Fylgiskjal.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/516 of 8 March 2023

amending Implementing Regulation (EU) 2020/2236 as regards the model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption

(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') ('), and in particular Articles 238(3), points (a) and (c), thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (²), and in particular Article 90 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/2236 (3) sets out the model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals.
- (2) In particular, Annex II to Implementing Regulation (EU) 2020/2236 sets out the model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption (model 'AQUA-ENTRY-ESTAB/ RELEASE/OTHER'). Article 166 of Commission Delegated Regulation (EU) 2020/692 (4) was recently amended by Delegated Regulation (EU) 2023/119 (5) in order to permit aquatic animal health professionals to perform clinical

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

^(*) Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008 (OJ L 442, 30.12.2020, p. 410).

^(*) Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

^(*) Commission Delegated Regulation (EU) 2023/119 of 9 November 2022 amending Delegated Regulation (EU) 2020/692 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 16, 18.1.2023, p. 5).

inspections on consignments of aquatic animals prior to export to the Union, provided they are authorised to do so under the law of the exporting third country or territory. Those new requirements for the entry into the Union of those consignments should be reflected in point II.3.2. of that model animal health certificate. Annex II to Implementing Regulation (EU) 2020/2236 should therefore be amended accordingly.

- (3) In order to avoid any disruption to trade as regards the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption, the use of animal health certificate issued in accordance with Implementing Regulation (EU) 2020/2236, as applicable prior to the amendments made by this Implementing Regulation, should continue to be authorised during a transitional period subject to certain conditions.
- (4) As Implementing Regulation (EU) 2020/2236 applies from 21 April 2021, in the interest of legal certainty and to facilitate trade, the amendments to be made to Implementing Regulation (EU) 2020/2236 by this Regulation should take effect as a matter of urgency.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Implementing Regulation (EU) 2020/2236 is amended in accordance with the Annex to this Regulation.

Article 2

For a transitional period until 15 December 2023, consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption, accompanied by the animal health certificate issued in accordance with the model set out in Annex II to Implementing Regulation (EU) 2020/2236, as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for entry into the Union provided that the certificate was issued no later than 15 September 2023.

Article 3

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

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

Done at Brussels, 8 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex II to Implementing Regulation (EU) 2020/2236 is replaced by the following:

'ANNEX II

Annex II contains the following model animal health certificate:

Model

AQUA-ENTRY-ESTAB/RELEASE/ OTHER	Model animal health certificate for the entry into the Union of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption
	other purposes, excluding direct human consumption

MODEL ANIMAL HEALTH CERTIFICATE FOR THE ENTRY INTO THE UNION OF AQUATIC ANIMALS INTENDED FOR CERTAIN AQUACULTURE ESTABLISHMENTS, FOR RELEASE INTO THE WILD OR FOR OTHER PURPOSES, EXCLUDING DIRECT HUMAN CONSUMPTION (MODEL 'AQUA-ENTRY-ESTAB/RELEASE/OTHER')

COU	NTRY			Animal health certificate to the EU				
	I.1	Consignor/Exporter		1.2	Certificate reference	I.2a IMSOC reference		
		Name Address		1.3	Central Competent Authority	QR CODE		
		Country	ISO country code	I.4	Local Competent Authority			
		Country	150 country code	1.4	Local Competent Authority			
	1.5	Consignee/Importer Name		I.6	Operator responsible for the consignment Name			
		Address			Address			
ıment		Country ISO country cod			Country	ISO country code		
isign	1.7	Country of origin	ISO country code	I.9	Country of destination	ISO country code		
con	1.8	Region of origin Code			Region of destination	Code		
tion of	I,11	Place of dispatch Name	Registration/Approval No	I.12	Place of destination Name	Registration/Approval No		
escript		Address			Address			
Part I: Description of consignment		Country ISO country code			Country	ISO country code		
Pa	I.13	Place of loading		I.14	Date and time of departure			
	I.15 Means of transport				Entry Border Control Post			
	☐ Aircraft ☐ Vessel			I.17	Accompanying documents			
	☐ Railway ☐ Road vehicle			Туре	Code			
		Identification			Country Commercial document reference	ISO country code		
	I.18	Transport conditions	☐ Ambient		□ Chilled	□ Frozen		
	I.19	Container number/Se Container No	eal number	Seal N	To.			
	1.20	Certified as or for		Seal N	10			
		☐ Further keeping	☐ Confined establishment	:	☐ Release into the wild			
					T Other			
	☐ Quarantine establishmen				☐ Other	☐ Ornamental aquaculture		
	☐ Relaying area					establishment		
	I.21		I.22	☐ For internal market				
	Third country ISO country code		1.23					

1.24	Total number of packages			Total quantity	I.26 Total net w	eight/gross v	weight (kg)
I.27	Description	of consignment					
CN code	1 1 0 1			Nature of commodity	Type of packaging	Quantity	
					Number of packages		Net weight
					Approval or registration number of establishment		

COUNTRY

Certificate model AQUA-ENTRY-ESTAB/RELEASE/OTHER

II. Health infor	mation		II.a	Certificate reference	II.b	IMSOC reference		
I, the undersigned official veterinarian, hereby certify:								
П.1.	II.1. According to official information, the aquatic animals of the consignment described in Box I.27 meet the following animal health requirements:							
	II.1.1.	The aquatic animals originate from national restriction measures for						

II.1.2. The aquatic animals are not intended to be killed under a national programme for the eradication of diseases, including the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and emerging diseases.

abnormal mortalities with an undetermined cause, including the listed diseases referred to in Annex I to Commission Delegated Regulation (EU) 2020/692 A relevant for the species and

- (1) [II.2. The aquaculture animals of the consignment described in Box I.27 meet the following requirements:
 - II.2.1. They come from an aquaculture establishment which is [registered] (1) [approved] (1) by, and under the control of, the competent authority of the third country or territory of origin and has a system in place to maintain and to keep for a period of at least three years, up-to-date records containing information regarding:
 - the species, categories and number of aquaculture animals on the aquaculture establishment;
 - movements of aquatic animals into, and aquaculture animals out of, the aquaculture establishment;
 - (iii) mortality in the aquaculture establishment.
 - II.2.2. They come from an aquaculture establishment which receives regular animal health visits from a veterinarian for the purpose of the detection of, and information on, signs indicative of the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and of emerging diseases, at a frequency that is proportionate to the risk posed by the aquaculture establishment.]

II.3. General health requirements

emerging diseases.

The aquatic animals of the consignment described in Box I.27 meet the following animal health requirements:

- II.3.1. The aquatic animals originate from a [country] (1) [territory] (1), [zone] (1) [compartment] (1) with code: ___ __ (2) which, at the date of issuing this animal health certificate is listed in Part 1 of Annex XXI to Commission Implementing Regulation (EU) 2021/404 ^B for the entry into the Union of certain species of aquatic animals.
- II.3.2. They have undergone clinical inspection in accordance with Article 166 of Delegated Regulation (EU) 2020/692 within a period of 72 hours prior to the time of loading. During the inspection, the aquatic animals showed no clinical symptoms of transmissible disease and, according to the relevant records of the aquaculture establishment, there was no indication of disease problems.
- II.3.3. They will be dispatched to the Union directly from the establishment of origin.
- II.3.4. They have not been in contact with aquatic animals of a lower health status.

(1) either [II.4. Specific health requirements

Part II: Certification

COUNTRY

(1) [II.4.1. Requirements for listed (3) species for Epizootic haematopoietic necrosis, Infection with *Mikrocytos mackini*, Infection with *Perkinsus marinus*, Infection with Taura syndrome virus and Infection with yellow head virus

The aquatic animals of the consignment described in Box I.27 originate from a [country] ⁽¹⁾ [territory] ⁽¹⁾ [zone] ⁽¹⁾ [compartment] ⁽¹⁾ declared free from [Epizootic haematopoietic necrosis] ⁽¹⁾ [Infection with *Mikrocytos mackini*] ⁽¹⁾ [Infection with *Perkinsus marinus*] ⁽¹⁾ [Infection with Taura syndrome virus] ⁽¹⁾ [Infection with yellow head virus] ⁽¹⁾ in accordance with conditions which are at least as stringent as those set out in Article 66 or in Article 73(1) and Article 73(2), point (a), of Commission Delegated Regulation (EU) 2020/689 ^C and where all listed ⁽³⁾ species for the relevant disease(s):

- are introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s);
- (ii) are not vaccinated against [that] (1) [those] (1) disease(s).]
- (I)(4) [II.4.2. Requirements for listed (3) species for Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), infection with HPR-deleted infectious salmon anaemia virus (ISAV), infection with *Marteilia refringens*, infection with *Bonamia exitiosa*, infection with *Bonamia ostreae*, and infection with White spot syndrome virus

The aquatic animals of the consignment described in Box I.27 originate from a [country] (1) [territory] (1) [zone] (1) [compartment] (1) declared free from [Viral haemorrhagic septicaemia (VHS)] (1) [Infectious haematopoietic necrosis (IHN)] (1) [infection with HPR-deleted infectious salmon anaemia virus (ISAV)] (1) [infection with *Marteilia refringens*] (1) [infection with *Bonamia exitiosa*] (1) [infection with *Bonamia ostreae*] (1) [infection with White spot syndrome virus] (1) in accordance with Part II, Chapter 4, of Delegated Regulation (EU) 2020/689 and where all listed (3) species for the relevant disease(s):

- (i) are introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s);
- (ii) are not vaccinated against [that] (1) [those] (1) disease(s).]
- (1)(5) [II.4.3. Requirements for species (6) susceptible to infection with Spring viraemia of carp virus (SVC), Bacterial Kidney disease (BKD), infection with Infectious pancreatic necrosis virus (IPN), infection with Gyrodactylus salaris (GS), infection with Salmonid alphavirus (SAV) infection with Ostreid herpes virus 1 µvar (OsHV-1 µvar) and species (3) susceptible to Koi herpes virus disease

The aquatic animals of the consignment described in Box I.27 originate from a [country] $^{(1)}$ [territory] $^{(1)}$ [zone] $^{(1)}$ [compartment] $^{(1)}$ which fulfils the health guarantees as regards [SVC,] $^{(1)}$ [BKD,] $^{(1)}$ [IPN,] $^{(1)}$ [GS,] $^{(1)}$ [SAV,] $^{(1)}$ [OsHV-1 μ var,] $^{(1)}$ [KHV,] $^{(1)}$ which are necessary to comply with the national measures which apply in the Member State of destination in accordance with Article 175 of Delegated Regulation (EU) 2020/692, and for which the Member State or part thereof, is listed in [Annex I] $^{(1)}$ [Annex II] $^{(1)}$ to Commission Implementing Decision (EU) 2021/260 $^{\rm D}$.]

(1) or [II.4. Specific health requirements

The aquatic animals of the consignment described in Box I.27 are aquatic animals destined for a confined establishment fulfilling the requirements of Article 9 of Commission Delegated Regulation (EU) 2020/691 ^E where they are to be used for research purposes.]

COUNTRY

(1) or [II.4. Specific health requirements

The aquatic animals of the consignment described in Box I.27 are wild aquatic animals which, [have been subject to quarantine in an establishment approved for that purpose by the competent authority in the [country] (1) [territory] (1) of origin in accordance with Article 15 of Delegated Regulation (EU) 2020/691.] (1) [will be subject to quarantine in an establishment which is approved for that purpose in accordance with Article 15 of Delegated Regulation (EU) 2020/691.] (1)

- II.5. To the best of my knowledge, and as declared by the operator, the aquatic animals of the consignment described in Box I.27 show no symptoms of disease and come from [an establishment] (1) [a habitat] (1) where:
 - (i) there were no abnormal mortalities with an undetermined cause; and
 - (ii) the aquatic animals have not been in contact with kept animals of listed ⁽³⁾ species which did not comply with the requirements referred to in point II.1.

II.6. Transport requirements

Arrangements have been made to transport the aquatic animals of the consignment described in Box I.27 in accordance with the requirements laid down in Articles 167 and 168 of Delegated Regulation (EU) 2020/692 and specifically that:

- II.6.1. the aquatic animals are dispatched to the Union directly from the establishment of origin and are not unloaded from their container when transported by air, sea, railway or by road;
- II.6.2. the water in which they are transported is not changed in a third country or territory, or zone, or compartment thereof which is not listed for entry into the Union of the particular species and category of aquatic animals;
- II.6.3. the animals are not transported under conditions that jeopardise their health status, in particular:
 - (i) when the aquatic animals are transported in water, it does not alter their health status;
 - the means of transport and the containers are constructed in such a way that the health status of the aquatic animals is not jeopardised during transportation;
 - (iii) the [container] (1) [well-boat] (1) is previously unused or cleaned and disinfected, in accordance with a protocol and with products approved by the competent authority of the third country or territory of origin, prior to loading for dispatch to the Union;
 - II.6.4. from the time of loading at the establishment of origin until the time of arrival in the Union, the aquatic animals of the consignment described in Box I.27 are not transported in the same water or [container] (1) [well-boat] (1) together with aquatic animals which are of a lower health status or which are not intended for entry into the Union;
- II.6.5. where a water exchange is necessary in a [country] (1) [territory] (1) [zone] (1) [compartment] (1) which is listed for entry into the Union of the particular species and category of aquatic animals, it only occurs [in the case of transport on land, at water exchange points approved by the competent authority of the third country or territory where the water exchange takes place.] (1) [in the case of transport by well-boat, at a distance which is at least 10 km from any aquaculture establishments which are located *en-route* from the place of origin to the place of destination in the Union.] (1)

Certificate model AQUA-ENTRY-ESTAB/RELEASE/OTHER

COUNTRY

II.7. Labelling requirements

Arrangements have been made to identify and label the [means of transport] (1) [containers] (1) in accordance with Article 169(1) and (2) of Delegated Regulation (EU) 2020/692 and specifically that:

- II.7.1. the consignment is identified by [a legible and visible label on the exterior of the container] (1) [an entry in the ships manifest when transported by well-boat,] (1) which clearly links the consignment to this animal health certificate;
- II.7.2. the legible and visible label will contain at least the following information:
 - (a) the number of containers in the consignment;
 - (b) the name of the species present in each container;
 - the number of aquatic animals in each container for each of the species present;
 - (d) the purpose for which the aquatic animals are intended.

II.8. Validity of the animal health certificate

This animal health certificate is valid for a period of 10 days from the date of issuing. In the case of transport by waterway/sea of aquatic animals, this period of 10 days may be extended by the duration of the journey by waterway/sea.

Notes

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, references to the Union in this animal health certificate include the United Kingdom in respect of Northern Ireland.

'Aquatic animals' are animals as defined in Article 4, point (3), of Regulation (EU) 2016/429.

'Aquaculture animals' are aquatic animals which are subject to aquaculture as defined in Article 4, point (7), of Regulation (EU) 2016/429.

This animal health certificate is intended for entry into the Union of aquatic animals for the purposes indicated in the title of the certificate, including when the Union is not the final destination of those animals.

This animal health certificate shall not be used for the entry into the Union of aquatic animals intended for human consumption in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ^H and Commission Regulation (EC) No 2073/2005 ^I, including those animals which are intended for the following aquaculture establishments:

- (i) a disease control aquatic food establishment as defined in Article 4, point (52), of Regulation (EU) 2016/429 or
- (ii) a dispatch centre as defined in Article 2, point (3), of Delegated Regulation (EU) 2020/691.

For those aquatic animals, the model certificate FISH-CRUST-HC as set out in Chapter 28 of Annex III to Commission Implementing Regulation (EU) 2020/2235 F, or MOL-HC as set out in Chapter 31 of Annex III to that Regulation, must be used, as relevant.

This animal health certificate shall be completed in accordance with the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.

COUNTRY

Certificate model AQUA-ENTRY-ESTAB/RELEASE/OTHER

Part II:

- (1) Keep if appropriate/delete if not applicable. In the case of Part II.4.1., deletion is not permitted if the consignment contains listed species for Epizootic haematopoietic necrosis, Infection with Mikrocytos mackini, Infection with Perkinsus marinus, Infection with Taura syndrome virus or Infection with yellow head virus.
- Code of the third country or territory, or zone or compartment thereof as it appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404.
- Listed species as referred to in columns 3 and 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882^G. Vector species listed in column 4 of that table shall only be regarded as vectors if they fulfil the conditions set out in Annex XXX to Delegated Regulation (EU) 2020/692.
- Applicable in all cases when aquatic animals are to be released into the wild in the Union or when the Member State of destination either has disease-free status for a category C disease as defined in Article 1, point (3), of Implementing Regulation (EU) 2018/1882 or is subject to an optional eradication programme established in accordance with Article 31(2) of Regulation (EU) 2016/429.
- Only applicable when the Member State of destination or part thereof, has approved national measures for a specific disease as listed in Annex I or Annex II to Implementing Decision (EU) 2021/260, otherwise delete.
- (6) Species listed in column 2 of the table in Annex III to Implementing Decision (EU) 2021/260.

Official veterinarian

Name (in capital letters)

Date Qualification and title

Stamp Signature

- A Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).
- Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).
- Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).
- Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU (OJ L 59, 19.2.2021, p. 1).
- Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for aquaculture establishments and transporters of aquatic animals (OJ L 174, 3.6.2020, p. 345).
- F Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).
- G 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).
- 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).
- Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

C-deild – Útgáfudagur: 26. október 2023