COMMISSION IMPLEMENTING REGULATION (EU) 2022/2504

of 19 December 2022

amending Annexes III and V to Implementing Regulation (EU) 2020/2235 as regards model animal health/official certificates and official certificates for the entry into the Union of consignments of certain fishery products and highly refined products of animal origin, and model private attestation for entering certain composite products into the Union

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on laying specific hygiene rules for food of animal origin ([1]), and in particular Article 7(2), point (a), thereof,

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') ([2]), and in particular Articles 238(3) and 239(3) 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) ([3]), and in particular Article 90, first paragraph , points (a) and (b), and Article 126(3) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2020/2235 ([4]) lays down rules regarding, inter alia, official certificates provided for in Regulation (EU) 2017/625 required for the entry into the Union of certain consignments of products of animals origin. In particular, Annex III to Implementing Regulation (EU) 2020/2235 lays down, inter alia, model animal health/official certificates and official certificates for the entry into the Union of consignments of certain fishery products and highly refined products of animal origin.

(2) Chapters 30 and 31 of Annex III to Implementing Regulation (EU) 2020/2235 set out, respectively, the model official certificate for the entry into the Union of fishery products or fishery products derived from bivalve molluscs intended for human consumption entering the Union directly from a reefer, freezer or factory vessel flying the flag of a third country as provided for in Article 11(3) of Commission Delegated Regulation (EU) 2019/625 ([5]) (model FISH/MOL-CAP) and the 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

([1]) OJ L 139, 30.4.2004, p. 55.
([2]) OJ L 84, 31.3.2016, p. 1.
([3]) OJ L 95, 7.4.2017, p. 1.
([4]) 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).
([5]) Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

for human consumption (model MOL-HC). Commission Delegated Regulation (EU) 2022/2258 ([6]) amended Article 11 of Delegated Regulation (EU) 2019/624 ([7]), whereby the classification of production and relaying areas is not required in relation to the harvesting of echinoderms which are not filter feeders. The model official certificate and the model animal health/official certificate for the entry into the Union of such fishery products should therefore be amended accordingly.

(3) Chapter 46 of Annex III to Implementing Regulation (EU) 2020/2235 sets out the model official certificate for the entry into the Union of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption (model HRP). Delegated Regulation (EU) 2022/2258 amended Regulation (EC) No 853/2004, adding fat derivatives and food flavourings that are authorised in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council ([8]), subject to treatments excluding any public or animal health risk, as highly refined products. The model official certificate for the entry into the Union of such highly refined products should be amended accordingly.

(4) Annex III to Implementing Regulation (EU) 2020/2235 should therefore be amended accordingly.

(5) The model private attestation set out in Annex V to Implementing Regulation (EU) 2020/2235 for operators entering shelf-stable composite products into the Union should also be updated to facilitate filling out of the document, reflecting the experience gained, adding explanations and notes in order to facilitate provision of the information by importing food business operators. Gelatine, collagen and certain highly refined products can be imported without submitting a residue monitoring plan and, consequently, it should not be necessary that countries are listed in the Annex to Commission Decision 2011/163/EU ([9]) to be allowed to export these products to the Union or to use these products as ingredients in composite products for export to the Union, although listing in accordance with Articles 18, 19 or 22 of Commission Implementing Regulation (EU) 2021/405 ([10]) remains mandatory. Therefore, the private attestation set out in Annex V to Implementing Regulation (EU) 2020/2235 should be replaced by an updated version.

(6) Annex V to Implementing Regulation (EU) 2020/2235 should therefore be amended accordingly.

(7) Implementing Regulation (EU) 2020/2235 should therefore be amended accordingly.

(8) In order to avoid any disruption to trade as regards the entry into the Union of consignments of certain fishery products, highly refined products of animal origin, and shelf-stable composite products, certificate/attestation issued in accordance with Implementing Regulation (EU) 2020/2235, issued prior to the amendments made by this Regulation, should continue to be authorised during a transitional period provided that such certificate/attestation was issued no later than 15 April 2023.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([6]) Commission Delegated Regulation (EU) 2022/2258 of 9 September 2022 amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs (OJ L 299, 18.11.2022, p. 5).

([7]) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

([8]) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

([9]) Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

([10]) Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

HAS ADOPTED THIS REGULATION:

Article 1

Annexes III and V to Implementing Regulation (EU) 2020/2235 are amended in accordance with the Annex to this Regulation.

Article 2

1. For a transitional period until 15 July 2023, consignments of certain fishery products and highly refined products of animal origin accompanied by the relevant model animal health/official certificates or official certificates issued in accordance with the models set out in Chapters 30, 31 and 46 of Annex III to Implementing Regulation (EU) 2020/2235 as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for the entry into the Union, provided that such certificate was issued no later than 15 April 2023.

2. For a transitional period until 15 July 2023, consignments of shelf-stable composite products accompanied by the private attestation issued in accordance with the model set out in Annex V to Implementing Regulation (EU) 2020/2235 as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for the entry into the Union, provided that such attestation was issued no later than 15 April 2023.

Article 3

This Regulation shall enter into force on the twentieth 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, 19 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes III and V to Implementing Regulation (EU) 2020/2235 are amended as follows:

(1) Annex III is amended as follows:

(a) in the introductory table setting out the list of the model animal health/official certificates and model official certificates for the entry into the Union contained in that Annex, the Section concerning the model official certificate for highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption, is replaced by the following:

'highly refined products as described in Annex III, Section XVI of Regulation (EC) No 853/2004, intended for human consumption	
HRP	Chapter 46: Model official certificate for the entry into the Union of highly refined products as described in Annex III, Section XVI of Regulation (EC) N° 853/2004, intended for human consumption'

(b) Chapters 30 and 31 are replaced by the following:

'CHAPTER 30

MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF FISHERY PRODUCTS OR FISHERY PRODUCTS DERIVED FROM BIVALVE MOLLUSCS INTENDED FOR HUMAN CONSUMPTION ENTERING THE UNION DIRECTLY FROM A REEFER, FREEZER OR FACTORY VESSEL FLYING THE FLAG OF A THIRD COUNTRY AS PROVIDED FOR IN ARTICLE 11(3) OF DELEGATED REGULATION (EU) 2019/625 (MODEL FISH/MOL-CAP)

COUNTRY				**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.3** **Central Competent Authority** **I.4** **Local Competent Authority**	**I.2a** **IMSOC reference** **QR CODE**	
	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		**I.14** **Date and time of departure**		
	I.15		**I.16** **Entry Border Control Post**		
			I.17 **Accompanying documents** Type Code Country ISO country code Commercial document reference		
	I.18				
	I.19				
	I.20 **Certified as or for**				
	☐ Products for human consumption		☐ Canning industry	☐ Further processing	
	I.21		**I.22** ☐ **For internal market** **I.23**		
	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 Number of packages Net weight Batch No Type of packaging Treatment type Date of collection/production Identification mark				

COUNTRY		Certificate model FISH/MOL-CAP
Part II: Certification	**II. Health information**	**II.a Certificate reference** **II.b IMSOC reference**

II.1 Public health attestation

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 ([A]), Regulation (EC) No 852/2004 of the European Parliament and of the Council ([B]), Regulation (EC) No 853/2004 of the European Parliament and of the Council ([C]) and Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ([D]) and hereby certify that the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods described in Part I:

(a) were produced in accordance with these requirements, in particular that the vessel appears on the list of vessels from which imports to the Union are permitted (being 'EU-listed');

(b) the vessel applies general hygiene requirements, implements 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 is listed as a Union approved establishment;

(c) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been caught and handled on board vessels, landed, handled and, where appropriate, prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV, of Annex III, to Regulation (EC) No 853/2004. Viscera and parts that may pose a danger to public health have been removed as quickly as possible and kept apart from products intended for human consumption;

(d) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods satisfy the health standards laid down in Section VIII, Chapter V, of Annex III, to Regulation (EC) No 853/2004 [satisfy the health standards laid down in Section VII, Chapter V, of Annex III to Regulation (EC) No 853/2004] (delete as appropriate) and, where appropriate, the criteria laid down in Commission Regulation (EC) No 2073/2005 ([E]);

(e) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII, of Annex III to Regulation (EC) No 853/2004;

(f) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

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

([A]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([B]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

([C]) 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).

([D]) 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 (OJ L 95, 7.4.2017, p. 1).

([E]) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

COUNTRY		Certificate model FISH/MOL-CAP
II. Health information	**II.a Certificate reference**	**II.b IMSOC reference**

(h) the fishery products fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Article 29 of Council Directive 96/23/EC ([F]), and the concerned animals and products are listed in Commission Decision 2011/163/EU ([G]) for the concerned country of origin;

(i) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been produced under conditions guaranteeing compliance with the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ([H]); and

(j) frozen fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been kept at a temperature of not more than -18°C in all parts of the product. Whole fish initially frozen in brine intended for the production of canned food may be kept at a temperature of not more than -9°C.

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 European Union in this official certificate include the United Kingdom in respect of Northern Ireland.

This official 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.

Part I:

Box reference I.2: A unique document number according to your own classification.

Box reference I.5: The name and address (street, town and post code) of the physical or legal person to whom the consignment is imported directly to in the Member State of destination.

Box reference I.7: The country whose flag is being flown by the vessel issuing this document.

Box reference I.11: The name of the vessel and approval number as listed in accordance with Article 10 of Commission Delegated Regulation (EU) 2019/625 ([I]) from which the fishery products are directly imported.

Box reference I.20: Tick "*Canning industry*" for whole fish initially frozen in brine at -9°C or at a temperature higher than -18°C and intended for canning in accordance with the requirements of Section VIII, Chapter I, point II(7), of Annex III to Regulation (EC) No 853/2004. Tick "*Products for human consumption*" or "*Further processing*" for the other cases.

Box reference I.27: Insert the appropriate Harmonised System (HS) code(s) using one or more of the following headings: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0511, 1504, 1516, 1518, 1603, 1604, 1605 or 2106.

Box reference I.27: Description of consignment:
"*Treatment type*": specify whether chilled, frozen or processed.

([F]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

([G]) Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

([H]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([I]) Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

	Captain of the vessel Name (in capital letters): Date: Stamp:	Signature:

CHAPTER 31

MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY IN THE UNION OF LIVE BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES, MARINE GASTROPODS AND PRODUCTS OF ANIMAL ORIGIN FROM THESE 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**	**Entry Border Control Post**	
			I.17	**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**		**I.22**	☐ **For internal market**
	Third country	ISO country code	**I.23**	
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			
	Cold store	Identification mark	Type of packaging	Net weight
	Treatment type	Nature of commodity	Number of packages	Batch No
☐ Final consumer	Date of collection/production	Manufacturing plant		

COUNTRY **Certificate model MOL-HC**

Part II: Certification

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

II.1. [1]**Public health attestation** [To be deleted 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 ([I]), Regulation (EC) No 852/2004 of the European Parliament and of the Council ([K]), Regulation (EC) No 853/2004 of the European Parliament and of the Council ([L]) and Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ([M]) and hereby certify that the [4][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] described in Part I were produced in accordance with these requirements, and in particular that they:

(a) have been obtained in a region/regions or a country/countries which, at the date of issue of this animal health/official certificate is/are authorised for the entry into the Union of [4][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], and listed in Annex VIII to Commission Implementing Regulation (EU) 2021/405 ([N]);

(b) come from (an) establishment(s) 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 being listed as a Union approved establishment;

(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][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;

(e) [4][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]];

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

(g) have been packaged, stored and transported in compliance with [4][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];

(h) have been marked and labelled in accordance with [4][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];

([I]) CRegulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([K]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

([L]) 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).

([M]) 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 (OJ L 95, 7.4.2017, p. 1).

([N]) Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

([O]) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

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

(j) come from a production area classified in accordance with Article 52 of Commission Implementing Regulation (EU) 2019/627 ([P]) as [A] [B] or [C] 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);

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

(l) fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Article 29 of Council Directive 96/23/EC ([R]), and the concerned animals and products are listed in Commission Decision 2011/163/EU ([S]) for the concerned country of origin;

(m) have been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council ([T]), and the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ([U]).

[2]**[II.2. Animal health attestation for live bivalve molluscs of [3]listed 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 [4][aquatic animals referred to in Box I.27 of Part I] [4] [products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] meet the following animal health requirements:

II.2.1.1. they originate from [4][an establishment] [4][a habitat] 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 ([V]) and emerging diseases;

([P]) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

([Q]) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

([R]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

([S]) Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

([T]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([U]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([V]) 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).

II.2.1.2. the [4][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] under a national programme for the eradication of diseases, including the relevant listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 and emerging diseases.

[4][II.2.2. The [4][aquaculture animals referred to in Box I.27 of Part I] [4][products of animal origin from aquaculture animals other than live aquaculture animals referred to in Box I.27 of Part I, have been obtained from animals which] meet the following requirements:

II.2.2.1. they come from an aquaculture establishment which is [4][registered] [4][approved] 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:

(i) the species, categories and number of aquaculture animals on the establishment;

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

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

II.2.3. General animal health requirements

The [4][aquatic animals referred to in Box I.27 of Part I] [4][products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I have been obtained from animals which] meet the following animal health requirements:

[4][6][II.2.3.1. they are subject to the requirements referred to in Part II.2.4, and originate from a [4][country] [4][territory] [4][zone] [4][compartment] with [5]code: __ __ - __ 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 [W] for the entry into the Union of those [4][aquatic animals] [4][products of animal origin from aquatic animals other than live aquatic animals];]

[4][6][II.2.3.2. they are aquatic animals that have undergone clinical inspection by an official veterinarian within a period of 72 hours prior to the time of loading for dispatch to the Union. During the inspection, the animals showed no clinical symptoms of transmissible disease and, according to the relevant records of the establishment, there was no indication of disease problems;]

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

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

[W] 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).

either[4][6][II.2.4.	**Specific health requirements**
[4] [II.2.4.1.	**Requirements for [3]listed species for infection with Mikrocytos mackini or infection with Perkinsus marinus**
	The [4][aquatic animals referred to in Box I.27 of Part I] [4][products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from a [4][country] [4][territory] [4][zone] [4][compartment] declared free from [4][Infection with Mikrocytos mackini] [4][Infection with Perkinsus marinus] 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 ([X]) and in the case of aquatic animals, all [3]listed species for the relevant disease(s) are: (i) introduced from another country, territory, zone or compartment which has been declared free from the same disease(s); (ii) not vaccinated against [4][that] [4][those] disease(s).]
[4][7] [II.2.4.2.	**Requirements for [3]listed species for infection with Marteilia refringens, infection with Bonamia exitiosa or infection with Bonamia ostreae**
	The [4][aquatic animals referred to in Box I.27 of Part I] [4][products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from a [4][country] [4][territory] [4][zone,] [4][compartment] declared free from [4][infection with Marteilia refringens] [4][infection with Bonamia exitiosa] [4][infection with Bonamia ostreae] in accordance with Part II, Chapter 4, of Delegated Regulation (EU) 2020/689 and in the case of aquatic animals, all [3]listed species for the relevant disease(s) are: — introduced from another country, territory, zone or compartment which has been declared free from the same disease(s); — not vaccinated against [4][that] [4][those] disease(s).]
[4][8] [II.2.4.3.	**Requirements for [9]species susceptible to infection with Ostreid herpes virus 1 µvar (OsHV-1 µvar)**
	The [4][aquatic animals referred to in Box I.27 of Part I] [4][products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from a [4][country] [4][territory] [4][zone] [4][compartment] 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 [4][Annex I] [4][Annex II] to Commission Implementing Decision (EU) 2021/260 ([Y]).]]
or [4][6][II.2.4.	**Specific health requirements**
	The [4][aquatic animals referred to in Box I.27 of Part I] [4][products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] 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 ([Z]), where they are to be processed for human consumption.]

([X]) 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).

([Y]) 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).

([Z]) Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals (OJ L 174, 3.6.2020, p. 345).

II.2.5. To the best of my knowledge, and as declared by the operator, the [4][aquatic animals referred to in Box I.27 of Part I] [4][products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from [4][an establishment] [4][a habitat] where:
(i) there were no abnormal mortalities with an undetermined cause; and
(ii) the animals have not been in contact with aquatic animals of [3]listed 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 referred to in Box I.27 of 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 animals are transported in water, the water is not changed in a third country or territory, zone or compartment which is not listed for entry of the particular species and category of aquatic animals into the Union;

II.2.6.2. the animals are not transported under conditions that jeopardise their health status, in particular:
(i) when the animals are transported in water, it does not alter their health status;
(ii) 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 [4][container] [4][well-boat] is [4][previously unused] [4][cleaned and disinfected in accordance with a protocol and with products approved by the competent authority of the [4][third country] [4][territory] of origin, 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 [4][container] [4][well-boat] together with aquatic animals which are of a lower health status or which are not intended for entry into the Union;

II.2.6.4. where a water exchange is necessary in a [4][country] [4][territory] [4][zone] [4][compartment] which is listed for entry of the particular species and category of aquatic animals into the Union, it only occurs [4][in the case of transport on land, at water exchange points approved by the competent authority of the [4][third country] [4][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 en-route from the place of origin to the place of destination in the Union].

II.2.7. Labelling requirements

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

II.2.7.1. the consignment is identified by [4][a legible and visible label on the exterior of the container] [4][an entry in the ships manifest when transported by well-boat], 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 animals in each container for each of the species present;
(d) the following statement: 'live molluscs intended for human consumption in the European 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: 'molluscs intended for human consumption after further processing in the European Union'.]

(4) (10) **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 Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this animal health/official certificate include the United Kingdom in respect of Northern Ireland.

This animal health/official certificate is intended for entry into the Union of live bi-valve 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 ([AA]) '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 Part II.2.4. of this animal health/official certificate applies, must originate from a country/territory/zone/compartment which appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404.

Part II.2.4. of the animal health/official certificate **shall not apply to** the following aquatic animals, and they may therefore originate from a 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 Implementing Regulation (EU) 2020/2235.

([AA]) 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')(OJ L 84, 31.3.2016, p. 1).

Part I:

Box reference I.8: Region of origin: indicate the production area and its classification at the time of harvest, except for Pectinidae, marine gastropods and echinoderms harvested outside classified production areas.

Part II:

(1) Part II.1 shall not apply to countries with 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 must be deleted when the consignment consists of: (a) species other than those listed in the Annex to Commission Implementing Regulation (EU) 2018/1882 ([AB]); 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 Part 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 footnote (6).

(5) Code of the third country/territory/zone/compartment as it appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404.

(6) Parts II.2.3.1, II.2.3.2. and II.2.4 shall not apply and must be deleted if the consignment contains only the following aquatic animals:

(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.

(7) Applicable only when the Member State/zone/compartment 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.

([AB]) 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).

(8)	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.
(9)	Susceptible species as referred to in the second column of the table in Annex III to Implementing Decision (EU) 2021/260.
(10)	Shall apply only to the consignments of live aquatic animals.
(11)	to be signed by: — an official veterinarian when Part II.2 Animal health attestation is not deleted, — a certifying officer or an official veterinarian when Part II.2 Animal health attestation is deleted.

[Official veterinarian] [(4)(11)]**/ [Certifying officer]**[(4)(11)]	
Name (in capital letters)	
Date	Qualification and title
Stamp	Signature

';

(c) Chapter 46 is replaced by the following:

'**CHAPTER 46**

MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF HIGHLY REFINED PRODUCTS AS DESCRIBED IN ANNEX III, SECTION XVI OF REGULATION (EC) NO 853/2004, INTENDED FOR HUMAN CONSUMPTION (MODEL HRP)

COUNTRY				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.3 **Central Competent Authority** I.4 **Local Competent Authority**	I.2a **IMSOC reference** **QR CODE**	
	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 **Entry Border Control Post** I.17 **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			
I.21		I.22 ☐ **For internal market**	
		I.23	
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 Date of collection/production	Identification mark Manufacturing plant	Type of packaging Number of packages Net weight Batch No

COUNTRY **Model certificate HRP**

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

Part II: Certification

II.1. Public health attestation

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 ([AC]), Regulation (EC) No 852/2004 of the European Parliament and of the Council ([AD]), Regulation (EC) No 853/2004 of the European Parliament and of the Council ([AE]) and Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ([AF]), and hereby certify that the highly refined products described in Part I were produced in accordance with these requirements, in particular that they:

(a) come from (an) establishment(s) that has(ve) been registered and implement(s) a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004 and regularly audited by the competent authority;

(b) have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004;

(c) comply with the requirements of Annex III, Section XVI, to Regulation (EC) No 853/2004; and

(d) [1] if amino acids, that

(i) human hair was not used as a source for their production; and

(ii) they comply with Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([AG]);

(e) [1] if fat derivatives, that they were submitted to one of the following processes:

[1] (i) transesterification or hydrolysis at a temperature of at least 200°C, under corresponding appropriate pressure, for at least 20 minutes; or

[1](ii) saponification with NaOH 12M, in a batch process at 95°C for three hours or in a continuous process at 140°C 2 bars (2 000 hPa) for eight minutes; or

[1](iii) hydrogenation at 160°C at 12 bars (12 000 hPa) for 20 minutes;

(f) if food flavourings, that they are authorised in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council ([AH])

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 European Union in this official certificate include the United Kingdom in respect of Northern Ireland.

This official certificate is intended for the entry into the Union of highly refined product as described in Section XVI of Annex III to Regulation (EC) No 853/2004.

([AC]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([AD]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

([AE]) 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).

([AF]) 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 (OJ L 95, 7.4.2017, p. 1).

([AG]) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16)

([AH]) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

COUNTRY				Model certificate HRP
II. Health information	**II.a**	**Certificate reference**	**II.b**	**IMSOC reference**

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

Part I:

Box reference I.27: Insert the appropriate Harmonised System (HS) code(s) using headings such as 2106, 2906, 2907, 2922, 2930, 2932, 2936, 3503, 3507, or 3913.

Part II:

(1) Delete as appropriate.

Certifying officer

Date	Qualification and title
Stamp	Signature

‘;

(2) Annex V is replaced by the following:

'ANNEX V

MODEL PRIVATE ATTESTATION BY THE OPERATOR ENTERING SHELF-STABLE COMPOSITE PRODUCTS INTO THE UNION IN ACCORDANCE WITH ARTICLE 14 OF REGULATION (EU) 2019/625

COUNTRY					
Part I: Description of consignment	**I.1**	**Consignor/Exporter** Name Address Country ISO country code	**I.2**	**Attestation**	**I.2a IMSOC reference** **QR CODE**
	I.5	**Consignee/Importer**(7) 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 Address Registration/Approval No Country ISO country code	**I.12**	**Place of destination** Name 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**	**Entry Border Control Post**	
			I.17	**Accompanying documents** Type Code Country ISO country code Commercial document reference	
	I.18	**Transport conditions** ☐ Ambient ☐ Chilled.			
	I.19	**Container number/Seal number** Container No Seal No			
	I.20	**Certified as or for** ☐Products for human consumption			
			I.22	**☐ For internal market**	
	I.24	**Total number of packages**			**I.26 Total net weight/gross weight (kg)**
	I.27	**Description of consignment**			
	CN code			Type of packaging	Net weight
		Nature of commodity		Number of packages	Batch No
	☐Final consumer	Manufacturing plant		Date of production	

Part II: Attestation

II. Health information	**II.a Attestation**	**II.b IMSOC reference**

I, the undersigned, ……

(*name, address, and full details of the importer*)

as representative of the importing food business operators of the consignment of composite products described in Part I declare that the composite products accompanied by this attestation:

1. comply with the applicable requirements referred to in Article 126(2) of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ([AI]);
2. do not need to be stored or transported under controlled temperature, unless the shelf-stable composite product needs to be transported chilled for organoleptic quality reasons;
3. contain no colostrum-based products and no processed meat other than gelatine[3], collagen[3] or highly refined products[3] referred to in Annex III, Section XVI, to Regulation (EC) No 853/2004 of the European Parliament and of the Council ([AJ]);
4. contain the following list of ingredients of plant origin and of processed products of animal origin[1]: ……;
5. contain processed products of animal origin, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 originating from the following approved establishment(s)[2]: ……;
6. contain processed products of animal origin which originate, with the exception of gelatine, collagen, and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, from third countries or regions thereof authorised to export each processed product of animal origin to the Union as listed in Commission Decision 2011/163/EC ([AK]) or from an EU Member State;
7. originate from third countries or regions thereof authorised to export meat products, dairy products, fishery products or egg products to the Union on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Commission Implementing Regulation (EU) 2021/405 ([AL]) or Commission Implementing Regulation (EU) 2021/404 ([AM]) and included in the list laid down in the Annex to Decision 2011/163/EU for the species/commodity from which the processed products of animal origin contained in the composite products, with the exception of collagen, gelatine and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, are derived;
8. have been produced in an establishment which fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004 of the European Parliament and of the Council ([AN]);

([AI]) 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 (OJ L 95, 7.4.2017, p. 1).

([AJ]) 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).

([AK]) Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

([AL]) Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

([AM]) 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).

([AN]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

9. have been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council ([AO]), and the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ([AP]);
10. contain dairy products[3], which:
    [3][4] *either* have not undergone a specific risk-mitigating treatment provided for in Annex XXVII to Commission Delegated Regulation (EU) 2020/692 ([AQ]);
    [3][5] *or* have undergone a specific risk-mitigating treatment provided for in column A or B of the table set out in Annex XXVII to Delegated Regulation (EU) 2020/692;
    [3][6] *or* have undergone a specific risk-mitigating treatment at least equivalent to one of the treatments provided for in column B of the table set out in Annex XXVII to Delegated Regulation (EU) 2020/692;
11. contain egg products, which have undergone a specific risk-mitigating treatment at least equivalent to one of the treatments provided for in the table set out in Annex XXVIII to Delegated Regulation (EU) 2020/692[3].

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 European Union in this attestation include the United Kingdom in respect of Northern Ireland.

Part I:

Box reference I.6: Optional in the case of products exempted from official controls at border control posts.

Box reference I.13: Optional in the case of products exempted from official controls at border control posts.

Box reference I.15: Optional in the case of products exempted from official controls at border control posts.

Box reference I.16: Optional in the case of products exempted from official controls at border control posts.

Box reference I.18: Indicate chilled when the shelf-stable composite product is being transported under controlled temperature for organoleptic quality reasons.

Box reference I.19: Optional in the case of products exempted from official controls at border control posts.

Box reference I.27: If the private attestation covers several composite products, the description of goods in Box I.27 must be presented clearly and separately for each composite product (one line by product).

Description of consignment:

"Type of packaging": Indicate the type of packaging according to the definition given in Recommendation No 21 (9) of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).

"Net weight": Indicate the mass of each composite product covered by the private attestation. Those data are needed to calculate the total net weight in box I.26.

([AO]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([AP]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([AQ]) 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).

	"Manufacturing plant": Indicate registration number or address of the plant where the final composite product is produced.	
	Date	Qualification and title of the importer
	Stamp	Signature

(1) Please list the ingredients in descending order of weight. Grouping certain ingredients by dairy products, fishery products, egg products, products of non-animal origin as relevant is allowed.

(2) Please introduce the approval number of the establishment(s) having produced the processed products of animal origin contained in the composite product and the third country or territory, or zone thereof, or the EU Member State, where the approved establishment is located, as provided for in Article 4(2) of Regulation (EC) No 853/2004, and indicated by the importing food business operator.

(3) Keep as appropriate.

(4) Only if:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is listed for the entry into the Union of raw milk and dairy products not subject to a risk-mitigating treatment in accordance with Annex XVII to Implementing Regulation (EU) 2021/404 ([AR]);

and

(b) the approved establishment of origin of the raw milk or the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of raw milk and dairy products not subject to a risk-mitigating treatment in accordance with Annex XVII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

(5) Only if:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is listed for the entry into the Union of dairy products subject to a risk-mitigating treatment in accordance with Annex XVIII to Implementing Regulation (EU) 2021/404;

and

(b) the approved establishment of origin of the raw milk or the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of raw milk and/or dairy products in accordance with Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

(6) If:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is not listed for the entry into the Union of raw milk and/or dairy products in Annexes XVII or XVIII to Implementing Regulation (EU) 2021/404;

([AR]) 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 the Council (OJ L 114, 31.3.2021, p. 1).

and

(b) the approved establishment of origin of the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of raw milk and/or dairy products in accordance with Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

[7] Importer: Representative of the importing food business operators as laid down in Article 14(1) of Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).'