COMMISSION REGULATION (EC) No 1250/2008

of 12 December 2008

amending Regulation (EC) No 2074/2005 as regards certification requirements for import of fishery products, live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals [1], and in particular Article 25(a) and (d) thereof,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2], and in particular Article 12 thereof,

Having regard to 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 [3], and in particular Article 9 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [4], and in particular Article 16 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [5], and in particular Article 63 thereof,

Whereas:

(1) Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 [6] provides in Appendix IV and Appendix V of Annex VI model health certificates for imports of fishery products and bivalve molluscs intended for human consumption.

(2) Council Directive 2006/88/EC and Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the introduction into the Community of aquaculture animals and products thereof and laying down a list of vector species [7] provide for animal health requirements applicable to placing on the market and import of aquaculture animals and products thereof for human consumption.

(3) These provisions include restrictions on import on certain consignments of aquaculture animals and products thereof of species susceptible to the aquatic animal diseases listed in Part II of Annex IV to Directive 2006/88/EC and transport requirements.

(4) The model certificates provided in Regulation (EC) No 2074/2005 should be amended to be in line with the requirements laid down in Directive 2006/88/EC and Regulation (EC) No 1251/2008.

(5) The specific requirements regarding live bivalve molluscs referred to in Section VII of Annex III to Regulation (EC) No 853/2004 also apply to live echinoderms, tunicates and marine gastropods. It is therefore appropriate to extend the scope of the certificate for imports of live bivalve molluscs intended for human consumption by including live echinoderms, live tunicates and live marine gastropods.

(6) Regulation (EC) No 2074/2005 should therefore be amended accordingly.

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[1] OJ L 328, 24.11.2006, p. 14.
[2] OJ L 139, 30.4.2004, p. 1.
[3] OJ L 139, 30.4.2004, p. 55.
[4] OJ L 139, 30.4.2004, p. 206.
[5] OJ L 165, 30.4.2004, p. 1.
[6] OJ L 338, 22.12.2005, p. 27.
[7] See page 41 of this Official Journal.

(7) It is appropriate to introduce a transitional period to permit Member States and industry to take the necessary measures to comply with the new requirements laid down in this Regulation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 2074/2005

Regulation (EC) No 2074/2005 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

1. For a transitional period until 30 June 2009, consignments for which a health certificate has been issued in accordance with the model laid down in Regulation (EC) No 2074/2005 as amended by Regulation (EC) No 1664/2006 may be imported into the Community.

2. For a transitional period until 31 July 2010, the following consignments for which a health certificate has been issued in accordance with the model laid down in Regulation (EC) No 2074/2005 as amended by Regulation (EC) No 1664/2006 may be imported into the Community:

(a) consignments of fishery products for which the animal health attestation laid down in Part II of the model health certificate laid down in Appendix IV to Annex VI to Regulation (EC) No 2074/2005 as amended by this Regulation is not applicable, as described in note (2) of that Part II;

(b) consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which the animal health attestation laid down in Part II of the model health certificate laid down in Appendix V to Annex VI to Regulation (EC) No 2074/2005 as amended by this Regulation is not applicable, as described in note (2) of that Part II.

Article 3

Entry into force

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

It shall apply from 1 January 2009.

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

Done at Brussels, 12 December 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Annex VI to Regulation (EC) No 2074/2005 is amended as follows:

(1) Appendix IV is replaced by the following:

'Appendix IV to Annex VI

MODEL HEALTH CERTIFICATE FOR IMPORTS OF FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Postal code Tel. No		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10.
I.11. Place of origin Name Approval number Address		I.12.	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/seal number		I.24. Type of packaging	
I.25. Commodities certified for Human consumption ☐			
I.26.		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Fishery products**

Part II: Certification

II. Health attestation	II.a. Certificate reference number	II.b.

II.1 (1) **Public health attestation**

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

— 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;

— satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;

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

— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

— the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; and

— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.

II.2 (2)(4)**Animal health attestation for fish and crustaceans of aquaculture origin**

II.2.1 (3)(4)**[Requirements for susceptible species to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Taura syndrome and Yellowhead disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

(5)originate from a country/territory, zone or compartment declared free from (4)[EUS] (4)[EHN (4)[Taura syndrome] (4)[Yellowhead disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services,

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]

II.2.2 (3)(4)**[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV) and White spot disease intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

(6)originate from a country/territory, zone or compartment declared free from (4)[VHS] (4)[IHN] (4)[ISA] (4)[KHV] (4)[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and

(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]

II.2.3 **Transport and labelling requirements**

I, the undersigned official inspector, hereby certify that:

II.2.3.1 the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;

II.2.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and

II.2.3.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:

"(4)**[Fish]**(4)**[Crustaceans] intended for human consumption in the Community".**

COUNTRY **Fishery products**

II. Health attestation	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.8: Region of origin: For frozen or processed bivalve molluscs, indicate the production area.

— Box reference I.11: Place of origin: name and address of the dispatch establishment.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS codes: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, 05.11.91, 15.04, 15.18.00, 16.03, 16.04, 16.05.

— Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.

— Box reference I.28: Nature of commodity: Specify whether aquaculture or wild origin.

Treatment type: Specify whether live, chilled, frozen or processed.

Manufacturing plant: includes factory vessel, freezer vessel, cold store, processing plant.

Part II:

([1]) Part II.1 of this certificate does not apply to countries with special public health certification requirements laid down in equivalence agreements or other Community legislation.

([2]) Part II.2 of this certificate does not apply to:

(a) non-viable crustaceans, which means crustaceans no longer able to survive as living animals if returned to the environment from which they were obtained,

(b) fish which are slaughtered and eviscerated before dispatch,

(c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,

(d) crustaceans destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,

(e) crustaceans which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.

([3]) Parts II.2.1 and II.2.2 of this certificate only apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.

([4]) Keep as appropriate.

([5]) For consignments of species susceptible to EUS, EHN, Taura syndrome and/or Yellowhead disease this statement must be kept for the consignment to be authorised into any part of the Community.

([6]) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, IHN, ISA, KHV or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Community are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

(2) Part A of Appendix V is replaced by the following:

'Appendix V to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF LIVE BIVALVE MOLLUSCS ECHINODERMS, TUNICATES AND MARINE GASTROPODS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Postal code Tel. No		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10.
I.11. Place of origin Name Approval number Address		I.12.	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code) **03 07**	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24. Type of packaging	
I.25. Commodities certified for Human consumption ☐			
I.26.		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments Manufacturing plant	Number of packages	Net weight

COUNTRY

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

Part II: Certification

II.	Health attestation	II.a. Certificate reference number	II.b.

II.1 (1)**Public health attestation for live bivalve molluscs, echinoderms, tunicates and marine gastropods**

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the (4)[live bivalve molluscs] (4)[live echinoderms] (4)[live tunicates] (4)[live marine gastropods] described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

— 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;

— 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;

— satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;

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

— 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;

— in the case of *pectinidae* harvested outside classified production areas, comply with the specific requirements laid down in Section VII, Chapter IX of Annex III to Regulation (EC) No 853/2004, and

— have satisfactorily undergone the official controls laid down in Annex II to Regulation (EC) No 854/2004.

II.2 (2)(4)**Animal health attestation for live bivalve molluscs of aquaculture origin**

II.2.1 (3)(4)**[Requirements for species susceptible to Bonamia exitiosa, Perkinsus marinus and Microcytos mackini**

I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to in Part I of this certificate:

(5)originate from a country/territory, zone or compartment declared free from (4)[Bonamia exitiosa] (4)[Perkinsus marinus] (4)[Mikrocytos mackini] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

— where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and

— all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.]

II.2.2 (3)(4)**[Requirements for species susceptible to Marteilia refringens and Bonamia ostreae intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease**

I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to above:

(6)originate from a country/territory, zone or compartment declared free from (4)[Marteilia refringens] (4)[Bonamia ostreae] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,

(i) where the relevant diseases are notifiable to the competent authority authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and

(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.]

II.2.3 **Transport and labelling requirements**

I, the undersigned official inspector, hereby certify that:

II.2.3.1 the live bivalve molluscs referred to above are placed under conditions, including with a water quality, that do not alter their health status,

II.2.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and

II.2.3.3 the consignment is identified by a legible label on the exterior of the micro container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:

"Live bivalve molluscs intended for human consumption in the Community".

COUNTRY

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

II. Health attestation	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.8: Region of origin: indicate the production area.

— Box reference I.11: Place of origin: name and address of the dispatch establishment.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.

— Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.

— Box reference I.28: Manufacturing plant: includes dispatch centre, purification centre.

Part II:

([1]) Part II.1 does not apply to countries with special public health certification requirements laid down in Equivalence Agreements or other Community legislation.

([2]) Part II.2 does not apply to:

(a) non-viable molluscs, which means molluscs no longer able to survive as living animals if returned to the environment from which they were obtained,

(b) live bivalve molluscs placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,

(c) live bivalve molluscs destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,

(d) live bivalve molluscs which are intended for further processing before human consumption without temporary storage at the place of processing and packed an labelled for that purpose in accordance with Regulation (EC) No 853/2004.

([3]) Parts II.2.1 and II.2.2 only apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.

([4]) Keep as appropriate.

([5]) For consignments of species susceptible to Bonamia exitiosa, Perkinsus marinus and Microcytos mackini this statement must be kept for the consignment to be authorised into any part of the Community.

([6]) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from Marteilia refringens or Bonamia ostreae or with a surveillance or eradication programme established in accordance with Article 44 (1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farms and mollusc farming areas in the Community are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp: