate) obtained from bovine animals kept in restricted zone I in compliance with special control measures against infection with LSDV as laid down in Article 10 of Commission Implementing Regulation (EU) 2021/1070.';
- (b) 'Germinal products (semen, ova and/or embryos, indicate as appropriate) obtained from bovine animals kept in restricted zone II in compliance with special control measures against infection with LSDV as laid down in Article 10 of Commission Implementing Regulation (EU) 2021/1070.'.

However, in the case of movements of the consignments referred to in the first paragraph of this Article within the same Member State, the competent authority may decide that an animal health certificate does not have to be issued as referred to in Article 161(2), second subparagraph, of Regulation (EU) 2016/429.

Article 15

Operators' obligations with regard to animal health certificates for movements of consignments of unprocessed animal by-products from bovine animals from restricted zones I and II outside of those zones

Operators shall only move consignments of unprocessed animal by-products from bovine animals from restricted zones I and II outside of those zones within the same Member State or to another Member State in the cases covered by Article 12, if those consignments are accompanied by:

- (a) a commercial document referred to in Chapter III of Annex VIII to Regulation (EU) No 142/2011; and
- (b) an animal health certificate referred to in Article 22(5) of Delegated Regulation (EU) 2020/687;

However, in the case of movements of the consignments referred to in the first paragraph of this Article within the same Member State, the competent authority may decide that an animal health certificate shall not be issued as referred to in Article 22(6) of Delegated Regulation (EU) 2020/687.

SECTION 3

Specific conditions for authorising movements of consignments of bovine animals kept in restricted zones I and II outside of those zones and channelling procedures

Article 16

Additional general conditions related to the means of transport used for the movement of consignments of bovine animals and unprocessed animal by-products from restricted zones I and II outside of those zones

The competent authority of the Member State shall only authorise movements of consignments of bovine animals and unprocessed animal by-products from restricted zones I and II outside of those zones if the means of transport used for the movement of those consignments:

- (a) in the case of transport of bovine animals, the means of transport:
 - (i) comply with requirements laid down in Article 24(1) of Delegated Regulation (EU) 2020/687; and
 - (ii) are cleaned and disinfected in accordance with Article 24(2) of Delegated Regulation (EU) 2020/687 under the control or supervision of the competent authority of the Member State;
- (b) only include animals or unprocessed animal by-products or untreated hides and skins of the same health status.

Article 17

Obligations of the competent authority of establishment of origin concerning channelling procedures

1. The competent authority of the Member State of the establishment of origin shall set up a channelling procedure, under the control of the competent authorities of the Member States of the places of origin, passage and destination for movements of consignments of bovine animals or unprocessed animal by-products covered by the derogations provided for in Articles 8, 9 and 12 when the destination is located in another Member State ('the channelling procedure').

2. The competent authority of the establishment of origin shall ensure that:

- (a) each means of transport, that is used for the movement of the consignments of bovine animals or unprocessed animal by-products referred to in paragraph 1, has been individually registered, by the competent authority of the Member State of the establishment of origin for the purpose of the transport of either bovine animals or unprocessed animal by-products using the channelling procedure, and is:
 - sealed by the official veterinarian after loading for dispatch. Only an official of the competent authority of the place of destination may break the seal and replace it with a new one; each loading or replacement of seals must be notified to the competent authority at the place of destination, or
 - individually accompanied by a satellite navigation system to determine, transmit and record its real time location.
- (b) the transport takes place:
 - (i) under the supervision of an official veterinarian;
 - (ii) directly, without stopping unless a rest period required by Chapter V of Annex I of Council Regulation (EC) No 1/2005 ⁽¹⁴⁾ takes place in a control post;

⁽¹⁴⁾ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

Where a rest period of one day or more is foreseen at a control post during the movement of the consignment through a restricted zone II, the animals shall be protected against attacks by vectors;

(iii) taking the route that has been authorised by the competent authority at the place of origin.

3. For the purposes of the channelling, the competent authority of the establishment of origin shall, before the first dispatch of a consignment from restricted zones I or II from which a channelling procedure takes place, ensure that the necessary arrangements are in place with the relevant competent authorities of the places of passage and destination and operators in order to ensure:

- (a) the emergency plan is agreed;
- (b) the chain of command and full cooperation of services and operators in the case of accidents during the transport, a major breakdown of the means of transport or any fraudulent action;
- (c) immediate notification by operators to the competent authority of any accident or major breakdown of the means of transport.

Article 18

Obligations of the competent authority of the place of destination concerning channelling procedures

The competent authority of the place of destination, following a channelling procedure, shall:

- (a) confirm each arrival to the competent authority of place of origin;
- (b) ensure that the bovine animals remain in the establishment of destination for at least the duration of the monitoring period for infection with LSDV set out in Annex II to Delegated Regulation (EU) 2020/687, except when the establishment of destination is a slaughterhouse;
- (c) ensure that after the unloading of the bovine animals, or the unprocessed animal by-products the means of transport and any other equipment which have been used in the transport of the bovine animals or the unprocessed animal by-products, are cleaned, disinfected and treated with authorised insecticides that are effective against known vectors of infection with LSDV in their entirety within a closed area of the place of destination under the supervision of an official veterinarian.

Article 19

Obligations of the Member State of the place of origin of the consignments of bovine animals, germinal products or unprocessed animal by-products concerning information to the Commission and the Member States for derogations granted based on risk assessments

Where the competent authority authorises movements of consignments of bovine animals or germinal products based on the favourable outcome of a risk assessment of measures against the spread of infection with LSDV, as referred to in Articles 7, 8 or 10, the Member State of the place of origin shall immediately inform the Commission and the other Member States of the animal health guarantees, and of the approval by the competent authorities of place of the establishment of destination.

CHAPTER IV

FINAL PROVISIONS

*Article 20***Entry into force and date of application**

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

It shall apply until 21 April 2023.

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

Done at Brussels, 28 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

RESTRICTED ZONES I and II

(as referred to in Article 3)

PART I

Restricted zone I

1. Bulgaria:
The entire territory of Bulgaria
2. Greece:
 - A. The following regions in Greece:
 - Region of Attica
 - Region of Central Greece
 - Region of Central Macedonia
 - Region of Crete
 - Region of Eastern Macedonia and Thrace
 - Region of Epirus
 - Region of the Ionian Islands, excluding the regional unit of Kerkyra
 - Region of North Aegean, excluding the regional unit of Limnos
 - Region of Peloponnese
 - Region of South Aegean
 - Region of Thessaly
 - Region of Western Greece
 - Region of Western Macedonia
 - B. The following regional units in Greece:
 - Regional unit of Limnos
 - Regional unit of Kerkyra

PART II

Restricted zone II

None

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ANNEX II

RULES FOR VACCINATION PLANS CONCERNING INFECTION WITH LUMPY SKIN DISEASE VIRUS

(as referred to in Article 3)

PART I

Information to be included in the vaccination plan as referred to in Article 3

Where a Member State carries out vaccination against infection with LSDV, such vaccination shall be carried out in accordance with a vaccination plan containing at least the following information:

- (a) the description and the results of the assessment performed in accordance with the criteria laid down in Article 46(2) of Regulation (EU) 2016/429, including the epidemiological situation and other relevant information used as a basis for the assessment;
- (b) the main objectives and targets with the chosen vaccination strategy and the vaccination plan;
- (c) the detailed geographic description of the vaccination zone in which vaccination is to be carried out and the location of establishments keeping bovine animals to be vaccinated, including maps;
- (d) the responsible authority to administer the vaccine to the bovine animals;
- (e) the system to supervise the administration of the vaccine;
- (f) the number of establishments keeping bovine animals located in the restricted zone and the number of establishments to be vaccinated, if different;
- (g) the estimated number of bovine animals, their categories and age of animals to be vaccinated;
- (h) the envisaged duration of the vaccination, from the start of the vaccination to the end of the surveillance carried out after vaccination;
- (i) the summary of the characteristics of the vaccine, including the name of the product and the name of the manufacturer, and routes of administration;
- (j) indicate if the vaccine is used in accordance with Article 110(2) and (3) of Regulation (EU) 2019/6 of the European Parliament and of the Council ⁽¹⁾;
- (k) the methods to assess the effectiveness of vaccination;
- (l) the hygiene and biosecurity rules to be applied;
- (m) the record keeping system on the vaccination;
- (n) other aspects of relevance for the specific situation.

PART II

Minimum requirements for infection with LSDV vaccination plans as referred to in Article 3

The vaccination plans against infection with LSDV shall be in accordance with the following technical requirements:

- (a) vaccination of all bovine animals independently of their sex, age and gestational or productive status within the restricted zones I and II where vaccination must be implemented;
- (b) vaccination of the offspring of vaccinated bovine animals older than four months of age in accordance with the instructions of the manufacturer of the vaccine used;
- (c) revaccination of all bovine animals in accordance with the instructions of the manufacturer;

⁽¹⁾ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

- (d) entry of the details for each vaccinated bovine animal by the competent authority in the dedicated online database connected with the central database established in accordance with Article 42 of Regulation (EU) 2019/2035 of the European Parliament and of the Council ⁽²⁾;
- (e) establishment of an increased surveillance area of at least 20 km around the restricted zones I and II where vaccination is carried out, in which intensified surveillance shall be carried out and the movement of bovine animals shall be subject to controls by the competent authority;
- (f) vaccine coverage of at least 95% of herds representing at least 75% of bovine animals population.

PART III

Preliminary information to be provided to the Commission and to the other Member States before starting vaccination as referred to in Article 3, point 3

Member States applying vaccination against lumpy skin disease shall provide the following information to the Commission and to the other Member States before starting the vaccination:

- (a) a brief justification for starting the vaccination;
- (b) the species of bovine animals that are to be vaccinated;
- (c) the estimated number of bovine animals that are to be vaccinated;
- (d) the estimated duration of the vaccination;
- (e) the type and commercial name of the vaccine applied indicating if the vaccine is to be used in accordance with Article 110(2) and (3) of Regulation (EU) 2019/6;
- (f) a description of the estimated vaccination zone.

⁽²⁾ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1071**of 29 June 2021****amending Implementing Regulation (EU) 2021/442 and Implementing Regulation (EU) 2021/521 related to the mechanism making certain products subject to the production of an export authorisation**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports ⁽¹⁾, and in particular Article 6 thereof,

Whereas:

- (1) On 30 January 2021, the Commission adopted Implementing Regulation (EU) 2021/111 ⁽²⁾ making the exportation of COVID-19 vaccines as well as active substances, including master and working cell banks, used to manufacture these vaccines, subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479, for a period of six weeks. Hereafter, on 12 March 2021, the Commission adopted Implementing Regulation (EU) 2021/442 ⁽³⁾ making the exportation of the same products subject to an export authorisation until 30 June 2021, pursuant to Article 6 of Regulation (EU) 2015/479.
- (2) On 24 March 2021, the Commission adopted Implementing Regulation (EU) 2021/521 ⁽⁴⁾ introducing as an additional factor when considering granting an export authorisation, the need to assess whether such authorisation does not pose a threat to the security of supply within the Union of the goods covered by Implementing Regulation (EU) 2021/442. By the same Regulation, the Commission decided on a temporary suspension of the exemption of certain destination countries from the scope of Implementing Regulation (EU) 2021/442.
- (3) Commission Implementing Regulation (EU) 2021/521 was adopted pursuant to Article 5 of Regulation (EU) 2015/479 and applied for a period of six weeks. The measures introduced by that Regulation were subsequently extended until 30 June 2021 by Commission Implementing Regulation (EU) 2021/734 ⁽⁵⁾.
- (4) Vaccine production capacity in the Union has stepped up in the meantime, resulting in an increase of deliveries of COVID-19 vaccine doses in the Union. This led to an acceleration of the vaccination campaign in the Union.
- (5) This vaccination campaign is however still on-going and uncertainties remain, in particular with the emergence of new variants of the COVID-19 virus. There is therefore a continuing need for transparency of export deliveries and Union supplies.
- (6) The risk that exports would threaten either the execution of the Advance Purchase Agreements between the Union and the vaccine manufacturers or the security of Union supplies of COVID-19 vaccines and their active substances also still persists.
- (7) Measures introduced by Implementing Regulation (EU) 2021/442 and Implementing Regulation (EU) 2021/521 should therefore continue to apply until 30 September 2021. Those Regulations should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 3(1) of Regulation (EU) 2015/479,

⁽¹⁾ OJ L 83, 27.3.2015, p. 34.

⁽²⁾ Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation (OJ L 31 I, 30.1.2021, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) 2021/442 of 11 March 2021 making the exportation of certain products subject to the production of an export authorisation (OJ L 85, 12.3.2021, p. 190).

⁽⁴⁾ Commission Implementing Regulation (EU) 2021/521 of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorisation (OJ L 104, 25.3.2021, p. 52).

⁽⁵⁾ Commission Implementing Regulation (EU) 2021/734 of 5 May 2021 amending Implementing Regulation (EU) 2021/521 making specific arrangements to the mechanism making certain products subject to the production of an export authorisation (OJ L 158, 6.5.2021, p. 13).

HAS ADOPTED THIS REGULATION:

Article 1

In Article 4 of Implementing Regulation (EU) 2021/442, the second paragraph is replaced by the following:

'It shall apply until 30 September 2021.'

Article 2

In Article 3 of Implementing Regulation (EU) 2021/521, the second paragraph is replaced by the following:

'It shall apply until 30 September 2021.'

Article 3

This Regulation shall enter into force on 1 July 2021.

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

Done at Brussels, 29 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COUNCIL DECISION (EU) 2021/1072

of 28 June 2021

on a temporary derogation from Decision 2013/471/EU on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee and their alternates in view of the travel difficulties caused by the COVID-19 pandemic in the Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the third paragraph of Article 301 thereof,

Whereas:

- (1) Since the outbreak of the COVID-19 pandemic, the extraordinary preventive and containment measures taken by Member States, such as quarantine, implementation of remote working policies, as well as movement and travel restrictions or bans, have made it impossible or very difficult for members of the European Economic and Social Committee ('the Committee') and their alternates (together referred to as 'the beneficiaries') to travel with a view to attending meetings physically.
- (2) In view of those exceptional circumstances, and in order to guarantee that the Committee's activities can take place in an appropriate and sustainable manner at all times to ensure institutional continuity, it is necessary to temporarily derogate from Articles 2, 3 and 4 of Council Decision 2013/471/EU ⁽¹⁾ as regards the payment of daily allowances and the reimbursement of travelling expenses to the beneficiaries. This derogation should apply only for the period of continued travel difficulties or sanitary restrictions to physical meetings caused by the COVID-19 pandemic in the Union.
- (3) Actual administrative costs incurred by a beneficiary who attends a meeting remotely by electronic means are lower than the rate of the daily allowance currently applicable for attendance of in-person meetings, while the time spent by a beneficiary remains the same. It is therefore appropriate that the daily allowance paid to the beneficiaries who attend meetings remotely by electronic means is adapted accordingly.
- (4) Where appropriate, detailed rules relating to the granting of the daily allowance for remote attendance should be established by the Committee. Those rules should in particular identify the cases in which travel difficulties linked to COVID-19 or related restrictive measures compromise the possibility to organise or attend meetings physically.
- (5) The Committee should submit to the Council regular reports on the application of this Decision so as to allow the Council to evaluate its impact and the continued existence of the conditions which justify the derogation. On the basis of those reports, the Council should consider the adoption of appropriate measures, in particular in the framework of a future comprehensive revision of Decision 2013/471/EU, to be undertaken before the end of the current term of office of the Committee,

⁽¹⁾ Council Decision 2013/471/EU of 23 September 2013 on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee and their alternates (OJ L 253, 25.9.2013, p. 22).

HAS ADOPTED THIS DECISION:

Article 1

By derogation from Articles 2, 3 and 4 of Decision 2013/471/EU, where COVID-19-related restrictive measures compromise the possibility to organise or attend a meeting physically, beneficiaries who attend the meeting remotely by electronic means shall be entitled only to a daily allowance set at EUR 145.

Article 2

The Committee shall adopt detailed provisions implementing Article 1 by 2 September 2021.

Article 3

By 2 January 2022 and every 6 months afterwards, the Committee shall submit to the Council an evaluation report on the application of this Decision, and particularly on its budgetary impact as well as on the continued existence of travel difficulties linked to COVID-19 or related restrictive measures that compromise the possibility to organise or attend meetings physically.

Article 4

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

Done at Luxembourg, 28 June 2021.

For the Council
The President
M. do C. ANTUNES

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****(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 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) and (3) 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 recovered from infection.
- (2) In order for the EU Digital COVID Certificate to be operational throughout the Union, it is necessary to establish technical specifications and rules to populate, securely issue and verify the 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. That trust framework also sets the premises for seeking to ensure interoperability with international standards and technological systems, and, as such, could provide the model for cooperation at global level.
- (3) The ability to read and interpret the EU Digital COVID Certificate requires a common data structure and agreement on the intended meaning of each data field of the payload and its possible values. In order to facilitate such interoperability, it is necessary to define a common coordinated data structure for the framework of the EU Digital COVID Certificate. The guidelines for this framework have been developed by the eHealth Network established on the basis of Directive 2011/24/EU of the European Parliament and of the Council ⁽²⁾. Those guidelines should be taken into account in laying down the technical specifications setting out the format and trust management for the EU Digital COVID Certificate. A data structure specification and encoding mechanisms should be specified, as well as a transport encoding mechanism in a machine-readable optical format (QR), which can be displayed on the screen of a mobile device or printed on a piece of paper.
- (4) In addition to the technical specifications for format and trust management of the EU Digital COVID Certificate, general rules for the purpose of populating the certificates should be established in order to be used for coded values in the content of the EU Digital COVID Certificate. The value sets implementing those rules should be regularly updated and published by the Commission, drawing upon the relevant work of the eHealth Network.
- (5) Pursuant to Regulation (EU) 2021/953, authentic certificates making up the EU Digital COVID Certificate are to be individually identifiable by means of a unique certificate identifier, taking into account that citizens may be issued more than one certificate during the time Regulation (EU) 2021/953 remains in force. The unique certificate identifier is to be composed of an alphanumeric string, and Member States should ensure that it does not contain any data linking it to other documents or identifiers, such as to passport or identity card numbers, in order to prevent that the holder can be identified. For the purpose of ensuring that the certificate identifier is unique, technical specifications and rules for the common structure thereof should be established.

⁽¹⁾ OJ L 211, 15.6.2021, p. 1.

⁽²⁾ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

- (6) The security, authenticity, validity and integrity of the certificates comprising the EU Digital COVID Certificate and their compliance with Union data protection law are key to their acceptance in all Member States. Those objectives are achieved by the trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of the EU Digital COVID certificates. Among others, the trust framework should be based on a public-key infrastructure with a trust chain from Member States' health authorities or other trusted authorities to the individual entities issuing the EU Digital COVID certificates. Therefore, with a view to ensuring an EU-wide interoperability system, the Commission has built a central system – the EU Digital COVID Certificate gateway (the 'gateway') – that stores public keys used for verification. When the QR code certificate is scanned, the digital signature is verified using the relevant public key, previously stored in that central gateway. Digital signatures can be used to ensure data integrity and authenticity. Public Key Infrastructures establish trust by binding public keys to certificate issuers. In the gateway, multiple public key certificates are used for authenticity. To ensure a secure data exchange for public key material between Member States and allow broad interoperability, it is necessary to establish the public key certificates that may be used and provide how they should be generated.
- (7) This Decision allows to make the requirements of Regulation (EU) 2021/953 operational in a way that minimises the processing of personal data to what is necessary to make the EU Digital COVID Certificate operational and contributes to an implementation by the final controllers that respects data protection by design.
- (8) In accordance with Regulation (EU) 2021/953, the authorities or other designated bodies responsible for issuing the certificates are controllers referred to in Article 4(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽³⁾ in their role of processing personal data in the course of the issuance process. Depending on how Member States organise the issuance process, there may be one or more authorities or designated bodies, for example regional health services. In accordance with the principle of subsidiarity, that is a choice for Member States. Therefore, Member States are best placed to ensure, where there are multiple authorities or other designated bodies, that their respective responsibilities are clearly allocated, independently of whether they are separate or joint controllers (including regional health services establishing a joint patient portal for issuing the certificates). Similarly, regarding verification of certificates by the competent authorities of the Member State of destination or transit, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, those verifiers have to comply with their obligations under data protection rules.
- (9) There is no processing of personal data through the EU Digital COVID Certificate gateway, as the gateway only contains the public keys of the signing authorities. Those keys relate to the signing authorities and do not allow either direct or indirect re-identification of a natural person to whom a certificate has been issued. In its role as the manager of the gateway, the Commission should thus be neither a controller nor processor of personal data.
- (10) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽⁴⁾ and delivered an opinion on 22 June 2021.
- (11) Considering that technical specifications and rules are necessary for the application of Regulation (EU) 2021/953 from 1 July 2021, the immediate application of this Decision is justified.
- (12) Therefore, in the light of the need for rapid implementation of the EU Digital COVID Certificate, this Decision should enter into force on the day of its publication,

⁽³⁾ 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).

⁽⁴⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

HAS ADOPTED THIS DECISION:

Article 1

The technical specifications for the EU Digital COVID Certificate laying down the generic data structure, the encoding mechanisms, and the transport encoding mechanism in a machine-readable optical format are set out in Annex I.

Article 2

The rules for populating the certificates referred to in Article 3(1) of Regulation (EU) 2021/953 are set out in Annex II to this Decision.

Article 3

The requirements laying down the common structure of the unique certificate identifier are set out in Annex III.

Article 4

The governance rules applicable to public key certificates in relation to the EU Digital COVID Certificate gateway supporting the interoperability aspects of the trust framework are set out in Annex IV.

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

Done at Brussels, 28 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

FORMAT AND TRUST MANAGEMENT

Generic data structure, encoding mechanisms and transport encoding mechanism in a machine-readable optical format (hereinafter called 'QR')**1. Introduction**

The technical specifications set out in this Annex contain a generic data structure and encoding mechanisms for the EU Digital COVID Certificate ('DCC'). They also specify a transport encoding mechanism in a machine-readable optical format ('QR'), which can be displayed on the screen of a mobile device or printed out. The electronic health certificate container formats of these specifications are generic, but in this context used to carry the DCC.

2. Terminology

For the purpose of this Annex, 'issuers' means organisations using these specifications for issuing health certificates and 'verifiers' means organisations accepting health certificates as proof of health status. 'Participants' means issuers and verifiers. Some aspects set out in this Annex must be coordinated between the participants, such as the management of a namespace and the distribution of cryptographic keys. It is assumed that a party, hereafter referred to as the 'Secretariat', carries out these tasks.

3. Electronic Health Certificate Container Format

The Electronic Health Certificate Container Format ('HCERT') is designed to provide a uniform and standardised vehicle for health certificates from their different issuers ('issuers'). The objective of these specifications is to harmonise how those health certificates are represented, encoded and signed with the goal of facilitating interoperability.

The ability to read and interpret a DCC issued by any issuer requires a common data structure and agreement on the significance of each data field of the payload. To facilitate such interoperability, a common coordinated data structure is defined through the use of a 'JSON' schema that constitutes the framing of the DCC.

3.1. Structure of the payload

The payload is structured and encoded as a CBOR with a COSE digital signature. This is commonly known as a "CBOR Web Token" (CWT), and is defined in RFC 8392 ⁽¹⁾. The payload, as defined in the following sections, is transported in a hcert claim.

The integrity and authenticity of origin of payload data must be verifiable by the verifier. To provide this mechanism, the issuer must sign the CWT using an asymmetric electronic signature scheme as defined in the COSE specification (RFC 8152 ⁽²⁾).

3.2. CWT Claims**3.2.1. CWT Structure Overview**

Protected Header

- Signature Algorithm (alg, label 1)
- Key Identifier (kid, label 4)

Payload

- Issuer (iss, claim key 1, optional, ISO 3166-1 alpha-2 of issuer)
- Issued At (iat, claim key 6)
- Expiration Time (exp, claim key 4)
- Health Certificate (hcert, claim key -260)
- EU Digital COVID Certificate v1 (eu_DCC_v1, claim key 1)

Signature

⁽¹⁾ rfc8392 (ietf.org)

⁽²⁾ rfc8152 (ietf.org)

3.2.2. Signature Algorithm

The Signature Algorithm (alg) parameter indicates what algorithm is used for the creating the signature. It must meet or exceed current SOG-IS guidelines as summarised in the following paragraphs.

One primary and one secondary algorithm is defined. The secondary algorithm should only be used if the primary algorithm is not acceptable within the rules and regulations imposed on the issuer.

In order to ensure the security of the system, all implementations have to incorporate the secondary algorithm. For this reason, both the primary and the secondary algorithm must be implemented.

The SOG-IS set levels for the primary and secondary algorithms are:

- Primary Algorithm: The primary algorithm is Elliptic Curve Digital Signature Algorithm (ECDSA) as defined in (ISO/IEC 14888-3:2006) section 2.3, using the P-256 parameters as defined in appendix D (D.1.2.3) of (FIPS PUB 186-4) in combination with the SHA-256 hash algorithm as defined in (ISO/IEC 10118-3:2004) function 4.

This corresponds to the COSE algorithm parameter ES256.

- Secondary Algorithm: The secondary algorithm is RSASSA-PSS as defined in (RFC 8230 ⁽³⁾) with a modulus of 2048 bits in combination with the SHA-256 hash algorithm as defined in (ISO/IEC 10118-3:2004) function 4.

This corresponds to the COSE algorithm parameter: PS256.

3.2.3. Key Identifier

The Key Identifier (kid) claim indicates the Document Signer Certificate (DSC) containing the public key to be used by the verifier for checking the correctness of the digital signature. Public key certificate governance, including requirements for DSCs, is described in Annex IV.

The Key Identifier (kid) claim is used by verifiers for selecting the correct public key from a list of keys pertaining to the issuer indicated in the Issuer (iss) Claim. Several keys may be used in parallel by an issuer for administrative reasons and when performing key rollovers. The Key Identifier is not a security-critical field. For this reason, it may also be placed in an unprotected header if required. Verifiers must accept both options. If both options are present, the Key Identifier in the protected header must be used.

Due to the shortening of the identifier (for size limitation reasons) there is a slim but non-zero chance that the overall list of DSCs accepted by a verifier may contain DSCs with duplicate kids. For this reason, a verifier must check all DSCs with that kid.

3.2.4. Issuer

The Issuer (iss) claim is a string value that may optionally hold the ISO 3166-1 alpha-2 Country Code of the entity issuing the health certificate. This claim can be used by a verifier to identify which set of DSCs to use for verification. The Claim Key 1 is used to identify this claim.

3.2.5. Expiration Time

The Expiration Time (exp) claim shall hold a timestamp in the integer NumericDate format (as specified in RFC 8392 ⁽⁴⁾, section 2) indicating for how long this particular signature over the payload shall be considered valid, after which a verifier must reject the payload as expired. The purpose of the expiry parameter is to force a limit of the validity period of the health certificate. The Claim Key 4 is used to identify this claim.

The Expiration Time must not exceed the validity period of the DSC.

⁽³⁾ rfc8230 (ietf.org)

⁽⁴⁾ rfc8392 (ietf.org)

3.2.6. Issued At

The Issued At (iat) claim shall hold a timestamp in the integer NumericDate format (as specified in RFC 8392 ⁽⁵⁾, section 2) indicating the time when the health certificate was created.

The Issued At field must not predate the validity period of the DCC.

Verifiers may apply additional policies with the purpose of restricting the validity of the health certificate based on the time of issue. The Claim Key 6 is used to identify this claim.

3.2.7. Health Certificate Claim

The Health Certificate (hcert) claim is a JSON (RFC 7159 ⁽⁶⁾) object containing the health status information. Several different types of health certificate may exist under the same claim, of which the DCC is one.

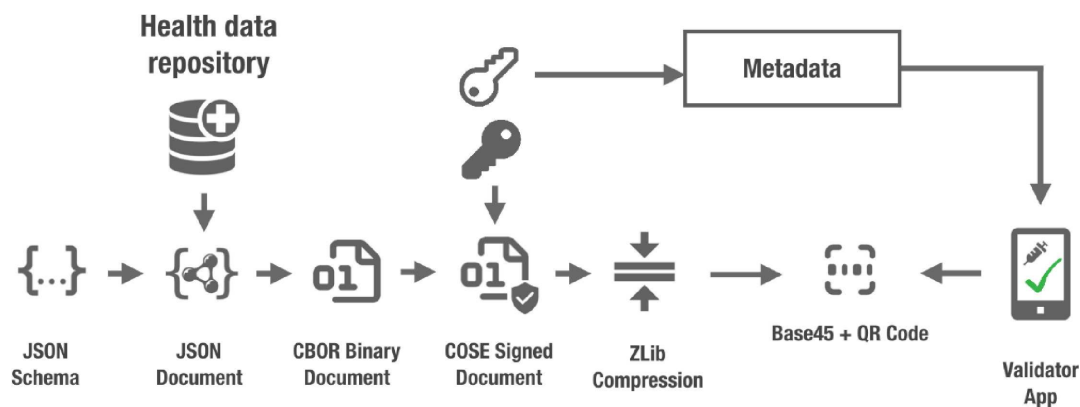
The JSON is purely for schema purposes. The representation format is CBOR, as defined in (RFC 7049 ⁽⁷⁾). Application developers may not actually ever decode, or encode to and from the JSON format, but use the in-memory structure.

The Claim Key to be used to identify this claim is -260.

Strings in the JSON object should be normalized according to the Normalization Form Canonical Composition (NFC) defined in the Unicode standard. Decoding applications should however be permissive and robust in these aspects, and acceptance of any reasonable type conversion is strongly encouraged. If non-normalised data is found during decoding, or in subsequent comparison functions, implementations should behave as if the input is normalised to NFC.

4. Serialisation and creation of the DCC payload

As serialization pattern, the following scheme is used:



The process starts with extraction of data, for example, from a Health Data Repository (or some external data source), structuring the extracted data according to the defined DCC Schemas. In this process, conversion to the defined data format and transformation for human readability may take place before the serialization to CBOR starts. The acronyms of the claims shall be mapped in every case to the display names before serialization and after deserialization.

Optional national data content is not allowed in certificates issued following the Regulation (EU) 2021/953 ⁽⁸⁾. The data content is limited to the defined data elements in the minimum data set specified in the Annex to Regulation 2021/953.

⁽⁵⁾ rfc8392 (ietf.org)

⁽⁶⁾ rfc7159 (ietf.org)

⁽⁷⁾ rfc7049 (ietf.org)

⁽⁸⁾ Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 211, 15.6.2021, p. 1.

5. Transport Encodings

5.1. Raw

For arbitrary data interfaces, the HCERT container and its payloads may be transferred as-is, utilising any underlying, 8 bit safe, reliable data transport. These interfaces may include Near-Field Communication (NFC), Bluetooth or transfer over an application layer protocol, for example transfer of an HCERT from the Issuer to a holder's mobile device.

If the transfer of the HCERT from the Issuer to the holder is based on a presentation-only interface (for example, SMS, email), the raw transport encoding is obviously not applicable.

5.2. Barcode

5.2.1. Payload (CWT) Compression

To lower size and to improve speed and reliability in the reading process of the HCERT, the CWT shall be compressed using ZLIB (RFC 1950 ⁽⁹⁾) and the Deflate compression mechanism in the format defined in RFC 1951 ⁽¹⁰⁾.

5.2.2. QR 2D Barcode

In order to better handle legacy equipment designed to operate on ASCII payloads, the compressed CWT is encoded as ASCII using Base45 before being encoded into a 2D barcode.

The QR format as defined in (ISO/IEC 18004:2015) shall be used for 2D barcode generation. An error correction rate of 'Q' (around 25 %) is recommended. Because Base45 is used, the QR code has to use Alphanumeric encoding (Mode 2, indicated by the symbols 0010).

In order for verifiers to be able to detect the type of data encoded and to select the proper decoding and processing scheme, the Base45 encoded data (as per this specification) shall be prefixed by the Context Identifier string "HC1:". Future versions of this specification that impact backwards-compatibility shall define a new Context Identifier, whereas the character following "HC" shall be taken from the character set [1-9A-Z]. The order of increments is defined to be in that order, i.e., first [1-9] and then [A-Z].

The optical code is recommended to be rendered on the presentation media with a diagonal size between 35 mm and 60 mm to accommodate readers with fixed optics where the presentation media is required to be placed on the surface of the reader.

If the optical code is printed on paper using low-resolution (< 300 dpi) printers, care must be taken to represent each symbol (dot) of the QR code exactly square. Non-proportional scaling will result in some rows or columns in the QR having rectangular symbols, which will hamper readability in many cases.

6. Trust List Format (CSCA and DSC list)

Each Member State is required to provide a list of one or more Country Signing Certificate Authorities (CSCAs) and a list of all valid Document Signer Certificates (DSCs), and keep these lists current.

6.1. Simplified CSCA/DSC

As of this version of the specifications, Member States shall not assume that any Certificate Revocation List (CRL) information is used; or that the Private Key Usage Period is verified by implementors.

Instead, the primary validity mechanism is the presence of the certificate on the most recent version of that certificate list.

⁽⁹⁾ rfc1950 (ietf.org)

⁽¹⁰⁾ rfc1951 (ietf.org)

6.2. ICAO eMRTD PKI and Trust Centers

Member States can use a separate CSCA – but may also submit their existing eMRTD CSCA certificates and/or DSCs; and may even chose to procure these from (commercial) trust centres – and submit these. However, any DSC must always be signed by the CSCA submitted by that Member State.

7. Security Considerations

When designing a scheme using this specification, Member States shall identify, analyse and monitor certain security aspects.

The following aspects should be taken into account as a minimum:

7.1. HCERT signature validity time

The issuer of HCERTs is required to limit the validity period of the signature by specifying a signature expiry time. This requires the holder of a health certificate to renew it at periodic intervals.

The acceptable validity period may be determined by practical constraints. For example, a traveller may not have the possibility to renew the health certificate during a trip overseas. However, it may also be the case that an issuer is considering the possibility of a security compromise of some sort, which requires the issuer to withdraw a DSC (invalidating all health certificates issued using that key which is still within their validity period). The consequences of such an event may be limited by regularly rolling Issuer keys and requiring renewal of all health certificates, on some reasonable interval.

7.2. Key management

This specification relies heavily on strong cryptographic mechanisms to secure data integrity and data origin authentication. Maintaining the confidentiality of the private keys is therefore necessary.

The confidentiality of cryptographic keys can be compromised in a number of different ways, for instance:

- The key generation process may be flawed, resulting in weak keys.
- The keys may be exposed by human error.
- The keys may be stolen by external or internal perpetrators.
- The keys may be calculated using cryptanalysis.

In order to mitigate against the risks that the signing algorithm is found to be weak, allowing the private keys to be compromised through cryptanalysis, this specification recommends all participants to implement a secondary fallback signature algorithm based on different parameters or a different mathematical problem than the primary.

As regards the risks mentioned related to the issuers' operating environments, mitigations measures to ensure effective control shall be implemented such as to generate, store and use the private keys in Hardware Security Modules (HSMs). Use of HSMs for signing health certificates is highly encouraged.

Regardless of whether an issuer decides to use HSMs or not, a key roll-over schedule should be established where the frequency of the key roll-overs is proportionate to the exposure of keys to external networks, other systems and personnel. A well-chosen roll-over schedule also limits the risks associated with erroneously issued health certificates, enabling an issuer to revoke such health certificates in batches, by withdrawing a key, if required.

7.3. Input data validation

These specifications may be used in a way that implies receiving data from untrusted sources into systems that may be of mission-critical nature. To minimise the risks associated with this attack vector, all input fields must be properly validated by data types, lengths and contents. The issuer signature shall also be verified before any processing of the contents of the HCERT takes place. However, the validation of the issuer Signature implies parsing the Protected Issuer Header first, in which a potential attacker may attempt to inject carefully crafted information designed to compromise the security of the system.

8. Trust Management

The signature of the HCERT requires a public key to verify. Member States shall make these public keys available. Ultimately, every verifier needs to have a list of all public keys it is willing to trust (as the public key is not part of the HCERT).

The system consists of (only) two layers; for each Member State one or more country level certificates that each signs one or more Document Signer Certificates that are used in day to day operations.

The Member State certificates are called Country Signing Certificate Authority (CSCA) certificates and are (typically) self-signed. Member States may have more than one (for example, in case of regional devolution). These CSCA certificates regularly sign the Document Signer Certificates (DSCs) used for signing HCERTs.

The “Secretariat” is a functional role. It shall regularly aggregate and publish the Member States’ DSCs, after having verified these against the list of CSCA certificates (which have been conveyed and verified by other means).

The resulting list of DSCs shall then provide the aggregated set of acceptable public keys (and the corresponding kids) that verifiers can use to validate the signatures over the HCERTs. Verifiers must fetch and update this list regularly.

Such Member State-specific lists may be adapted in the format for their own national setting. As such, the file format of this trust list may vary, for example, it can be a signed JWKS (JWK set format per RFC 7517 ⁽¹⁾, section 5) or any other format specific to the technology used in that Member State.

In order to ensure simplicity, Member States may both submit their existing CSCA certificates from their ICAO eMRTD systems or, as recommended by the WHO, create one specifically for this health domain.

8.1. *The Key Identifier (kids)*

The key identifier (kid) is calculated when constructing the list of trusted public keys from DSCs and consists of a truncated (first 8 bytes) SHA-256 fingerprint of the DSC encoded in DER (raw) format.

Verifiers do not need to calculate the kid based on the DSC and can directly match the key identifier in issued health certificate with the kid on the trust list.

8.2. *Differences to the ICAO eMRTD PKI trust model*

While patterned on best practices of the ICAO eMRTD PKI trust model, a number of simplifications shall be made in the interest of speed:

- A Member State may submit multiple CSCA certificates.
- The DSC (key usage) validity period may be set to any length not exceeding that of the CSCA certificate and may be absent.
- The DSC may contain policy identifiers (Extended Key Usage) that are specific to health certificates.
- Member States may choose to never do any verification of published revocations; but instead purely rely on the DSC lists they get daily from the Secretariat or compile themselves.

⁽¹⁾ rfc7517 (ietf.org)

ANNEX II

RULES FOR THE PURPOSE OF POPULATING THE EU DIGITAL COVID CERTIFICATE

The general rules concerning the value sets established in this Annex aim to ensure interoperability on semantic level and shall allow uniform technical implementations for the DCC. Elements contained in this Annex may be used for the three different settings (vaccination/testing/recovery), as provided for in Regulation (EU) 2021/953. Only elements with the necessity of semantic standardisation through coded value sets are listed in this Annex.

Translation of the coded elements into the national language are under the responsibility of the Member States.

For all data fields not mentioned in the following value set descriptions, encoding in UTF-8 is recommended (name, testing centre, certificate issuer). Data fields containing calendar dates (date of birth, date of vaccination, date of test sample collection, date of first positive test result, certificate validity dates) are recommended to be encoded following the ISO 8601.

If for any reason the preferred code systems listed below cannot be used, other international code systems may be used and advice on how to map the codes from the other code system to the preferred code system should be put in place. Text (display names) may be used in exceptional cases as a backup mechanism when a suitable code is not available in the defined value sets.

Member States using other coding in their systems should map such codes to the described value sets. Member States are responsible for any such mappings.

The value sets shall be regularly updated by the Commission with the support of the eHealth Network and the Health Security Committee. The updated value sets shall be published on the relevant website of the Commission, as well as on the webpage of the eHealth Network. A history of changes should be provided.

1. Disease or agent targeted/Disease or agent from which the holder has recovered: COVID-19 (SARS-CoV-2 or one of its variants)

Preferred Code System: SNOMED CT.

To be used in certificate 1, 2 and 3.

The selected codes shall refer to COVID-19 or, if more detailed information on the genetic variant of SARS-CoV-2 is needed, to these variants if such detailed information is needed due to epidemiological reasons.

Example of a code that should be used is the SNOMED CT code 840539006 (COVID-19).

2. COVID-19 vaccine or prophylaxis

Preferred Code System: SNOMED CT or ATC Classification.

To be used in certificate 1.

Examples of codes that should be used from the preferred code systems are the SNOMED CT code 1119305005 (SARS-CoV-2 antigen vaccine), 1119349007 (SARS-CoV-2 mRNA vaccine) or J07BX03 (covid-19 vaccines). The value set should be extended when new vaccine types are developed and put into use.

3. COVID-19 vaccine medicinal product

Preferred Code Systems (in the order of preference):

- Union Register of medicinal products for vaccines with EU-wide authorisation (authorisation numbers)
- A global vaccine register such as one that could be established by the World Health Organisation
- Name of the vaccine medicinal product in other cases. If the name includes whitespaces, these should be replaced by a hyphen (-).

Name of the Value Set: Vaccine.

To be used in certificate 1.

An example of a code that should be used from the preferred code systems is EU/1/20/1528 (Comirnaty). An example of the name of the vaccine to be used as a code: Sputnik-V (standing for Sputnik V).

4. COVID-19 vaccine marketing authorisation holder or manufacturer

Preferred Code System:

- Organisation code from EMA (SPOR system for ISO IDMP)
- A global vaccine marketing authorisation holder or manufacturer register, such as one that could be established by the World Health Organisation
- Name of the organisation in other cases. If the name includes whitespaces, these should be replaced by a hyphen (-).

To be used in certificate 1.

Example of a code that should be used from the preferred code system is ORG-100001699 (AstraZeneca AB). An example of the name of the organisation to be used as a code: Sinovac-Biotech (standing for Sinovac Biotech).

5. Number in a series of doses as well as the overall number of doses in the series

To be used in certificate 1.

Two fields:

- (1) Number of dose administered in a cycle
- (2) Number of expected doses for a complete cycle (specific for a person at the time of administration)

For example, 1/1, 2/2 will be presented as completed; including the option 1/1 for vaccines including two doses, but for which the protocol applied by the Member State is to administer one dose to citizens that were diagnosed with COVID-19 prior to the vaccination. The overall number of doses in the series should be indicated as per information available at the time when the dose is administered. For example, if a specific vaccine requires a third shot (booster) at the time of the latest administered shot, the second field number shall reflect this (for example 2/3, 3/3 etc.).

6. Member State or third country in which the vaccine was administered/test was carried out

Preferred Code System: ISO 3166 Country Codes.

To be used in certificates 1, 2 and 3.

Value set content: the complete list of 2-letter codes, available as a value set defined in FHIR (<http://hl7.org/fhir/ValueSet/iso3166-1-2>)

7. The type of test

Preferred Code System: LOINC.

To be used in certificate 2, and certificate 3 if support for the issuance of recovery certificates based on types of test other than NAAT is introduced through a delegated act.

The codes in this value set shall refer to the method of the test and shall be selected at least to separate the NAAT tests from RAT tests as expressed in Regulation (EU) 2021/953.

An example of a code that should be used from the preferred code system is LP217198-3 (Rapid immunoassay).

8. Manufacturer and commercial name of the test used (optional for NAAT test)

Preferred Code System: List from the HSC of Rapid Antigen Tests as maintained by the JRC (COVID-19 In Vitro Diagnostic Devices and Test Methods Database).

To be used in certificate 2.

The content of the Value Set shall include the selection of rapid antigen test as listed in the common and updated list of COVID-19 rapid 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>

For this code system, relevant fields such as the identifier of the test device, name of the test and manufacturer shall be used, following the JRC structured format available at <https://covid-19-diagnostics.jrc.ec.europa.eu/devices>

9. Result of the test

Preferred Code System: SNOMED CT.

To be used in certificate 2.

The codes selected shall allow distinguishing between positive and negative test results (detected or not detected). Additional values (like undetermined) may be added if the use cases do require this.

Examples of codes that should be used from the preferred code system are 260415000 (Not detected) and 260373001 (Detected).

ANNEX III

COMMON STRUCTURE OF THE UNIQUE CERTIFICATE IDENTIFIER

1. Introduction

Each EU Digital COVID Certificate (DCC) shall include a unique certificate identifier (UCI) which supports the interoperability of the DCCs. The UCI may be used to verify the certificate. Member States shall be responsible for implementing the UCI. The UCI is a means to verify the veracity of the certificate and, where applicable, to link to a registration system (for example, an IIS). These identifiers shall also enable (paper and digital) assertions by the Member States that individuals have been vaccinated or tested.

2. Composition of the unique certificate identifier

The UCI shall follow a common structure and format easing human- and/or machine-interpretability of information and may relate to elements such as Member State of vaccination, the vaccine itself and a Member State specific identifier. It ensures flexibility to Member States to format it, in full respect of data protection legislation. The order of the separate elements follows a defined hierarchy that can enable future modifications of the blocks while maintaining its structural integrity.

The possible solutions for the composition of the UCI form a spectrum wherein the modularity and human-interpretability are the two main diversifying parameters and one fundamental characteristic:

- Modularity: the degree to which the code is composed of distinct building blocks that contain semantically different information
- Human-interpretability: the degree to which the code is meaningful or can be interpreted by the human reader
- Globally unique; the Country or Authority identifier is well-managed; and each country (authority) is expected to manage its segment of the namespace well by never recycling or re-issuing identifiers. The combination of this ensures that each identifier is globally unique.

3. General requirements

The following overarching requirements should be satisfied in relation to the UCI:

- (1) Charset: only uppercase US-ASCII alpha numerical characters ('A' to 'Z', '0' to '9') are allowed; with additional special characters for separation from RFC3986 ⁽¹⁾ ⁽²⁾, namely {'/', '#', ':'};
- (2) Maximum length: designers should try to aim for a length of 27-30 characters ⁽³⁾;
- (3) Version prefix: this refers to the version of the UCI schema. The version prefix is '01' for this version of the document; the version prefix is composed of two digits;
- (4) Country prefix: the country code is specified by ISO 3166-1. Longer codes (e.g. 3 characters and up (for example, 'UNHCR')) are reserved for future use;
- (5) Code suffix/Checksum:
 - 5.1. Member States should use a checksum when it is likely that transmission, (human) transcription or other corruptions may occur (that is to say when used in print).
 - 5.2. The checksum must not be relied upon for validating the certificate and is not technically part of the identifier but is used to verify the integrity of the code. This checksum should be the ISO-7812-1 (LUHN-10) ⁽⁴⁾ summary of the entire UCI in digital/wire transport format. The checksum is separated from the rest of the UCI by a '#' character.

⁽¹⁾ rfc3986 (ietf.org)

⁽²⁾ Fields such as Sex, Batch/lot number, Administering centre, Health Professional identification, Next vaccination date may not be needed for purposes other than medical use.

⁽³⁾ For implementation with QR codes, Member States could consider an extra set of characters up to a total length of 72 characters (including the 27-30 of the identifier itself) may be used to convey other information. The specification of this information is up to the Member States to define.

⁽⁴⁾ The Luhn mod N algorithm is an extension to the Luhn algorithm (also known as mod 10 algorithm) which works for numeric codes and is used for example for calculating the checksum of credit cards. The extension allows the algorithm to work with sequences of values in any base (in our case alpha characters).

Backwards-compatibility should be ensured: Member States that over time change the structure of their identifiers (within the main version, currently set at v1) must ensure that any two identifiers that are identical represent the same vaccination certificate/assertion. Or, in other words, Member States cannot recycle identifiers.

4. **Options for unique certificate identifiers for vaccination certificates**

The eHealth Network guidelines for verifiable vaccination certificates and basic interoperability elements ⁽⁵⁾ provide for different options available to Member States and other parties that may co-exist among different Member States. Member States may deploy such different options in different version of the UCI schema.

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⁽⁵⁾ https://ec.europa.eu/health/sites/default/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

ANNEX IV

PUBLIC KEY CERTIFICATE GOVERNANCE

1. Introduction

The secure and trusted exchange of signature keys for EU digital COVID certificates (DCCs) between Member States is realised by the EU Digital COVID Certificate Gateway (DCCG), which acts as a central repository for the public keys. With the DCCG, Member States are empowered to publish the public keys corresponding to the private keys that they use to sign digital COVID certificates. Relying Member States can use the DCCG to fetch up-to-date public key material on a timely basis. Later, the DCCG can be extended to exchange trustworthy supplementary information that the Member States provide, like validation rules for DCCs. The trust model of the DCC framework is a Public Key Infrastructure (PKI). Each Member State maintains one or more Country Signing Certificate Authority (CSCA), certificates of which are relatively long lived. Following the Member State's decision, the CSCA may be the same or different than the CSCA used for machine-readable travel documents. The CSCA issues public key certificates for the national, short lived, Document Signers (i.e. signers for DCCs), which are called Document Signer Certificates (DSCs). The CSCA acts as a trust anchor such that relying Member States can use the CSCA certificate to validate the authenticity and integrity of the regularly changing DSCs. Once validated, Member States can provide these certificates (or just the public keys contained therein) to their DCC validation applications. Besides CSCAs and DSCs, the DCCG also relies on PKI to authenticate transactions, sign data, as the basis for authentication and as a means to ensure integrity of the communication channels between Member States and the DCCG.

Digital signatures can be used to achieve data integrity and authenticity. Public Key Infrastructures establish trust by binding public keys to verified identities (or issuers). This is necessary to allow other participants to verify the data origin and the identity of the communication partner and decide about trust. In the DCCG, multiple public key certificates are used for authenticity. This Annex defines which public key certificates are used and how they shall be designed in order to allow broad interoperability among Member States. It provides more details on the necessary public key certificates and it gives guidance on certificate templates and validity periods for Member States that want to operate their own CSCA. Since DCCs shall be verifiable for a defined timeframe (starting from the issuing, expire after a given time), it is necessary to define a verification model for all signatures applied on the public key certificates and the DCCs.

2. Terminology

The following table contains abbreviations and terminology used throughout this Annex.

Term	Definition
Certificate	Or public key certificate. An X.509 v3 certificate that contains the public key of an entity
CSCA	Country Signing Certificate Authority
DCC	EU Digital COVID Certificate. A signed digital document that contains vaccination, test or recovery information
DCCG	EU Digital COVID Certificate Gateway. This system is used to exchange DSCs between the Member States
DCCG _{TA}	The Trust Anchor certificate of the DCCG. The corresponding private key is used to sign the list of all CSCA certificates offline
DCCG _{TLS}	The TLS server certificate of the DCCG
DSC	Document Signer Certificate. The Public Key Certificate of a Member State's document signing authority (for example, a system that is allowed to sign DCCs). This certificate is issued by the CSCA of the Member State
EC-DSA	Elliptic Curve Digital Signature Algorithm. A cryptographic signature algorithm based on elliptic curves
Member State	Member State of the European Union

Term	Definition
mTLS	Mutual TLS. The Transport Layer Security Protocol with mutual authentication
NB	National backend of a Member State
NB _{CSCA}	The CSCA certificate of a Member State (could be more than one)
NB _{TLS}	The TLS client authentication certificate of a national backend
NB _{UP}	The certificate that a national backend uses to sign data packages that are uploaded to the DCCG
PKI	Public Key Infrastructure. Trust model based on public key certificates and certificate authorities
RSA	Asymmetric cryptographic algorithm based on integer factorization used for digital signatures or asymmetric encryption

3. DCCG communication flows and security services

This section gives an overview of the communication flows and security services in the DCCG system. It also defines which keys and certificates are used to protect the communication, the uploaded information, the DCCs, and a signed trust list that contains all onboarded CSCA certificates. The DCCG works as a data hub that allows the exchange of signed data packages for Member States.

Uploaded data packages are provided by the DCCG “as is”, meaning that the DCCG does not add or delete DSCs from the packages it receives. The national backend (NB) of the Member States shall be enabled to verify the end-to-end integrity and authenticity of the uploaded data. In addition to this, national backends and the DCCG will use mutual TLS authentication to establish a secure connection. This is in addition to the signatures in the data exchanged.

3.1. Authentication and connection establishment

The DCCG uses Transport Layer Security (TLS) with mutual authentication to establish an authenticated encrypted channel between the Member State’s national backend (NB) and the Gateway environment. Therefore, the DCCG holds a TLS server certificate, abbreviated DCCG_{TLS}, and the national backends hold a TLS client certificate – abbreviated NB_{TLS}. Certificate templates are provided in *Section 5*. Every national backend can provide their own TLS certificate. This certificate will be whitelisted explicitly and thus may be issued by a publicly trusted certificate authority (for example, a certificate authority that follows the baseline requirements of the CA Browser Forum), by a national certificate authority or it can be self-signed. Every Member State is responsible for their national data and the protection of the private key used to establish the connection to the DCCG. The “bring your own certificate” approach requires a well-defined registration and identification process, as well as revocation and renewal procedures as described in *sections 4.1, 4.2 and 4.3*. The DCCG uses a whitelist where the TLS certificates of NBs are added after their successful registration. Only NBs that authenticate themselves with a private key that corresponds to a certificate from the whitelist can establish a secure connection to the DCCG. The DCCG will also use a TLS certificate that allows the NBs to verify that they are indeed establishing a connection to the “real” DCCG and not some malevolent entity posing as DCCG. The certificate of the DCCG will be provided to the NBs after successful registration. The DCCG_{TLS} certificate will be issued from a publicly trusted CA (included in all major browsers). It is the responsibility of the Member States to verify that their connection to the DCCG is secure (for example, by checking the fingerprint of the DCCG_{TLS} certificate of the server connected to against the one provided post registration).

3.2. Country Signing Certificate Authorities and Validation Model

Member States taking part in the DCCG framework must use a CSCA to issue the DSCs. Member States may have more than one CSCA, for example, in case of regional devolution. Each Member State can either use existing certificate authorities or they can set up a dedicated (possibly self-signed) certificate authority for the DCC system.

Member States must present their CSCA certificate(s) to the DCCG operator during the official onboarding procedure. After successful registration of the Member State (*see section 4.1 for more details*), the DCCG operator will update a signed trust list that contains all CSCA certificates that are active in the DCC framework. The DCCG operator will use a dedicated asymmetric key pair to sign the trust list and the certificates in an offline environment. The private key will not be stored on the online DCCG system, such that a compromise of the online system does not enable an attacker to compromise the trust list. The corresponding trust anchor certificate $DCCG_{TA}$, will be provided to the national backends during the onboarding process.

Member States can retrieve the trust list from the DCCG for their verification procedures. The CSCA is defined as the certificate authority that issues DSCs, hence Member States that use a multi-tier CA hierarchy (for example, Root CA -> CSCA -> DSCs) must provide the subordinate certificate authority that issues the DSCs. In this case, if a Member State uses an existing certificate authority, then the DCC system will ignore anything above the CSCA and whitelist only the CSCA as the trust anchor (even though it is a sub-ordinate CA). This is as the ICAO model, only allows for exactly 2 levels – a ‘root’ CSCA and a ‘leaf’ DSC signed by just that CSCA.

In case a Member State operates its own CSCA, the Member State is responsible for the secure operation and key management of this CA. The CSCA acts as the trust anchor for DSCs, and therefore protecting the private key of the CSCA is essential for the integrity of the DCC environment. The verification model in the DCC PKI is the shell model, which states that all certificates in the certificate path validation must be valid at a given time (i.e. the time of signature validation). Therefore, the following restrictions apply:

- The CSCA shall not issue certificates that are longer valid than the CA certificate itself;
- The document signer shall not sign documents that are longer valid than the DSC itself;
- Member States that operate their own CSCA must define validity periods for their CSCA and all issued certificates and they must take care of certificate renewal.

Section 4.2 contains recommendations for validity periods.

3.3. Integrity and authenticity of uploaded data

National backends can use the DCCG to upload and download digitally signed data packages after successful mutual authentication. In the beginning, these data packages contain the DSCs of the Member States. The key pair that is used by the national backend for the digital signature of uploaded data packages in the DCCG system is called national backend upload signature key pair and the corresponding public key certificate is abbreviated by NB_{UP} certificate. Each Member State brings its own NB_{UP} certificate, which can be self-signed, or issued by an existing certificate authority, such as a public certificate authority (i.e. a certificate authority that issues certificate in accordance with the CAB-Forum baseline requirements). The NB_{UP} certificate shall be different from any other certificates used by the Member State (i.e. CSCA, TLS client or DSCs).

The Member States must provide the upload certificate to the DCCG operator during the initial registration procedure (*see Section 4.1 for more details*). Every Member State is responsible for their national data and it must protect the private key that is used for signing the uploads.

Other Member States can verify the signed data packages using the upload certificates that are provided by the DCCG. The DCCG verifies the authenticity and integrity of the uploaded data with the NB_{UP} certificate before they are provided to other Member States.

3.4. Requirements on the technical DCCG architecture

The requirements on the technical DCCG architecture are as follows:

- The DCCG uses mutual TLS authentication to establish an authenticated encrypted connection with the NBs. Therefore, the DCCG maintains a whitelist of registered NB_{TLS} client certificates;
- The DCCG uses two digital certificates ($DCCG_{TLS}$ and $DCCG_{TA}$) with two distinct key pairs. The private key of the $DCCG_{TA}$ key pair is maintained offline (not on the online components of the DCCG);

- The DCCG maintains a trust list of the NB_{CSCA} certificates that is signed with the $DCCG_{TA}$ private key;
- The ciphers used must meet the requirements from *Section 5.1*.

4. Certificate Lifecycle Management

4.1. Registration of National Backends

Member States must register with the DCCG operator to take part in the DCCG system. This section describes the technical and operational procedure that must be followed to register a national backend.

The DCCG operator and the Member State must exchange information on technical contact persons for the onboarding process. It is assumed that the technical contact persons are legitimated by their Member States and identification/authentication is performed over other channels. For example, the authentication can be achieved when a Member State's technical contact provides the certificates as password-encrypted files via email and shares the corresponding password with the DCCG operator via telephone. Also other secure channels defined by the DCCG operator may be used.

The Member State must provide three digital certificates during the registration and identification process:

- The Member State's TLS certificate NB_{TLS}
- The Member State's upload certificate NB_{UP}
- The Member State's CSCA certificate(s) NB_{CSCA}

All provided certificates must adhere to the requirements defined in *Section 5*. The DCCG operator will verify that the provided certificate adheres to the requirements of *Section 5*. After the identification and registration, the DCCG operator:

- adds the NB_{CSCA} certificate(s) to the trust list signed with the private key that corresponds to the $DCCG_{TA}$ public key;
- adds the NB_{TLS} certificate to the whitelist of the DCCG TLS endpoint;
- adds the NB_{UP} certificate to the DCCG system;
- provides the $DCCG_{TA}$ and $DCCG_{TLS}$ public key certificate to the Member State.

4.2. Certificate authorities, validity periods and renewal

In case that a Member State wants to operate its own CSCA, the CSCA certificates may be self-signed certificates. They act as the trust anchor of the Member State and therefore the Member State must strongly protect the private key corresponding to the CSCA certificate's public key. It is recommended that the Member States use an offline system for their CSCA, i.e. a computer system that is not connected to any network. Multi person control shall be used to access the system (for example, following the four eyes principle). After signing DSCs, operational controls shall be applied and the system that holds the private CSCA key shall be stored safely with strong access controls. Hardware Security Modules or Smart Cards can be used to further protect the CSCA private key. Digital certificates contain a validity period that enforces certificate renewal. Renewal is necessary to use fresh cryptographic keys and to adapt the key sizes when new improvements in computation or new attacks threaten the security of the cryptographic algorithm that is used. The shell model applies (see *Section 3.2*).

The following validity periods are recommended, given the one-year validity for digital COVID certificates:

- CSCA: 4 years
- DSC: 2 years
- Upload: 1-2 years
- TLS Client authentication: 1-2 years

For a timely renewal, the following usage periods for the private keys are recommended:

- CSCA: 1 year
- DSC: 6 months

Member States must create new upload certificates and TLS certificates timely, for example, one month, before expiration in order to allow smooth operation. CSCA certificates and DSCs should be renewed at least one month before the private key usage ends (considering the necessary operational procedures). Member States must provide updated CSCA certificates, upload and TLS certificates to the DCCG operator. Expired certificates shall be removed from the whitelist and trust list.

Member States and the DCCG operator must keep track of the validity of their own certificates. There is no central entity that keeps record of the certificate validity and informs the participants.

4.3. *Revocation of certificates*

In general, digital certificates can be revoked by their issuing CA using certificate revocation lists or Online Certificate Status Protocol Responder (OCSP). CSCAs for the DCC system should provide certificate revocation lists (CRLs). Even if these CRLs are currently not used by other Member States, they should be integrated for future applications. In case a CSCA decides not to provide CRLs, the DSCs of this CSCA must be renewed when CRLs become mandatory. Verifiers should not use OCSP for validation of the DSCs and should use CRLs. It is recommended that the national backend performs necessary validation of DSCs downloaded from the DCC Gateway and only forwards a set of trusted and validated DSC to national DCC validators. DCC validators should not perform any revocation checking on DSC in their validation process. One reason for this is to protect the privacy of DCC holders by avoiding any chance that the use of any particular DSC can be monitored by its associated OCSP responder.

Member States can remove their DSCs from the DCCG on their own using valid upload and TLS certificates. Removing a DSC means that all DCCs issued with this DSC will become invalid when Member States fetch the updated DSC lists. The protection of private key material corresponding to DSCs is crucial. Member States must inform the DCCG operator when they must revoke upload or TLS certificates, for example due to compromise of the national backend. The DCCG operator can then remove the trust for the affected certificate, for example by removing it from the TLS whitelist. The DCCG operator can remove the upload certificates from the DCCG database. Packages signed with the private key corresponding to this upload certificate will become invalid when national backends remove the trust of the revoked upload certificate. In case that a CSCA certificate must be revoked, Member States shall inform the DCCG operator as well as other Member States that they have trust relationships with. The DCCG operator will issue a new trust list where the affected certificate is not contained anymore. All DSCs issued by this CSCA will become invalid when Member States update their national backend trust store. In case that the DCCG_{TLS} certificate or the DCCG_{TA} certificate must be revoked, the DCCG operator and the Member States must work together to establish a new trusted TLS connection and trust list.

5. **Certificate Templates**

This section sets out cryptographic requirements and guidance as well as requirements on certificate templates. For the DCCG certificates, this section defines the certificate templates.

5.1. *Cryptographic requirements*

Cryptographic algorithms and TLS cipher suites shall be chosen based on the current recommendation from the German Federal Office for Information Security (BSI) or SOG-IS. These recommendations and the recommendations of other institutions and standardization organization are similar. The recommendations can be found in the technical guidelines TR 02102-1 and TR 02102-2 ⁽¹⁾ or SOG-IS Agreed Cryptographic Mechanisms ⁽²⁾.

5.1.1. Requirements on the DSC

The requirements provided for in *Annex I, Section 3.2.2* shall apply. Hence, it is strongly recommended that Document Signers use the Elliptic Curve Digital Signature Algorithm (ECDSA) with NIST-p-256 (as defined in appendix D of FIPS PUB 186-4). Other elliptic curves are not supported. Due to the space restrictions of the DCC,

⁽¹⁾ BSI - Technical Guidelines TR-02102 (bund.de)

⁽²⁾ SOG-IS - Supporting documents (sogis.eu)

Member States should not use RSA-PSS, even if it is allowed as a fall back algorithm. In case that Member States use RSA-PSS, they should use a modulus size of 2048 or max. 3072 bit. SHA-2 with an output length of ≥ 256 bits shall be used as cryptographic hash function (see ISO/IEC 10118-3:2004) for the DSC signature.

5.1.2. Requirements on TLS, Upload and CSCA certificates

For digital certificates and cryptographic signatures in the DCCG context, the major requirements on cryptographic algorithms and key length are summarized in the following table (as of 2021):

Signature Algorithm	Key size	Hash function
EC-DSA	Min. 250 Bit	SHA-2 with an output length ≥ 256 Bit
RSA-PSS (recommended padding) RSA-PKCS#1 v1.5 (legacy padding)	Min. 3000 Bit RSA Modulus (N) with a public exponent $e > 2^{16}$	SHA-2 with an output length ≥ 256 Bit
DSA	Min. 3000 Bit prime p, 250 Bit key q	SHA-2 with an output length ≥ 256 Bit

The recommended elliptic curve for EC-DSA is NIST-p-256 due to its widespread implementation.

5.2. CSCA certificate (NB_{CSCA})

The following table gives guidance on the NB_{CSCA} certificate template if a Member State decides to operate its own CSCA for the DCC system.

Bold entries are required (must be included in the certificate), *italic* entries are recommended (should be included). For absent fields, no recommendations are defined.

Field	Value
Subject	cn=<non-empty and unique common name>, o=<Provider>, c=<Member State operating the CSCA>
Key usage	certificate signing, CRL signing (at minimum)
Basic Constraints	CA = true, path length constraints = 0

The subject name must be non-empty and unique within the specified Member State. The country code (c) must match the Member State that will use this CSCA certificate. The certificate must contain a unique subject key identifier (SKI) according to RFC 5280 ⁽³⁾.

5.3. Document Signer Certificate (DSC)

The following table provides guidance on the DSC. **Bold** entries are required (must be included in the certificate), *italic* entries are recommended (should be included). For absent fields, no recommendations are defined.

Field	Value
Serial Number	unique serial number
Subject	cn=<non-empty and unique common name>, o=<Provider>, c=<Member State that uses this DSC>
Key Usage	digital signature (at minimum)

⁽³⁾ rfc5280 (ietf.org)

The DSC must be signed with the private key corresponding to a CSCA certificate that is used by the Member State.

The following extensions are to be used:

- The certificate must contain a Authority Key Identifier (AKI) matching the Subject Key Identifier (SKI) of the issuing CSCA certificate
- The certificate should contain a unique Subject Key Identifier (in accordance to RFC 5280 ⁽⁴⁾)

In addition, the certificate should contain the CRL distribution point extension pointing to the certificate revocation list (CRL) that is provided by the CSCA that issued the DSC.

The DSC may contain an extended key usage extension with zero or more key usage policy identifiers that constrain the types of HCERTs this certificate is allowed to verify. If one or more are present, the verifiers shall verify the key usage against the stored HCERT. The following extendedKeyUsage values are defined for this:

Field	Value
extendedKeyUsage	1.3.6.1.4.1.1847.2021.1.1 for Test Issuers
extendedKeyUsage	1.3.6.1.4.1.1847.2021.1.2 for Vaccination Issuers
extendedKeyUsage	1.3.6.1.4.1.1847.2021.1.3 for Recovery Issuers

In absence of any key usage extension (i.e. no extensions or zero extensions), this certificate can be used to validate any type of HCERT. Other documents may define relevant additional extended key usage policy identifiers used with validation of HCERTs.

5.4. Upload Certificates (NBUP)

The following table provides guidance for the national backend upload certificate. **Bold** entries are required (must be included in the certificate), *italic* entries are recommended (should be included). For absent fields, no recommendations are defined.

Field	Value
Subject	cn=<non-empty and unique common name>, o=<Provider>, c=<Member State that uses this upload certificate>
Key Usage	digital signature (at minimum)

5.5. National Backend TLS Client Authentication (NB_{TLS})

The following table provides guidance for the national backend TLS client authentication certificate. **Bold** entries are required (must be included in the certificate), *italic* entries are recommended (should be included). For absent fields, no recommendations are defined.

Field	Value
Subject	cn=<non-empty and unique common name>, o=<Provider>, c=<Member State on the NB>
Key Usage	digital signature (at minimum)
Extended key usage	client authentication (1.3.6.1.5.5.7.3.2)

⁽⁴⁾ rfc5280 (ietf.org)

The certificate may also contain the extended key usage *server authentication* (1.3.6.1.5.5.7.3.1), but it is not required.

5.6. *Trust list signature certificate (DCCG_{TA})*

The following table defines the DCCG Trust Anchor certificate.

Field	Value
Subject	cn = Digital Green Certificate Gateway ⁽⁵⁾, o=<Provider>, c=<country>
Key Usage	digital signature (at minimum)

5.7. *DCCG TLS Server certificates (DCCG_{TLS})*

The following table defines the DCCG TLS certificate.

Field	Value
Subject	cn=<FQDN or IP address of the DCCG>, o=<Provider>, c= <country>
SubjectAltName	dNSName: <DCCG DNS name> or iPAddress: <DCCG IP address>
Key Usage	digital signature (at minimum)
Extended Key usage	server authentication (1.3.6.1.5.5.7.3.1)

The certificate may also contain the extended key usage *client authentication* (1.3.6.1.5.5.7.3.2), but it is not required.

The TLS certificate of the DCCG shall be issued by a publicly trusted certificate authority (included in all major browsers and operating systems, following the CAB Forum baseline requirements).

⁽⁵⁾ The terminology of 'Digital Green Certificate' instead of 'EU Digital COVID Certificate' has been maintained in this context because this is the terminology which has been hardcoded and deployed in the certificate before the co-legislators decided on a new terminology.

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