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CHAPTER 31

MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF LIVE BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES, MARINE GASTROPODS AND PRODUCTS OF ANIMAL ORIGIN FROM THOSE ANIMALS INTENDED FOR HUMAN CONSUMPTION (MODEL MOL-HC)

COUNTRY			**Animal health/official certificate to the EU**		
Part I: Description of consignment	**I.1**	**Consignor/Exporter** Name Address Country ISO country code	**I.2**	**Certificate reference**	**I.2a IMSOC reference**
			I.3	**Central Competent Authority**	**QR CODE**
			I.4	**Local Competent Authority**	
	I.5	**Consignee/Importer** Name Address Country ISO country code	**I.6**	**Operator responsible for the consignment** Name Address Country ISO country code	
	I.7	**Country of origin** ISO country code	**I.9**	**Country of destination** ISO country code	
	I.8	**Region of origin** Code	**I.10**	**Region of destination** Code	
	I.11	**Place of dispatch** Name Registration/Approval No Address Country ISO country code	**I.12**	**Place of destination** Name Registration/Approval No Address Country ISO country code	
	I.13	**Place of loading**	**I.14**	**Date and time of departure**	
	I.15	**Means of transport** ☐ Aircraft ☐ Vessel ☐ Railway ☐ Road vehicle Identification	**I.16** **I.17**	**Entry Border Control Post** **Accompanying documents** Type Code Country ISO country code Commercial document reference	
	I.18	**Transport conditions** ☐ Ambient	☐ Chilled	☐ Frozen	
	I.19	**Container number/Seal number** Container No Seal No			
	I.20	**Certified as or for**			
		☐ Products for human consumption ☐ Live aquatic animals for human consumption ☐ Dispatch centre ☐ Further processing			
	I.21	☐ **For transit** Third country ISO country code	**I.22** **I.23**	☐ **For internal market**	
	I.24	**Total number of packages**	**I.25**	**Total quantity**	**I.26 Total net weight/gross weight (kg)**
	I.27	**Description of consignment**			
	CN code Species ☐ Final consumer	Cold store Treatment type Date of collection/production	Nature of commodity Manufacturing plant	Type of packaging Number of packages	Net weight Batch No

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Part II: Certification

II. Health information | **II.a Certificate reference** | **II.b IMSOC reference**

(1) [**II.1. Public health attestation** (*Delete when the Union is not the final destination of the live bivalve molluscs, echinoderms, tunicates, marine gastropods and products of animal origin from these animals*)

I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council, Regulation (EC) No 852/2004 of the European Parliament and of the Council, Regulation (EC) No 853/2004 of the European Parliament and of the Council and Regulation (EU) 2017/625 of the European Parliament and of the Council and hereby certify that the [live bivalve molluscs] (4) [live echinoderms] (4) [live tunicates] (4) [live marine gastropods] (4) [products of animal origin derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods] (4) described in Part I were produced in accordance with these requirements, and in particular that they:

(a) have been obtained in (a) region(s)s or (a) country(ries) which, at the date of issue of this animal health/official certificate is/are authorised for the entry into the Union of [live bivalve molluscs] (4) [live echinoderms] (4) [live tunicates] (4) [live marine gastropods] (4) [products of animal origin derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods] (4), and is/are listed in Annex VIII to Commission Implementing Regulation (EU) 2021/405;

(b) come from establishments applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities, and listed as Union approved establishments;

(c) have been harvested, where necessary relayed and transported in accordance with Section VII, Chapters I and II, of Annex III to Regulation (EC) No 853/2004;

(d) (4) *either* [were handled, where necessary purified, and packaged in compliance with Section VII, Chapters III and IV, of Annex III to Regulation (EC) No 853/2004;]

(4) *or* [were prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters III and IV, of Annex III to Regulation (EC) No 853/2004;]

(e) satisfy the health standards laid down in Section VII, Chapter V, of Annex III to Regulation (EC) No 853/2004, [Section VIII, Chapter V, of Annex III to Regulation (EC) No 853/2004] (4) and the criteria laid down in Commission Regulation (EC) No 2073/2005;

(f) have been packaged, stored and transported in compliance with [Section VII, Chapters VI and VIII, of Annex III to Regulation (EC) No 853/2004] (4) [Section VIII, Chapters VI, VII and VIII, of Annex III to Regulation (EC) No 853/2004] (4);

(g) have been marked and labelled in accordance with [Section I of Annex II and Section VII, Chapter VII, of Annex III to Regulation (EC) No 853/2004] (4) [Section I of Annex II to Regulation (EC) No 853/2004] (4);

(h) are *Pectinidae*, marine gastropods and echinoderms that are not filter feeders harvested outside classified production areas, which comply with the specific requirements laid down in Section VII, Chapter IX, of Annex III to Regulation (EC) No 853/2004;

(i) come from a production area classified in accordance with Article 52 of Commission Implementing Regulation (EU) 2019/627 as [A] (4) [B] (4) or [C] (4) at the moment of their harvesting (*please indicate the classification of the production area at the moment of harvesting*) (except for *Pectinidae*, marine gastropods and echinoderms that are not filter feeders, which are harvested outside classified production areas);

(j) have satisfactorily undergone the official controls laid down in [Articles 51 to 66 of Implementing Regulation (EU) 2019/627 or in Article 11 of Commission Delegated Regulation (EU) 2019/624] (4) [Articles 69, 70 and 71 of Implementing Regulation (EU) 2019/627] (4);

(k) fulfil the guarantees covering aquaculture provided by the control plan submitted in accordance with Article 6(2) of Commission Delegated Regulation (EU) 2022/2292 and the third country or region thereof of the origin of the animals and products described in Part I is listed in Annex -I to Implementing Regulation (EU) 2021/405 and marked with an "M" for the category "aquaculture".]

(4) (14) [**II.1a. Attestation as regards Commission Delegated Regulation (EU) 2023/905** (*Delete when the Union is not the final destination of the live bivalve molluscs, live echinoderms, live tunicates, live marine gastropods of on-land aquaculture origin and the products of animal origin derived therefrom*)

I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EU) 2019/6 of the European Parliament and of the Council and Delegated Regulation (EU) 2023/905 and hereby certify that the [live bivalve molluscs] (4) [live echinoderms] (4) [live tunicates] (4) [live marine gastropods] (4) of on-land aquaculture origin and the products of animal origin derived therefrom described in Part I were produced in accordance with these requirements, and in particular, that the aquaculture animals from which the products have been derived have not been administered antimicrobial medicinal products for growth promotion or yield increase or antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down

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in Commission Implementing Regulation (EU) 2022/1255 as set out in Article 3 of Delegated Regulation (EU) 2023/905 and originate from a third country or region thereof listed in the Annex to Commission Implementing Regulation (EU) 2024/2598.]

(2) [**II.2. Animal health attestation for live bivalve molluscs of listed (3) species intended for human consumption and products of animal origin from those molluscs which are intended for further processing in the Union before human consumption, excluding wild molluscs and their products landed from fishing vessels**

I, the undersigned official veterinarian, hereby certify that:

II.2.1. According to official information, the [aquatic animals described in Part I] (4) [products of animal origin from aquatic animals other than live aquatic animals described in Part I, have been obtained from animals which] (4) meet the following animal health requirements:

II.2.1.1. they originate from [an establishment] (4) [a habitat] (4) which is not subject to national restriction measures for animal health reasons or because of the occurrence of abnormal mortalities with an undetermined cause, including the relevant listed diseases referred to in Annex I to Commission Delegated Regulation (EU) 2020/692 and emerging diseases;

II.2.1.2. the [aquatic animals are not intended to be killed] (4) [products of animal origin from aquatic animals other than live aquatic animals, have been obtained from animals which were not intended to be killed] (4) 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.

(4) [II.2.2. The [aquaculture animals described in Part I] (4) [products of animal origin from aquaculture animals other than live aquaculture animals described in Part I, have been obtained from animals which] (4) meet the following requirements:

II.2.2.1. they come from an aquaculture establishment which is [registered] (4) [approved] (4) by, and under the control of, the competent authority of the third country or territory of origin and which has a system in place to maintain and to keep for a period of at least 3 years, up-to-date records containing information regarding:

(a) the species, categories and number of aquaculture animals in the establishment;

(b) the movements of aquatic animals into, and aquaculture animals out of, the establishment;

(c) the mortality in the establishment;

II.2.2.2. 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 occurrence of diseases, including the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and emerging diseases, at a frequency that is proportionate to the risk posed by the establishment.]

II.2.3. General animal health requirements

The [aquatic animals described in Part I] (4) [products of animal origin from aquatic animals other than live aquatic animals described in Part I have been obtained from animals which] (4) meet the following animal health requirements:

(4) (8) *either* [II.2.3.1. they are subject to the requirements referred to in point II.2.4, and originate from a [country] (4) [territory] (4) [zone] (4) [compartment] (4) with code ____ (5) which, at the date of issue of this animal health/official certificate, is listed in Part 1 of Annex XXI to Commission Implementing Regulation (EU) 2021/404 for the entry into the Union of those [aquatic animals] (4) [products of animal origin from aquatic animals other than live aquatic animals] (4);]

(4) (6) *or* [II.2.3.1. they are subject to the requirements referred to in point II.2.4, and originate from a [country] (5) [territory] (5) [zone] (5) [compartment] (5) with code ____ (7) which, at the date of issue of this animal health/official certificate, is listed in Part 1 of Annex XXII to Commission Implementing Regulation (EU) 2021/404 for the transit though the Union of [aquatic animals] (5) [products of animal origin from aquatic animals other than live aquatic animals] (5) intended for a destination outside the Union;]

(4) (8) [II.2.3.2. they are aquatic animals that have undergone clinical inspection in accordance with Article 166 of Delegated Regulation (EU) 2020/692 within 72 hours prior to the time of loading for dispatch to the Union, and during the inspection, they showed no clinical symptoms of transmissible disease, and, according to the relevant records of the establishment, there was no indication of disease problems;]

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[8] [II.2.3.3. they are aquatic animals which are dispatched to the Union directly from the place of origin;]

II.2.3.4. they have not been in contact with aquatic animals of a lower health status.

[4] [8] *either* [**II.2.4. Specific health requirements**

[4] [**II.2.4.1. Requirements for listed [3] species for infection with *Mikrocytos mackini* or infection with *Perkinsus marinus***

The [aquatic animals described in Part I] [4] [products of animal origin from aquatic animals other than live aquatic animals described in Part I, have been obtained from animals which] [4] originate from a [country] [4] [territory] [4] [zone] [4] [compartment] [4] declared free from [infection with *Mikrocytos mackini*] [4] [infection with *Perkinsus marinus*] [4] in accordance with conditions which are at least as stringent as those laid down in Article 66 or in Article 73(1) and Article 73(2), point (a), of Commission Delegated Regulation (EU) 2020/689, and in the case of aquatic animals, all listed [3] species for the relevant disease(s) are:

(a) introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s);

(b) not vaccinated against [that] [4] [those] [4] disease(s).]

[4] [9] [**II.2.4.2. Requirements for listed [3] species for infection with *Marteilia refringens*, infection with *Bonamia exitiosa* or infection with *Bonamia ostreae***

The [aquatic animals described in Part I] [4] [products of animal origin from aquatic animals other than live aquatic animals described in Part I, have been obtained from animals which] [4] originate from a [country] [4] [territory] [4] [zone,] [4] [compartment] [4] declared free from [infection with *Marteilia refringens*] [4] [infection with *Bonamia exitiosa*] [4] [infection with *Bonamia ostreae*] [4] in accordance with Part II, Chapter 4, of Delegated Regulation (EU) 2020/689, and in the case of aquatic animals, all listed [3] species for the relevant disease(s) are:

(a) introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s);

(b) not vaccinated against [that] [4] [those] [4] disease(s).]

[4] [10] [**II.2.4.3. Requirements for species [11] susceptible to infection with Ostreid herpes virus 1 µvar (OsHV-1 µvar)**

The [aquatic animals described in Part I] [4] [products of animal origin from aquatic animals other than live aquatic animals described in Part I, have been obtained from animals which] [4] originate from a [country] [4] [territory] [4] [zone] [4] [compartment] [4] which fulfils the health guarantees as regards OsHV-1 µvar 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] [4] [Annex II] [4] to Commission Implementing Decision (EU) 2021/260.]]

[4] [8] *or* [**II.2.4. Specific health requirements**

The [aquatic animals described in Part I] [4] [products of animal origin from aquatic animals other than live aquatic animals described in Part I, have been obtained from animals which] [4] are destined for a disease control aquatic food establishment within the Union which is approved in accordance with Article 11 of Commission Delegated Regulation (EU) 2020/691, where they are to be processed for human consumption.]

II.2.5. To the best of my knowledge, and as declared by the operator, the [aquatic animals described in Part I] [4] [products of animal origin from aquatic animals other than live aquatic animals described in Part I, have been obtained from animals which] [4] originate from [an establishment] [4] [a habitat] [4] where:

(a) there were no abnormal mortalities with an undetermined cause;

(b) the animals have not been in contact with aquatic animals of listed [3] species which did not comply with the requirements referred to in point II.2.1.

II.2.6. Transport requirements

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

II.2.6.1. when the aquatic animals are transported in water, the water 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

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particular species and category of aquatic animals;

II.2.6.2. the aquatic animals are not transported under conditions that jeopardise their health status, in particular:

(a) when the aquatic animals are transported in water, it does not alter their health status;

(b) 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;

(c) the [container] (4) [well-boat] (4) is [previously unused] (4) [cleaned and disinfected in accordance with a protocol and with products approved by the competent authority of the third country or territory of origin] (4), prior to loading for dispatch to the Union;

II.2.6.3. from the time of loading at the place of origin until the time of arrival in the Union, the animals in the consignment are not transported in the same water or [container] (4) [well-boat] (4) together with aquatic animals which are of a lower health status or which are not intended for the entry into the Union;

II.2.6.4. where a water exchange is necessary in a [country] (4) [territory] (4) [zone] (4) [compartment] (4) which is listed for the 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] (4) [in the case of transport by well-boat, at a distance which is at least 10 km from any aquaculture establishments which are located *enroute* from the place of origin to the place of destination in the Union] (4).

II.2.7. Labelling requirements

Arrangements have been made to identify and label the [means of transport] (4) [containers] (4) in accordance with Article 169 of Delegated Regulation (EU) 2020/692 and specifically that:

II.2.7.1. the consignment is identified by [a legible and visible label on the exterior of the container] (4) [an entry in the ship's manifest when transported by well-boat] (4), which clearly links the consignment to this animal health/official certificate;

(4) [II.2.7.2. in the case of live aquatic animals, the legible and visible label referred to in point II.2.7.1 contains:

(a) details of the number of containers in the consignment;

(b) the name of the species present in each container;

(c) details of the number of aquatic animals in each container for each of the species present;

(d) the following statement: "live molluscs intended for human consumption in the Union";]

(4) [II.2.7.3. in the case of products of animal origin from aquatic animals other than live aquatic animals, the legible and visible label referred to in point II.2.7.1 contains at least the following statement:

"products of animal origin from molluscs, other than live molluscs, intended for further processing in the Union".]

(4) (12) **II.2.8. Validity of animal health/official certificate**

This animal health/official certificate shall be valid for the period of 10 days from the date of issue. 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 Windsor Framework (see Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by 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 of 24 March 2023, OJ L 102, 17.4.2023, p. 87) in conjunction with Annex 2 to that Framework, references to the Union in this animal health/official certificate include the United Kingdom in respect of Northern Ireland.

This animal health/official certificate is intended for the entry into the Union of live bivalve molluscs and products of animal origin from those animals intended for human consumption, including when the Union is not the final destination of such bivalve molluscs and their products.

"Aquatic animals" are animals as defined in Article 4, point (3), of Regulation (EU) 2016/429 of the European Parliament and of the Council.

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

"Further processing" means any type of measures and techniques, carried out before the placing on the market for human consumption, affecting anatomical wholeness, such as bleeding, evisceration, heading, slicing and filleting which produce waste or by-products which could cause a risk of disease spread.

All aquatic animals and products of animal origin from aquatic animals other than live aquatic animals to which point II.2.4 of this animal health/official certificate applies shall originate from a third country or territory, or zone or compartment thereof which appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404.

Point II.2.4 of this animal health/official certificate **shall not apply to** the following aquatic animals, and they may therefore originate from a third country or region thereof which is listed in Annex VIII to Implementing Regulation (EU) 2021/405:

(a) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are no longer able to survive as living animals if returned to the aquatic environment;

(b) molluscs which are intended for human consumption without further processing, provided they are packaged for retail sale in compliance with the requirements for such packages laid down in Regulation (EC) No 853/2004;

(c) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing.

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

Part I:

Box reference I.8: Indicate the production area, except for *Pectinidae*, marine gastropods and echinoderms harvested outside classified production areas.

Part II:

(1) Part II.1 of this animal health/official certificate shall not apply to third countries or territories with the special public health certification requirements laid down in equivalence agreements or other Union legislation.

(2) Part II.2 of this animal health/official certificate shall not apply and shall be deleted when the consignment consists of:

(a) species other than those listed in the Annex to Commission Implementing Regulation (EU) 2018/1882; or

(b) wild aquatic animals and products of animal origin from those aquatic animals which are landed from fishing vessels for direct human consumption; or

(c) products of animal origin from aquatic animals other than live aquatic animals which are ready for direct human consumption, without undergoing further processing in the Union.

(3) Species listed in columns 3 and 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882. Species listed in column 4 shall only be regarded as vectors under the conditions set out in Article 171 of Delegated Regulation (EU) 2020/692.

(4) Keep if appropriate/delete if not applicable. In the case of point II.2.4.1, deletion is not permitted if the consignment contains listed species for infection with *Mikrocytos mackini* or infection with *Perkinsus marinus*, other than in the circumstances referred to in note (8).

(5) 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.

(6) Only applicable to consignments transiting through the Union and intended for a destination outside the Union, originating from third country or territory, or zone, or compartment thereof listed in Part 1 of Annex XXII to Implementing Regulation (EU) 2021/404 as authorised for transit through the Union of aquatic animals or products of animal origin from aquatic animals other than live aquatic animals accompanied by an animal health certificate corresponding to the present model in accordance with column 5 of the table in Part 1 of Annex XXII to Implementing Regulation (EU) 2021/404.

(7) 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 XXII to Implementing Regulation (EU) 2021/404.

(8) Points II.2.3.1, II.2.3.2, II.2.3.3 and II.2.4 of this animal health/official certificate shall not apply and shall be deleted if the consignment contains only the following aquatic animals:

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(a) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are no longer able to survive as living animals if returned to the aquatic environment,

(b) molluscs which are intended for human consumption without further processing, provided they are packaged for retail sale in compliance with the requirements for such packages laid down in Regulation (EC) No 853/2004,

(c) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing.

(9) Applicable only when the Member State or zone or compartment thereof of destination in the Union 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, otherwise delete.

(10) Applicable when the Member State of destination in the Union 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.

(11) Susceptible species as referred to in column 2 of the table in Annex III to Implementing Decision (EU) 2021/260.

(12) Shall apply only to consignments of live aquatic animals.

(13) To be signed by:

(a) an official veterinarian when Part II.2 Animal health attestation is not deleted,

(b) a certifying officer or an official veterinarian when Part II.2 Animal health attestation is deleted.

(14) Applicable to consignments entering the Union as from 3 September 2026.

[Official veterinarian] (4) (13)**/[Certifying officer]** (4) (13)

Name (in capital letters)

Date Qualification and title

Stamp Signature