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Price: EUR 3

⁽¹⁾ Text with EEA relevance

EN

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

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1012/2012

of 5 November 2012

amending Regulation (EC) No 2074/2005 and Regulation (EC) No 1251/2008 as regards the list of vector species, the health requirements and the certification requirements concerning epizootic ulcerative syndrome and as regards the entry for Thailand in the list of third countries from which imports of certain fish and fishery products into the Union are permitted

(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 laying down specific hygiene rules for food of animal origin⁽¹⁾, and in particular the second paragraph of 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⁽²⁾, and in particular the second paragraph of Article 16 thereof,

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⁽³⁾, and in particular Article 17(2), Articles 22 and 25 and Article 61(3) 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⁽⁴⁾ lays down

model animal health certificates for the introduction into the Union of certain aquatic animals and products of animal origin intended for human consumption.

- (2) The model health certificate for imports of fishery products intended for human consumption, set out in Appendix IV of Annex VI to Regulation (EC) No 2074/2005, contains an animal health attestation with regard to the requirements for susceptible species to certain diseases listed in Part II of Annex IV to Directive 2006/88/EC, including epizootic ulcerative syndrome.
- (3) Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species⁽⁵⁾ lays down animal health conditions and certification requirements for imports into the Union of certain aquaculture animals and of certain products thereof.
- (4) Annex I to Regulation (EC) No 1251/2008 sets out a list of vector species for the diseases listed in Part II of Annex IV to Directive 2006/88/EC. The vector species for epizootic ulcerative syndrome are currently included in that list.
- (5) Annex III to Regulation (EC) No 1251/2008 sets out, *inter alia*, the list of third countries, territories, zones or compartments from which the import into the Union of ornamental fish susceptible to one or more of the diseases listed in Annex IV to Directive 2006/88/EC and intended for closed ornamental facilities is permitted.
- (6) India and Vietnam are listed in that Annex to make the import of fish species susceptible to epizootic ulcerative syndrome subject to specific animal health provisions eliminating the risks of that disease.

⁽¹⁾ OJ L 139, 30.4.2004, p. 55.

⁽²⁾ OJ L 139, 30.4.2004, p. 206.

⁽³⁾ OJ L 328, 24.11.2006, p. 14.

⁽⁴⁾ OJ L 338, 22.12.2005, p. 27.

⁽⁵⁾ OJ L 337, 16.12.2008, p. 41.

- (7) In addition, the model animal health certificates set out in Parts A and B of Annex IV to Regulation (EC) No 1251/2008 contain animal health attestations with regard to the requirements for susceptible species and vector species to certain diseases listed in Part II of Annex IV to Directive 2006/88/EC, including epizootic ulcerative syndrome.
- (8) Directive 2006/88/EC, as amended by Commission Implementing Directive 2012/31/EU ⁽¹⁾, no longer lists epizootic ulcerative syndrome (EUS) as an exotic disease in Part II of Annex IV thereto.
- (9) For reasons of consistency and clarity of Union law, Regulation (EC) No 2074/2005 and Regulation (EC) No 1251/2008 should be amended in order to remove the provisions therein making references to epizootic ulcerative syndrome.
- (10) Following the removal of epizootic ulcerative syndrome from the list in Part II of Annex IV to Directive 2006/88/EC the corresponding animal health provisions applicable to India and Vietnam have become redundant and therefore those countries should be removed from the list of countries that are to apply disease specific animal health measures to aquatic animals intended for export to the Union.
- (11) Thailand is listed in Annex III to Regulation (EC) No 1251/2008, as a third country from which imports of cyprinidae intended for farming, relaying areas, put and take fisheries and open and closed ornamental facilities into the Union is permitted. Thailand has request to be listed in Annex III for the purposes of permitting exports of also other fish species from that third country into the Union.
- (12) An inspection by the Food and Veterinary Office (FVO) concerning aquatic animal health was carried out in Thailand in November 2009. The FVO recommendations following that inspection have been satisfactorily implemented by the competent authority in Thailand. It is therefore appropriate to permit imports into the Union from that third country also of other fish species. The

entry for Thailand in Annex III to Regulation (EC) No 1251/2008 should therefore be amended accordingly.

- (13) Regulation (EC) No 2074/2005 and Regulation (EC) No 1251/2008 should therefore be amended accordingly.
- (14) It is appropriate to provide for transitional measures to allow Member States and the industry to take the necessary measures to comply with the requirements laid down in this Regulation.
- (15) 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

Appendix IV of Annex VI to Regulation (EC) No 2074/2005 is replaced by the text in Annex I to this Regulation.

Article 2

Annexes I, III and IV to Regulation (EC) No 1251/2008 are amended in accordance with Annex II to this Regulation.

Article 3

For a transitional period until 1 March 2013, consignments of aquatic animals accompanied by animal health certificates issued in accordance with the models set out in Part A or B of Annex IV to Regulation (EC) No 1251/2008, and fishery products accompanied by animal health certificates issued in accordance with the model set out in Appendix IV of Annex VI to Regulation (EC) No 2074/2005, in their version prior to the amendments introduced by this Regulation, may be placed on the market or introduced into the Union provided that they reach their place of final destination before that date.

Article 4

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, 5 November 2012.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 297, 26.10.2012, p. 26.

ANNEX I

‘Appendix IV to Annex VI

Model health certificate for imports of fishery products intended for human consumption

		Veterinary certificate to EU		
Part I: Details of dispatched consignment	I.1. Consignor Name Address Tel.		I.2. Certificate reference No I.2.a.	
			I.3. Central competent authority	
			I.4. Local competent authority	
	I.5. Consignee Name Address Postcode Tel.		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 Address Approval number		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 Documentation 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. Seal/Container No		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 Treatment type of establishment Approval number Manufacturing plant Number of packages Net weight				

COUNTRY		Fishery products	
II. Health information		II.a. Certificate reference number	II.b.
Part II: Certification	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) 852/2004, (EC) 853/2004 and (EC) 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 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) [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 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.2.2. (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		

COUNTRY

Fishery products

II.	Health information	II.a. Certificate reference number	II.b.
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 Union". 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 Harmonised System (HS) codes of the World Customs Organisation of the following headings: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 05.11, 15.04, 1516, 1518, 1603, 1604, 1605 or 2106. — 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: <i>Nature of commodity</i>: Specify whether aquaculture or wild origin. <i>Treatment type</i>: Specify whether live, chilled, frozen or processed. <i>Manufacturing plant</i>: 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 Union 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 heading of the point concerned. Susceptible species are listed in Annex IV to Directive 2006/88/EC. ⁽⁴⁾ Keep as appropriate. ⁽⁵⁾ For consignments of species susceptible to EHN, Taura syndrome and/or Yellowhead disease this statement must be kept for the consignment to be authorised into any part of the Union.		

COUNTRY**Fishery products**

II. Health information	II.a. Certificate reference No	II.b.						
(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 drawn up 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 Union 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 <table border="0"> <tr> <td data-bbox="220 577 443 607">Name (in capital letters):</td> <td data-bbox="1042 577 1236 607">Qualification and title:</td> </tr> <tr> <td data-bbox="220 633 272 663">Date:</td> <td data-bbox="1042 633 1137 663">Signature:'</td> </tr> <tr> <td data-bbox="220 689 288 719">Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Date:	Signature:'	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:'							
Stamp:								

ANNEX II

Annexes I, III and IV to Regulation (EC) No 1251/2008 are amended as follows:

(1) in Annex I, the entry for epizootic ulcerative syndrome is deleted.

(2) Annex III is replaced by the following:

‘ANNEX III

List of third countries, territories, zones or compartments ⁽¹⁾

(referred to in Article 10(1) and Article 11)

Country/territory		Aquaculture Species			Zone/Compartment	
ISO-code	Name	Fish	Molluscs	Crustaceans	Code	Description
AU	Australia	X ^(A)				
BR	Brazil	X ^(B)				
CA	Canada	X			CA 0 ^(C)	Whole territory
					CA 1 ^(D)	British Columbia
					CA 2 ^(D)	Alberta
					CA 3 ^(D)	Saskatchewan
					CA 4 ^(D)	Manitoba
					CA 5 ^(D)	New Brunswick
					CA 6 ^(D)	Nova Scotia
					CA 7 ^(D)	Prince Edward Island
					CA 8 ^(D)	Newfoundland and Labrador
					CA 9 ^(D)	Yukon
					CA 10 ^(D)	Northwest Territories
					CA 11 ^(D)	Nunavut
CL	Chile	X ^(A)				Whole country
CN	China	X ^(B)				Whole country
CO	Colombia	X ^(B)				Whole country
CG	Congo	X ^(B)				Whole country
CK	Cook Islands	X ^(F)	X ^(F)	X ^(F)		Whole country
HR	Croatia	X ^(A)				Whole country

⁽¹⁾ According to Article 11 ornamental fish which are not of species susceptible to any of the diseases listed in Part II of Annex IV to Directive 2006/88/EC, and ornamental molluscs and ornamental crustaceans, intended for closed ornamental facilities, may also be imported into the Union from third countries or territories that are members of the World Organisation for Animal health (OIE).

Country/territory		Aquaculture Species			Zone/Compartment	
ISO-code	Name	Fish	Molluscs	Crustaceans	Code	Description
HK	Hong Kong	X ^(B)				Whole country
ID	Indonesia	X ^(A)				Whole country
IL	Israel	X ^(A)				Whole country
JM	Jamaica	X ^(B)				Whole country
JP	Japan	X ^(B)				Whole country
KI	Kiribati	X ^(F)	X ^(F)	X ^(F)		Whole country
LK	Sri Lanka	X ^(B)				Whole country
MH	Marshall Islands	X ^(F)	X ^(F)	X ^(F)		Whole country
MK ^(B)	the former Yugoslav Republic of Macedonia	X ^(B)				Whole country
MY	Malaysia	X ^(B)				Peninsular, Western Malaysia
NR	Nauru	X ^(F)	X ^(F)	X ^(F)		Whole country
NU	Niue	X ^(F)	X ^(F)	X ^(F)		Whole country
NZ	New Zealand	X ^(A)				Whole country
PF	French Polynesia	X ^(F)	X ^(F)	X ^(F)		Whole country
PG	Papua New Guinea	X ^(F)	X ^(F)	X ^(F)		Whole country
PN	Pitcairn Islands	X ^(F)	X ^(F)	X ^(F)		Whole country
PW	Palau	X ^(F)	X ^(F)	X ^(F)		Whole country
RU	Russia	X ^(A)				Whole country
SB	Solomon Islands	X ^(F)	X ^(F)	X ^(F)		Whole country
SG	Singapore	X ^(B)				Whole country
ZA	South Africa	X ^(A)				Whole country
TW	Taiwan	X ^(B)				Whole country
TH	Thailand	X ^(A)				Whole country
TR	Turkey	X ^(A)				Whole country
TK	Tokelau	X ^(F)	X ^(F)	X ^(F)		Whole country
TO	Tonga	X ^(F)	X ^(F)	X ^(F)		Whole country
TV	Tuvalu	X ^(F)	X ^(F)	X ^(F)		Whole country

Country/territory		Aquaculture Species			Zone/Compartment	
ISO-code	Name	Fish	Molluscs	Crustaceans	Code	Description
US	United States ^(c)	X		X	US 0 ^(c)	Whole country
		X			US 1 ^(d)	Whole country, except the following states: New York, Ohio, Illinois, Michigan, Indiana, Wisconsin, Minnesota and Pennsylvania
			X		US 2	Humboldt Bay (California)
					US 3	Netarts Bay (Oregon)
					US 4	Wilapa Bay, Totten Inlet, Oakland Bay, Quilcense Bay and Dabob Bay (Washington)
					US 5	NELHA (Hawaii)
WF	Wallis and Futuna	X ^(f)	X ^(f)	X ^(f)		Whole country
WS	Samoa	X ^(f)	X ^(f)	X ^(f)		Whole country

^(a) Apply to all fish species.

^(b) Apply only to *Cyprinidae*.

^(c) Apply not to fish species susceptible to or vector species for viral haemorrhagic septicaemia according to Part II of Annex IV to Directive 2006/88/EC.

^(d) Apply only to fish species susceptible to or vector species for viral haemorrhagic septicaemia according to Part II of Annex IV to Directive 2006/88/EC.

^(e) Provisional code that does not prejudice in any way the definitive denomination for this country, which will be agreed following the conclusion of the negotiations currently taking place on this subject at the United Nations.

^(f) Apply only to imports of ornamental fish which are not of susceptible species to any of the diseases listed in Part II of Annex IV to Directive 2006/88/EC, and ornamental molluscs and ornamental crustaceans, intended for closed ornamental facilities.

^(g) For the purposes of this Regulation United States includes Puerto Rico, U.S. Virgin Islands, American Samoa, Guam and Northern Mariana Islands.

(3) in Annex IV, Parts A and B are replaced by the following:

PART A

Model animal health certificate for the import into the European Union of aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities

Veterinary certificate to EU

I.1. Consignor Name Address Tel.		I.2. Certificate reference No		I.2.a.			
		I.3. Central competent authority					
		I.4. Local competent authority					
I.5. Consignee Name Address Postal code Tel.		I.6.					
I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
I.11. Place of origin Name Address Approval number		I.12.					
I.13. Place of loading Address Approval number		I.14. Date of departure		Time 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. No. of CITES					
I.18. Description of commodity				I.19. Commodity code (HS code)			
				I.20. Quantity			
I.21.				I.22. Number of packages			
I.23. Identification of container/seal number				I.24.			
I.25. Commodities certified for: Breeding ☐ Quarantine ☐ Relaying ☐ Other ☐ Pets ☐ Circus/exhibition ☐							
I.26.				I.27. For import or admission into EU ☐			
I.28. Identification of the commodities Species (scientific name) Quantity							

COUNTRY		Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities	
		II.a. Certificate reference number	II.b.
Part II: Certification	II.	Health information	
	II.1.	General requirements	
		I, the undersigned official inspector, hereby certify that the aquaculture animals referred to in Part I of this certificate:	
	II.1.1.	have been inspected within 72 hours of loading, and showed no clinical signs of disease;	
	II.1.2.	are not subject to any prohibitions due to unresolved increased mortality;	
	II.1.3.	are not intended for destruction or slaughter for the eradication of diseases; and	
	II.1.4.	originate from aquaculture farms which are all under the supervision of the competent authority;	
	II.1.5.	(1) [in the case of molluscs, were subject to an individual visual check of each part of the consignment, and no molluscs species other than those specified in Part I of the certificate were detected.]	
	II.2.	(1)(2)(3) [Requirements for species susceptible to Epizootic haematopoietic necrosis (EHN), Bonamia exitiosa, Perkinsus marinus, Mikrocytos mackini, Taura syndrome and/or Yellowhead disease]	
		I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:	
	<i>either</i> (1)(5) [originate from a country/territory, zone or compartment declared free from (1) [EHN] (1) [Bonamia exitiosa] (1) [Perkinsus marinus] (1) [Mikrocytos mackini] (1) [Taura syndrome] (1) [Yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority, (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s);		
	<i>or</i> (1)(3)(5) [in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]		
II.3.	(1)(4) [Requirements for vector species to Epizootic haematopoietic necrosis (EHN), Bonamia exitiosa, Perkinsus marinus, Mikrocytos mackini, Taura syndrome and/or Yellowhead disease]		
	I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above which are to be regarded as possible vectors to (1) [EHN] (1) [Bonamia exitiosa] (1) [Perkinsus marinus] (1) [Mikrocytos mackini] (1) [Taura syndrome] (1) [Yellowhead disease] as they are of species listed in Column 2 and fulfil the conditions set out in Column 3 of the table in Annex I to Regulation (EC) No 1251/2008:		
	<i>either</i> (1)(5) [originate from a country/territory, zone or compartment declared free from (1) [EHN] (1) [Bonamia exitiosa] (1) [Perkinsus marinus] (1) [Mikrocytos mackini] (1) [Taura syndrome] (1) [Yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority, (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s);		
	<i>or</i> (1)(5) [have been subject to quarantine in accordance with Decision 2008/946/EC.]]		
II.4.	(1)(2)(3) [Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease]		
	I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:		
	<i>either</i> (1)(6) [originate from a country/territory, zone or compartment declared free from (1) [VHS] (1) [IHN] (1) [ISA] (1) [KHV] (1) [Marteilia refringens] (1) [Bonamia ostreae] (1) [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority, (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and		

COUNTRY		Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities	
II.	Health information	II.a. Certificate reference number	II.b.
	(iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s)] or (1)(3)(6) [in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]		
II.5.	(1)(4) [Requirements for vector species to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease] I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above which are to be regarded as possible vectors to (1) [VHS] (1) [IHN] (1) [ISA] (1) [KHV] (1) [Marteilia refringens] (1) [Bonamia ostreae] (1) [White spot disease] as they are of species listed in Column 2 and fulfil the conditions set out in Column 3 of the table in Annex I to Regulation (EC) No 1251/2008: <i>either</i> (1)(6) [originate from a country/territory, zone or compartment declared free from (1) [VHS] (1) [IHN] (1) [ISA] (1) [KHV] (1) [Marteilia refringens] (1) [Bonamia ostreae] (1) [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority, (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s)] or (1)(6) [have been subject to quarantine in accordance with Decision 2008/946/EC.]]		
II.6.	Transport and labelling requirements I, the undersigned official inspector, hereby certify that:		
II.6.1.	the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;		
II.6.2.	the transport container or well boat prior to loading is clean and disinfected or previously unused; and		
II.6.3.	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.13 of Part I of this certificate, and the following statement:		
	<i>either</i> (1) [(1) [Wild] (1) [Fish] (1) [Molluscs] (1) [Crustaceans] intended for farming in the European Union"] or (1) [(1) [Wild] (1) [Molluscs] intended for relaying in the European Union"], or (1) [(1) [Wild] (1) [Fish] (1) [Molluscs] (1) [Crustaceans] intended for put and take fisheries in the European Union"] or (1) [(1) [Ornamental] (1) [fish] (1) [molluscs] (1) [crustaceans] intended for open ornamental facilities in the European Union"] or (1)(3) [(1) [Wild] (1) [Fish] (1) [Molluscs] (1) [Crustaceans] intended for quarantine in the European Union"].		
II.7.	(1)(7) [Requirements for species susceptible to Spring viraemia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN) and Infection with Gyrodactylus salaris (GS)] I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above, <i>either</i> (1) [originate from a country/territory or part thereof: (a) where (1) [SVC] (1) [GS] (1) [BKD] (1) [IPN] is (are) are notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority, (b) where all aquaculture animals of species susceptible to the relevant disease(s) introduced into that country/territory or part thereof comply with the requirements set out in II.7 of this certificate, (c) where species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s), and (d) <i>either</i> (1) [which, in the case of (1) [IPN] (1) [BKD], complies with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC.]		

COUNTRY		Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities	
II.	Health information	II.a. Certificate reference number	II.b.
	<i>and/or</i> ⁽¹⁾ [which, in the case of ⁽¹⁾ [SVC] ⁽¹⁾ [GS], complies with requirements for disease freedom laid down in the relevant OIE Standard.] <i>and/or</i> ⁽¹⁾ [which, in the case of ⁽¹⁾ [SVC] ⁽¹⁾ [IPN] ⁽¹⁾ [BKD], comprises one individual farm which under the supervision of the competent authority: (i) has been emptied, cleansed and disinfected, and fallowed in at least 6 weeks, (ii) has been restocked with animals from areas certified free from the relevant disease by the competent authority.]] <i>and/or</i> ⁽¹⁾ [in the case of wild aquatic animals susceptible to ⁽¹⁾ [SVC] ⁽¹⁾ [IPN] ⁽¹⁾ [BKD], have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.] <i>and/or</i> ⁽¹⁾ [in the case consignments for which GS requirements apply, have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days and no other live aquatic animals of the species susceptible to GS have been introduced during that period.] <i>and/or</i> ⁽¹⁾ [in the case of eyed fish eggs for which GS requirements apply, have been disinfected by a method demonstrated to be effective against GS.]] Notes Part I: — Box I. 19: Use the appropriate Harmonised System (HS) codes of the World Customs Organisation of the following headings: 0301, 0306, 0307, 0308 or 0511. — Box I. 20 and I. 28: As regards quantity, give the total number in kg, except for the ornamental fish. — Box I.25: Use the option "Breeding" if intended for farming, "Relaying" if intended for relaying, "Pets" for ornamental aquatic animals intended for pet shops or similar businesses for further sale, "Circus/exhibition" for ornamental aquatic animals intended for exhibition aquaria or similar businesses not for further sale, "Quarantine" if the aquaculture animals are intended for a quarantine facility, and "Other" if intended for put and take fisheries. Part II: ⁽¹⁾ Keep as appropriate. ⁽²⁾ Parts II.2 and II.4 of this certificate only applies to species susceptible to one or more of the diseases referred to in the heading of the part concerned. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC. ⁽³⁾ Consignments of wild aquatic animals may be imported regardless of the requirements in Parts II.2 and II.4 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC. ⁽⁴⁾ Parts II.3 and II.5 of this certificate only applies to vector species to one or more of the diseases referred to in the heading of the point concerned. Possible vector species and the conditions, under which consignments of such species are to be considered vector species, are listed in Annex I to Regulation (EC) No 1251/2008. Consignments of possible vector species may be imported regardless of the requirements in Parts II.3 and II.5 if the conditions set out in Column 4 of the table in Annex I to Regulation (EC) No 1251/2008 are not fulfilled or they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC. ⁽⁵⁾ To be authorised into the Union one of these statements must be kept if the consignments contain susceptible or vector species to EHN, <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i>, <i>Mikrocytos mackini</i>, Taura syndrome and/or Yellowhead disease. ⁽⁶⁾ To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, <i>Marteilia refringens</i>, <i>Bonamia ostreae</i>, or Whitespot disease or with a surveillance or eradication programme drawn up in accordance with Article 44 (1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain susceptible or vector species 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 Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm ⁽⁷⁾ Part II.7 of this certificate only applies to consignments intended for a Member State or part thereof which is regarded as disease-free, or for which an programme is approved by Decision 2010/221/EU as regards SVC, BKD, IPN or GS, and the consignment comprises species listed in Part C of Annex II as susceptible to the disease(s) for which the disease-free status or programme(s) apply(ies). Part II.7 also applies to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with GS, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of GS.		

COUNTRY**Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities**

II. Health information	II.a. Certificate reference number	II.b.						
Consignments of wild aquatic animals for which SVC, IPN and/or BKD related requirements are applicable, may be imported regardless of the requirements in Part II.7 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC. — The colour of the stamp and signature must be different to that of the other particulars in the certificate.								
Official inspector <table><tr><td>Name (in capital letters):</td><td>Qualification and title:</td></tr><tr><td>Date:</td><td>Signature:</td></tr><tr><td>Stamp:</td><td></td></tr></table>			Name (in capital letters):	Qualification and title:	Date:	Signature:	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:							
Stamp:								

PART B

Model animal health certificate for the import into the European Union of ornamental aquatic animals intended for closed ornamental facilities

Veterinary certificate to EU

I.1. Consignor Name Address Tel.		I.2. Certificate reference No		I.2.a.			
		I.3. Central competent authority					
		I.4. Local competent authority					
I.5. Consignee Name Address Postal code Tel.		I.6.					
I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
I.11. Place of origin Name Address Approval number		I.12.					
I.13. Place of loading Address Approval number		I.14. Date of departure Time 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. No. of CITES					
I.18. Description of commodity				I.19. Commodity code (HS code)			
				I.20. Quantity			
I.21.				I.22. Number of packages			
I.23. Identification of container/seal number				I.24.			
I.25. Commodities certified for: Pets ☐ Quarantine ☐ Circus/exhibition ☐							
I.26.				I.27. For import or admission into EU ☐			
I.28. Identification of the commodities Species (scientific name) Quantity							

COUNTRY

Ornamental aquatic animals intended for closed ornamental facilities

II. Health information	II.a. Certificate reference number	II.b.
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Part II: Certification

II.1. General requirements

I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to in Part I of this certificate:

II.1.1. have been inspected within 72 hours of loading, and showed no clinical signs of disease;

II.1.2. are not subject to any prohibitions due to unresolved increased mortality; and

II.1.3. are not intended for destruction or slaughter for the eradication of diseases.

II.2. ⁽¹⁾ ⁽²⁾ ⁽³⁾ [Requirements for species susceptible to Epizootic haematopoietic necrosis (EHN), *Bonamia exitiosa*, *Perkinsus marinus*, *Mikrocytos mackini*, Taura syndrome and/or Yellowhead disease]

I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to above:

either ⁽¹⁾ ⁽⁴⁾ [originate from a country/territory, zone or compartment declared free from ⁽¹⁾ [EHN] ⁽¹⁾ [*Bonamia exitiosa*] ⁽¹⁾ [*Perkinsus marinus*] ⁽¹⁾ [*Mikrocytos mackini*] ⁽¹⁾ [Taura syndrome] ⁽¹⁾ [Yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and

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

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

(iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s);

or ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾ [have been subject to quarantine in accordance with Decision 2008/946/EC].]

II.3. ⁽¹⁾ ⁽²⁾ ⁽³⁾ [Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), *Marteilia refringens*, *Bonamia ostreae*, and/or White spot disease]

I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to above:

either ⁽¹⁾ ⁽⁵⁾ [originate from a country/territory, zone or compartment declared free from ⁽¹⁾ [VHS] ⁽¹⁾ [IHN] ⁽¹⁾ [ISA] ⁽¹⁾ [KHV] ⁽¹⁾ [*Marteilia refringens*] ⁽¹⁾ [*Bonamia ostreae*] ⁽¹⁾ [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and

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

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

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

or ⁽¹⁾ ⁽³⁾ ⁽⁵⁾ [have been subject to quarantine in accordance with Decision 2008/946/EC].]

II.4. Transport and labelling requirements

I, the undersigned official inspector, hereby certify that:

II.4.1. the ornamental aquatic animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;

II.4.2. the transport container is clean and disinfected or previously unused; and

II.4.3. the consignment is identified by a legible label on the exterior of the container with the relevant information referred to in boxes I.7 to I.13 of Part I of this certificate, and the following statement:

either ⁽¹⁾ ["Ornamental ⁽¹⁾ [fish] ⁽¹⁾ [molluscs] ⁽¹⁾ [crustaceans] intended for closed ornamental facilities in the European Union"]

or ⁽¹⁾ ["Ornamental ⁽¹⁾ [fish] ⁽¹⁾ [molluscs] ⁽¹⁾ [crustaceans] intended for quarantine in the European Union"].

II.5. ⁽¹⁾ ⁽³⁾ ⁽⁶⁾ [Requirements for species susceptible to Spring viraemia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN) and Infection with *Gyrodactylus salaris* (GS)]

I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to above:

COUNTRY

Ornamental aquatic animals intended for closed ornamental facilities

II. Health information	II.a. Certificate reference number	II.b.
<i>either</i> ⁽¹⁾ [originate from a country/territory or part thereof: (a) where ⁽¹⁾ [SVC] ⁽¹⁾ [GS] ⁽¹⁾ [BKD] ⁽¹⁾ [IPN] is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority; (b) where all aquaculture animals of species susceptible to the relevant disease(s) introduced into that country/territory or part thereof comply with the requirements set in Part II.5 of this certificate; (c) where species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s); and (d) which comply with the requirements for disease freedom as regards ⁽¹⁾ [SVC] ⁽¹⁾ [GS] ⁽¹⁾ [BKD] ⁽¹⁾ [IPN] laid down in the relevant OIE standard or at least equivalent to those laid down in Chapter VII of Directive 2006/88/EC.] <i>or</i> ⁽¹⁾ ⁽³⁾ [have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]]		
Notes		
Part I:		
— Box I.19: Use the appropriate Harmonised System (HS) codes of the World Customs Organisation of the following headings: 0301, 0306, 0307, 0308 or 0511. — Box I.20 and I.28: As regards quantity, give the total number in kg, except for the ornamental fish. — Box I.25: Use the option “Pets” for ornamental aquatic animals intended for pet shops or similar businesses for further sale, “Circus/exhibition” for ornamental aquatic animals intended for exhibition aquaria or similar businesses not for further sale and “Quarantine” if the ornamental aquatic animals are intended for a quarantine facility.		
Part II:		
⁽¹⁾ Keep as appropriate. ⁽²⁾ Parts II.2 and II.3 of this certificate only applies to species susceptible to one or more of the diseases referred to in the heading of the part concerned. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC. ⁽³⁾ Consignments of ornamental aquatic animals may be imported regardless of the requirements in Parts II.2 and II.3 if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC. ⁽⁴⁾ To be authorised into the Union one of these statements must be kept if the consignments contain species susceptible to EHN, <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i>, <i>Mikrocytos mackini</i>, Taura syndrome and/or Yellowhead disease. ⁽⁵⁾ To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, <i>Marteilia refringens</i>, <i>Bonamia ostreae</i>, or Whitespot disease or with a surveillance or eradication programme drawn up 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 surveillance or eradication programme(s) apply(ies). Data on the disease status in different parts of the Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm ⁽⁶⁾ Part II.5 of this certificate only applies to consignments intended for a Member State or part thereof which is regarded as disease-free, or for which an programme is approved by Decision 2010/221/EU as regards SVC, BKD, IPN or GS, and the consignment comprises species listed in Part C of Annex II as susceptible to the disease(s) for which the disease-free status or programme(s) apply(ies). Part II.5 also applies to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with GS, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of GS. Consignments of ornamental aquatic animals for which SVC, IPN and/or BKD related requirements are applicable, may be imported regardless of the requirements in Part II.5 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC. — The colour of the stamp and signature must be different to that of the other particulars in the certificate.		

COUNTRY**Ornamental aquatic animals intended for closed ornamental facilities**

II. Health information	II.a. Certificate reference number	II.b.
Official inspector Name (in capital letters): Date: Stamp: Qualification and title: Signature:'		

COMMISSION IMPLEMENTING REGULATION (EU) No 1013/2012**of 5 November 2012****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 5 November 2012.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	AL	43,2
	MA	38,2
	MK	36,1
	TR	53,3
	ZZ	42,7
0707 00 05	AL	31,8
	TR	82,1
	ZZ	57,0
0709 93 10	TR	116,3
	ZZ	116,3
0805 20 10	PE	54,9
	ZA	158,5
	ZZ	106,7
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	HR	62,5
	TR	85,3
	UY	101,2
	ZA	180,3
	ZZ	107,3
0805 50 10	AR	60,7
	TR	83,5
	UY	56,9
	ZA	99,3
	ZZ	75,1
0806 10 10	BR	275,4
	PE	307,5
	TR	172,2
	US	362,2
	ZZ	279,3
0808 10 80	CL	150,4
	CN	91,3
	MK	34,4
	NZ	164,0
	ZA	136,0
0808 30 90	ZZ	115,2
	CN	66,2
	TR	109,1
	ZZ	87,7

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION DELEGATED DECISION

of 29 June 2012

on investigations and fines related to the manipulation of statistics as referred to in Regulation (EU) No 1173/2011 of the European Parliament and of the Council on the effective enforcement of budgetary surveillance in the euro area

(2012/678/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1173/2011 of the European Parliament and of the Council of 16 November 2011 on the effective enforcement of budgetary surveillance in the euro area ⁽¹⁾, and in particular Article 8(4) thereof,

Whereas:

- (1) Regulation (EU) No 1173/2011 sets out a system of sanctions for enhancing the enforcement of the preventive and corrective parts of the Stability and Growth Pact in the euro area. It applies to Member States whose currency is the euro.
- (2) The availability of sound fiscal data is essential for budgetary surveillance in the euro area. In order to guarantee sound and independent statistics, Member States should ensure the principle of professional independence of national statistical authorities in conformity with Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics ⁽²⁾, and as further set out in the European Statistics Code of Practice.
- (3) Regulation (EU) No 1173/2011 empowers the Commission to survey the economic and monetary cooperation with a view to detecting and exposing manipulation of general government deficit and debt data relevant for the application of the multilateral surveillance system and the excessive deficit procedure.
- (4) For that purpose, the Commission should conduct all necessary investigations to confirm the existence of

misrepresentations of actual deficit and debt data, as a result of intent or serious negligence, as referred to in Article 8(1) of Regulation (EU) No 1173/2011.

- (5) It is necessary to establish the detailed rules concerning the procedures for investigations, detailed criteria establishing the amount of the fine, detailed rules guaranteeing the rights of the defence, access to the file, legal representation, confidentiality, and provisions as to the timing and collection of fines.
- (6) A decision by the Commission to launch investigations should be justified, and the investigations undertaken should be proportionate so as not to go beyond what is necessary to establish the possible existence of manipulation of the relevant deficit and debt data.
- (7) When undertaking such investigations, the Commission should be able to conduct on-site inspections and request information from any entity to be classified in the general-government sector, whether at central, State, local or social-security level, in accordance with Council Regulation (EC) No 2223/96 of 25 June 1996 on the European system of national and regional accounts in the Community ⁽³⁾, hereinafter referred to as 'ESA 95'.
- (8) In order to confirm a suspicion following serious indications of misrepresentation of the relevant deficit and debt data, the launch of an investigation should normally be preceded by a methodological visit conducted by the Commission (Eurostat) in accordance with Article 11b of Council Regulation (EC) No 479/2009 of 25 May 2009 on the application of the Protocol on the excessive deficit procedure annexed to the Treaty establishing the European Community ⁽⁴⁾.
- (9) In assessing what constitutes a misrepresentation of deficit and debt data within the meaning of Regulation (EU) No 1173/2011, incorrect implementation of ESA 95 accounting rules which is not the result of either

⁽¹⁾ OJ L 306, 23.11.2011, p. 1.

⁽²⁾ OJ L 87, 31.3.2009, p. 164.

⁽³⁾ OJ L 310, 30.11.1996, p. 1.

⁽⁴⁾ OJ L 145, 10.6.2009, p. 1.

intent or serious negligence should not be considered as such. Further excluded from the application of this Decision should be revisions, including major revisions due to changes in methodology for all historical years, that are clearly and adequately explained, insignificant mistakes and cases where a doubt has been expressed by the Member State concerned and clarification has been requested from the Commission (Eurostat) in accordance with Article 10 of Regulation (EC) No 479/2009.

- (10) Users of European statistics have a legitimate expectation that they are produced by statistical authorities that conduct their activities professionally and with due diligence. An unintentional act or omission should be considered a case of serious negligence if a person responsible for the production of general government deficit and debt data is in patent breach of his duty of care.
- (11) For the purpose of its defence, the Member State concerned should be duly notified of the opening of as well as of the results of the Commission investigations. The results of the investigations should be communicated by means of a Commission report to be transmitted to the European Parliament and to the Council, and to be made public. The Commission (Eurostat) should keep the European Statistical System Committee and the European Statistical Governance Advisory Board appropriately informed.
- (12) The rights of defence and the principle of confidentiality should be respected in accordance with the general principles of law and the case-law of the Court of Justice of the European Union. In particular, the Member State concerned should have the right to be heard by the Commission during the investigations, as well as to access the file compiled by the Commission.
- (13) Recommendations to the Council to impose a fine should be based exclusively on grounds on which the Member State concerned has been able to comment.
- (14) Criteria determining the amount of the fine should be established. These criteria should be used to ensure that the fine proposed is fixed at an appropriate level, making it effective, proportionate and dissuasive, based on a reference amount adapted upwards or downwards where necessary in the light of specific circumstances.
- (15) This Decision should be without prejudice to the Commission (Eurostat) exercising its powers under Regulation (EC) No 479/2009.
- (16) The content and form of the measures laid down in this Decision do not exceed what is necessary to achieve the

objectives established in Regulation (EU) No 1173/2011, in accordance with Article 5 of the Treaty on European Union.

- (17) This Decision should apply without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ⁽¹⁾,

HAS ADOPTED THIS DECISION:

CHAPTER I

SUBJECT MATTER AND SCOPE

Article 1

Subject matter and scope

1. This Decision lays down detailed rules concerning the procedures for investigating misrepresentations of general government deficit and debt data that are the result of intent or serious negligence, detailed rules concerning the right of defence and confidentiality, detailed criteria establishing the amount of the fine and provisions as to the timing and collection of the fines referred to in Article 8(1) of Regulation (EU) No 1173/2011.

2. This Decision shall apply to Member States whose currency is the euro.

CHAPTER II

PROCEDURES FOR INVESTIGATIONS

Article 2

Initiation of the investigations

1. The Commission shall notify the Member State concerned of its decision to initiate an investigation, including information of the serious indications found of the existence of facts liable to constitute a misrepresentation of general government deficit and debt data arising from the manipulation of such data as a result of either intent or serious negligence.

2. During an investigation, the Commission (Eurostat) may request information, interview persons, conduct on-site inspections and accede to the accounts of all government entities at central, State, local and social security level, in accordance with the procedures laid down in Articles 3 to 5. Those means of investigation may be employed by the Commission (Eurostat), either individually or in combination. Where relevant and while fully respecting national rules governing such institutions, the court of auditors or other supreme audit institutions of the Member State concerned may be invited to assist and participate.

⁽¹⁾ OJ L 145, 31.5.2001, p. 43.

3. The Commission may opt not to conduct such an investigation until a methodological visit has been carried out in accordance with a decision taken by the Commission (Eurostat) under Regulation (EC) No 479/2009.

4. The Commission shall inform the European Parliament and the Council of its decision to initiate an investigation.

Article 3

Request for information

1. At the request of the Commission, any government entity, directly or indirectly involved in compiling debt and deficit data of the Member State concerned, or whose accounts are used for this compilation (hereinafter referred to as 'the entity concerned') shall provide the Commission with all necessary information to perform its task of investigation. The Member State concerned shall be informed about any such request by the Commission to the entity concerned.

2. The Commission shall state the purpose of the request, specifying that the request is made pursuant to this Decision, and shall indicate a deadline for the reply, which shall be no less than four weeks.

Article 4

Interviews

The Commission may interview any person directly or indirectly involved in compiling deficit and debt data, who agrees to be interviewed, for the purpose of collecting information or explanations concerning facts or documents relating to the subject matter of an investigation and to record the answers. The entity concerned shall be informed before any of its representatives or members of staff are interviewed. The person interviewed may request the assistance of a representative of the entity concerned or of a legal counsel.

Article 5

Inspections

1. The Commission officials and other accompanying persons authorised by the Commission to conduct an inspection shall be empowered to:

- (a) enter any premises of the entity concerned;
- (b) accede all records and accounts of the entity concerned, irrespective of the medium on which they are stored;
- (c) take or obtain any form of copy or extract of any records and accounts;
- (d) seal any records and accounts to the extent and for the period of time necessary to compile the factual evidence for the investigation while not hampering the essential activities of the entity concerned;

(e) ask any representative or member of staff of the entity concerned for explanations on facts or documents relating to the subject matter and purpose of the inspection, under the conditions laid down in Article 4.

2. The Commission officials and other accompanying persons authorised by the Commission to conduct an inspection shall present a written authorisation specifying the subject matter and purpose of the inspection, stating the date on which the inspection begins.

3. The entity concerned shall fully cooperate with the Commission for the purposes of the inspection.

4. Staff members of statistical authorities of the Member State concerned shall, at the request of the Commission, actively assist the officials and other accompanying persons authorised by the Commission. To this end, they shall enjoy the powers specified in paragraph 1.

5. Where the Commission officials and other accompanying persons authorised by the Commission find that an entity opposes an inspection ordered pursuant to this Article, the Member State concerned shall provide them the necessary assistance according to national rules.

6. If, by national rules, the authorisation from a judicial authority is necessary for the conduct of the inspection, such authorisation shall be applied for by the Commission. In those cases the authorisation from a judicial authority shall be presented along with the written authorisation referred to in paragraph 2.

Article 6

Right to be heard

Before adoption of the report referred to in Article 7, the Commission shall invite the Member State concerned to submit written observations on the preliminary findings.

It shall do so in writing, indicating a deadline for the submission of those observations, which shall be no less than four weeks.

Article 7

Reporting

1. The Commission shall adopt a report presenting its findings and the observations submitted by the Member State concerned in the light of the investigations conducted in accordance with this Chapter and submit it to that Member State.

2. The Commission shall transmit this report to the European Parliament and the Council. This report shall be made public.

3. The Commission (Eurostat) shall inform the European Statistical System Committee and the European Statistical Governance Advisory Board about the outcome of the investigation.

4. Any Commission recommendation to the Council to impose a fine on the Member State concerned shall be based on the report referred to in paragraph 1.

Article 8

Duration

1. The Commission shall adopt the report referred to in Article 7 no later than 10 months after notification of its decision to initiate an investigation according to Article 2. In exceptional cases, where the investigations are obstructed or where the acquisition of the information necessary for the investigations involves excessively long procedures, the Commission may extend the deadline by five months.

2. The inspections shall be completed within six months of the starting date of the inspection. In exceptional cases, where the inspections are obstructed or where the acquisition of the information in connection with the inspections involves excessively long procedures, the Commission may extend the deadline by three months.

CHAPTER III

RIGHT OF DEFENCE AND CONFIDENTIALITY

Article 9

Right of defence

The principle of the right of defence shall apply to any implementation of this Decision.

Article 10

Access to the file

The Member State concerned shall have the right, on request, to access all documents and other factual materials compiled by the Commission which could serve as supporting evidence for the recommendation to the Council to impose the said Member State a fine.

Documents obtained by the Member State concerned through access to the file shall be used solely for the purposes of this Decision.

Article 11

Legal representation

The Member State concerned, any entity concerned, any person working for such an entity or any other natural person concerned shall have the right to legal representation during the investigations.

Article 12

Confidentiality and professional secrecy

The investigations set out in Chapter II shall be conducted subject to the principles of confidentiality and professional secrecy. The Commission officials and other accompanying persons authorised by the Commission shall not disclose information that is acquired in the framework of the investigation which is covered by the obligation of professional secrecy and confidentiality.

Documents or information obtained by the Commission in the course of the investigations shall be used solely for the purposes of this Decision.

CHAPTER IV

CRITERIA FOR ESTABLISHING THE AMOUNT OF THE FINE

Article 13

Maximum amount

The total amount of the fine shall not exceed 0,2 % of the latest official gross domestic product at current market prices of the Member State concerned, as defined in ESA 95, in the preceding year.

Article 14

Criteria with regard to the amount of the fine

1. The Commission shall ensure that the fine to be recommended is effective, proportionate and dissuasive. The fine shall be established on the basis of a reference amount that may be modulated upwards or downwards when taking into account the specific circumstances referred to in paragraph 3.

2. The reference amount shall be equal to 5 % of the larger impact of the misrepresentation on the level of either the general government deficit or debt of the Member State for the relevant years covered by the notification in the context of the excessive deficit procedure.

3. Taking into account the maximum amount established in Article 13, the Commission shall in each case take into consideration, where relevant, the following circumstances:

- (a) the seriousness and the wider effects of the misrepresentation; in particular, the impact of the misrepresentation on the functioning of the strengthened economic governance of the Union;
- (b) the fact that the misrepresentation has been shown to be the result of serious negligence or, alternatively, the misrepresentation has been shown to be intentional;

- (c) the fact that the misrepresentation was the work of one entity acting alone or, alternatively, the misrepresentation was the result of a concerted action by two or more entities;
- (d) the repetition, frequency or duration of the misrepresentation by the Member State concerned; in such cases, the reference amount shall be the highest magnitude detected and shall be multiplied by the number of years, across the four years of the last notification, in which the relevant misrepresentation occurred;
- (e) the degree of diligence and cooperation, alternatively the degree of obstruction, shown by the Member State concerned in the detection of the misrepresentation and in the course of the investigations.

Article 15

Limitation period for the collection of fines

1. The right of the Commission to enforce decisions taken by the Council pursuant to Article 8(1) of Regulation (EU) No 1173/2011 shall be exercised within a period of five years.
2. The period shall begin to run on the day on which the Member State concerned is notified of the decision of the Council.

3. The limitation period for the recovery of fines shall be interrupted by any action of the Commission designed to enforce payment of the fine or shall be suspended for so long as enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union.

CHAPTER V

FINAL PROVISION

Article 16

Entry into force

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

Done at Brussels, 29 June 2012.

For the Commission

The President

José Manuel BARROSO

COMMISSION IMPLEMENTING DECISION

of 31 October 2012

approving restrictions of authorisations of biocidal products containing difenacoum notified by Germany in accordance with Article 4(4) of Directive 98/8/EC of the European Parliament and of the Council

*(notified under document C(2012) 7568)***(Only the German text is authentic)**

(2012/679/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽¹⁾, and in particular Article 4(4) thereof,

Whereas:

- (1) Annex I to Directive 98/8/EC contains the list of active substances approved at Union level for inclusion in biocidal products. The active substance difenacoum was approved for inclusion in products belonging to product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC, by Commission Directive 2008/81/EC of 29 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum as an active substance in Annex I thereto⁽²⁾.
- (2) Difenacoum is an anticoagulant rodenticide known to pose risks of accidental incidents with children, as well as risks for animals and the environment. It has been identified as potentially persistent, liable to bioaccumulate and toxic ('PBT'), or very persistent and very liable to bioaccumulate ('vPvB').
- (3) For reasons of public health and hygiene, it was nevertheless found to be justified to include difenacoum and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise difenacoum-based products. However, Directive 2008/81/EC obliges Member States to ensure, when granting authorisation of products containing difenacoum, that primary as well as secondary exposure of humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures. The risk mitigation measures mentioned in Directive 2008/81/EC therefore include, amongst others, restriction to professional use only.
- (4) The company Lodi S.A.S. ('the applicant') has, in accordance with Article 8 of Directive 98/8/EC,

submitted an application to Ireland for authorisation of two rodenticides containing difenacoum ('the products'). The products' names and reference numbers in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this Decision.

- (5) Ireland granted the authorisations on 1 July 2011. The products were authorised with restrictions to ensure the conditions of Article 5 of Directive 98/8/EC were met in Ireland. Those restrictions did not include restriction to trained or licensed professional users.
- (6) On 30 March 2010, the applicant submitted a complete application to Germany for mutual recognition of the first authorisations in respect of the products.
- (7) On 7 February 2012, Germany notified the Commission, the other Member States and the applicant of its proposal to restrict the first authorisations in accordance with Article 4(4) of Directive 98/8/EC. Germany proposed to impose a restriction on the products to use by trained or licensed professionals.
- (8) The Commission invited the other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. No comments were submitted within that deadline. The notification was also discussed between Commission representatives, representatives of Member States' Competent Authorities for biocidal products in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 22-23 May 2012.
- (9) The Commission notes that, in accordance with Directive 2008/81/EC, authorisations of biocidal products containing difenacoum are to be subject to all appropriate and available risk mitigation measures, including the restriction to professional use only. The scientific evaluation leading to the adoption of Directive 2008/81/EC concluded that only professional users could be expected to follow the instructions minimising the risk of secondary poisoning of non-target animals, and to use products in a way that prevents the development and spreading of resistance. A restriction to professional users should therefore in principle be considered to be an appropriate risk mitigation measure, in particular in Member States where resistance to difenacoum occurs.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 201, 30.7.2008, p. 46.

- (10) In the absence of any indication to the contrary, the Commission therefore considers that restriction to professional users is an appropriate and available risk mitigation measure for the authorisation of products containing difenacoum in Germany. This conclusion is reinforced by the arguments put forward by Germany that resistance against difenacoum in rats has been found and is thought to be developing in the country, and that the country has a well-functioning infrastructure of trained pest control operators and licensed professionals, such as farmers, gardeners and foresters who received professional training, which means that the proposed restriction does not hinder infection prevention.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Germany may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC for the products mentioned in the Annex to this Decision to use by trained or licensed professionals.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 31 October 2012.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

Products for which Germany may restrict the authorisations granted in accordance with Article 4 of Directive 98/8/EC to use by trained or licensed professionals:

Product name in Ireland	Irish application reference number in R4PB	Product name in Germany	German application reference number in R4PB
Ruby Block	2010/6249/5607/IE/AA/6647	Rubis Bloc	2010/6249/5607/DE/MA/6893
Ruby Paste	2010/6249/5586/IE/AA/6645	Rubis Pasta	2010/6249/5586/DE/MA/6765

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