

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1096**of 6 July 2016****amending Regulation (EC) No 1251/2008 as regards the requirements for placing on the market of consignments of certain fish species intended for the Member States or parts thereof with national measures for salmonid alphavirus (SAV) approved by Decision 2010/221/EU****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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 43 and Article 61(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1251/2008 ⁽²⁾ lays down conditions and certification requirements for the placing on the market and the import of aquaculture animals in Member States or parts thereof which are subject to national measures approved by Commission Decision 2010/221/EU ⁽³⁾.
- (2) Decision 2010/221/EU, allows the Member States listed in Annex I or II thereto to impose requirements for the placing on the market and the import of fish species susceptible to salmonid alphavirus (SAV) into areas regarded as free of that disease or covered by an approved surveillance programme. Consignments of fish of species susceptible to SAV intended for farming, relaying areas, put and take fisheries, open ornamental facilities and restocking, introduced into such Member States or parts thereof, should originate from areas with an equivalent health status and be accompanied by an animal health certificate certifying compliance with those requirements.
- (3) In order to ensure that those requirements are complied with, it is appropriate to include a reference to SAV in in the model health certificate set out in Part A of Annex II to Regulation (EC) No 1251/2008.
- (4) Part C of Annex II to Regulation (EC) No 1251/2008 lists species susceptible to diseases for which national measures are approved under Decision 2010/221/EU. The Aquatic Animal Health Code (Aquatic Code) and the Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual) adopted by the World Animal Health Organisation (OIE) currently list Atlantic Salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*) and brown trout (*Salmo trutta*) as species susceptible to SAV. In the interest of legal clarity with regard to the scope of Regulation (EC) No 1251/2008, a reference to SAV and to the fish species susceptible to that virus should be included in Part C of Annex II to that Regulation.
- (5) Regulation (EC) No 1251/2008 should therefore be amended accordingly.
- (6) It is appropriate to allow Member States and the industry sufficient time to take the measures necessary to comply with the requirements laid down in this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 328, 24.11.2006, p. 14.

⁽²⁾ 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 list of vector species (OJ L 337, 16.12.2008, p. 41).

⁽³⁾ Commission Decision 2010/221/EU of 15 April 2010 approving national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Council Directive 2006/88/EC (OJ L 98, 20.4.2010, p. 7).

HAS ADOPTED THIS REGULATION:

Article 1

Parts A and C of Annex II to Regulation (EC) No 1251/2008 are replaced by the text set out in the Annex to this Regulation.

Article 2

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

It shall apply from 1 October 2016.

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

Done at Brussels, 6 July 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex II to Regulation (EC) No 1251/2008 is amended as follows:

(1) Part A is replaced by the following:

PART A

Model animal health certificate for the placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking

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Intra trade certificate

Part I: Details of consignment presented	I.1. Consignor Name Address Postal code			I.2. Certificate reference No	I.2.a. Local reference No	
				I.3. Central competent authority		
				I.4. Local competent authority		
	I.5. Consignee Name Address Postal code			I.6.		
				I.7.		
	I.8. Country of origin	ISO code	I.9.	I.10. Country of destination	ISO code	I.11.
	I.12. Place of origin Approved aquaculture holding <input type="checkbox"/> Other <input type="checkbox"/> Name Approval number Address Postal code			I.13. Place of destination Approved aquaculture holding <input type="checkbox"/> Other <input type="checkbox"/> Name Approval number Address Postal code		
	I.14. Place of loading Postal code			I.15. Date and time of departure		
	I.16. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification			I.17. Transporter Name Approval number Address Postal code Member State		
	I.18. Description of commodity				I.19. Commodity code (HS code)	
				I.20. Quantity		
I.21.				I.22. Number of packages		
I.23. Seal/Container No				I.24. Type of packaging		

I.25. Commodities certified for:	
Breeding <input type="checkbox"/> Game restocking <input type="checkbox"/> Relaying <input type="checkbox"/> Pets <input type="checkbox"/> Quarantine <input type="checkbox"/> Other <input type="checkbox"/>	
I.26. Transit through third country <input type="checkbox"/>	I.27. Transit through Member States <input type="checkbox"/>
Third country ISO code	Member State ISO code
Exit point Code	Member State ISO code
Entry point BIP No	Member State ISO code
I.28. Export <input type="checkbox"/>	I.29.
Third country ISO code	
Exit point Code	
I.30.	
I.31. Identification of the commodities	
Species (Scientific name)	Quantity

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Part II: Certification	II. Health information	II.a. Certificate reference No	II.b.
	<p>II.1 General requirements</p> <p>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to in Part I of this certificate:</p> <p>II.1.1 <i>either</i> (1) [have been inspected within (1) (2) [72] (1) [24] hours of loading, and showed no clinical signs of disease]</p> <p><i>or</i> (1) [in the case of eggs and molluscs, come from a farm or mollusc farming area where, according to the records of the farm or mollusc farming area, there is no indication of disease problems]</p> <p><i>or</i> (1) (3) [in the case of wild aquatic animals, according to the best of my knowledge and belief are clinically healthy];</p> <p>II.1.2 are not subject to any prohibitions due to unresolved increased mortality;</p> <p>II.1.3 are not intended for destruction or slaughter for the eradication of diseases;</p> <p>II.1.4 comply with the requirements for placing on the market laid down in Directive 2006/88/EC;</p> <p>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.]</p> <p>II.2 (1) (4) (5) [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</p> <p>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:</p> <p><i>either</i> (1) (6) [originate from a Member State, 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.]</p> <p><i>or</i> (1) (5) (6) [in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]</p> <p>II.3 (1) (7) [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</p> <p>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:</p> <p><i>either</i> (1) (6) [originate from a Member State, 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.]</p> <p><i>or</i> (1) (6) (7) [have been subject to quarantine in accordance with Decision 2008/946/EC.]]</p> <p>II.4 Transport and labelling requirements</p> <p>I, the undersigned official inspector, hereby certify that:</p> <p>II.4.1 the aquaculture animals referred to above,</p> <p>(i) are placed under conditions, including with a water quality, that do not alter their health status,</p> <p>(ii) as appropriate, comply with the general conditions for the transport of animals laid down in Article 3 of Regulation (EC) No 1/2005;</p>		

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II.4.2	the transport container or well boat prior to loading 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, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 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'],		
	<i>or</i> (1) [(1) [Wild] (1) [Molluscs] intended for relaying in the European Union'],		
	<i>or</i> (1) [(1) [Wild] (1) [Fish] (1) [Molluscs] (1) [Crustaceans] intended for put and take fisheries in the European Union'],		
	<i>or</i> (1) [(1) [Wild] (1) [Ornamental fish] (1) [Ornamental molluscs] (1) [Ornamental crustaceans] intended for open ornamental facilities in the European Union'],		
	<i>or</i> (1) [(1) [Fish] (1) [Molluscs] (1) [Crustaceans] intended for restocking in the European Union'],		
	<i>or</i> (1) [(1) [Wild] (1) [Fish] (1) [Molluscs] (1) [Crustaceans] intended for quarantine in the European Union'],		
II.5	(1) (8) [Attestation for consignments originating from an area subject to disease control measures as provided for in Section 3 to 6 of Chapter V of Directive 2006/88/EC]		
	I, the undersigned official inspector, hereby certify that:		
II.5.1	the animals referred to above originate from an area subject to disease control measures regarding (1) [Epizootic haematopoietic necrosis (EHN)] (1) [Viral haemorrhagic septicaemia (VHS)] (1) [Infectious haematopoietic necrosis (IHN)] (1) [Infectious salmon anaemia (ISA)] (1) [Koi herpes virus (KHV)] (1) [Bonamia exitiosa] (1) [Perkinsus marinus] (1) [Mikrocytos mackini] (1) [Martellia refringens] (1) [Bonamia ostreae] (1) [Taura syndrome] (1) [Yellowhead disease] (1) [White spot disease] (1) (9) [the following emerging disease:];		
II.5.2	the animals referred to above are allowed to be placed on the market according to the control measures laid down; and		
II.5.3	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.8 to I.13 of Part I of this certificate, and the following statement:		
	'(1) [Wild] (1) [Fish] (1) [Molluscs] (1) [Crustaceans] originating from an area subject to disease control measures.'		
II.6	(1) (10) [Requirements for species susceptible to Spring vireamia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN), Infection with Gyrodactylus salaris (GS) and Infections with salmonid alphavirus (SAV)]		
	I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,		
	<i>either</i> (1) [originate from a Member State or part thereof:		
	(a) where (1) [SVC] (1) [GS] (1) [BKD] (1) [IPN] (1) [SAV] are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,		
	(b) where all aquaculture animals of species susceptible to the relevant diseases introduced into that Member State or part thereof comply with the requirements set out in II.6 of this certificate,		
	(c) where species susceptible to the relevant diseases are not vaccinated against the relevant diseases, and		

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	<p>(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.]</p> <p><i>and/or</i> (1) [which, in the case of (1) [SVC] (1) [GS] (1) [SAV], comply with requirements for disease freedom laid down in the relevant OIE Standard.]</p> <p><i>and/or</i> (1) [which, in the case of (1) [SVC] (1) [IPN] (1) [BKD] (1) [SAV], comprises one individual farm which under the supervision of the competent authority:</p> <p>(i) has been emptied, cleansed and disinfected, and fallowed in at least 6 weeks,</p> <p>(ii) has been restocked with animals from areas certified free from the relevant disease by the competent authority.]]</p> <p><i>and/or</i> (1) [in the case of wild aquatic animals susceptible to (1) [SVC] (1) [IPN] (1) [BKD] (1) [SAV], have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]</p> <p><i>and/or</i> (1) [in the case of consignments for which GS requirements apply, have been held, immediately prior to the placing on the market, 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.]</p> <p><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.]]</p>		
II.7	<p>(1) ⁽¹¹⁾ [Requirements for species susceptible to OshV-1 µvar</p> <p>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,</p> <p><i>either</i> (1) [originate from a Member State or compartment:</p> <p>(a) where OshV-1 µvar is notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,</p> <p>(b) where all aquaculture animals of species susceptible to OshV-1 µvar introduced into that Member State or compartment comply with the requirements set out in II.7 of this certificate,</p> <p>(c) <i>either</i> (1) [which comply with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC.]</p> <p><i>and/or</i> (1) [in the case of consignments intended for a Member State or compartment covered by a programme approved by Decision 2010/221/EU, which itself is also covered by a surveillance programme approved by Decision 2010/221/EU,]]</p> <p><i>and/or</i> (1) [have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]]</p>		
Notes			
Part I:			
— Box I.12: If appropriate, use the authorisation number for the farm or mollusc farming area in question. Use 'other' if wild aquatic animals.			
— Box I.13: If appropriate, use the authorisation number for the farm or mollusc farming area in question. Use 'other' if intended for restocking.			
— Box I.19: Use the appropriate HS codes: 0301, 0306, 0307, 030110 or 030270.			
— Box I.20 and I. 31: As regards quantity, give the total number.			
— Box I.25: Use the option 'Breeding' if intended for farming, 'Relaying' if intended for relaying, 'Pets' if intended for open ornamental facilities, 'Game restocking' if intended for restocking, 'Quarantine' if the aquaculture animals are intended for a quarantine facility, and 'Other' if intended for put and take fisheries.			

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II. Health information	II.a. Certificate reference No	II.b.
<p>Part II:</p> <p>(¹) Keep as appropriate.</p> <p>(²) The 24-hour option applies only to consignments of aquaculture animals which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive. In all other cases the 72-hour option applies.</p> <p>(³) Only applicable to consignments of aquaculture animals caught in the wild and immediately transported to a farm or mollusc farming area without any temporary storage.</p> <p>(⁴) Part II.2 of this certificate applies to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC.</p> <p>(⁵) Consignments of wild aquatic animals may be placed on the market regardless of the requirements in Part II.2 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> <p>(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 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 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</p> <p>(⁷) Part II.3 of this certificate applies to vector species to one or more of the diseases referred to in the title. 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 placed on the market regardless of the requirements in Part II.3 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.</p> <p>(⁸) Part II.5 of this certificate applies to consignments of aquaculture animals which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive.</p> <p>(⁹) Applicable when measures are taken in accordance with Article 41 of Directive 2006/88/EC.</p> <p>(¹⁰) Part II.6 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 in accordance with Decision 2010/221/EU as regards SVC, BKD, IPN, GS or SAV, 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).</p> <p>Part II.6 shall also apply 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.</p> <p>Consignments of wild aquatic animals for which SVC, SAV, IPN and/or BKD related requirements are applicable, may be placed on the market regardless of the requirements in Part II.6 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p>		

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II. Health information	II.a. Certificate reference No	II.b.
<p>(¹¹) Part II.7 of this certificate only applies to consignments intended for a Member State or compartment which is regarded as disease-free, or for which a programme is approved by Decision 2010/221/EU as regards OsHV-1 μvar, and the consignment comprises species listed in Part C of Annex II to Regulation (EC) No 1251/2008 as susceptible to OsHV-1 μvar.</p> <p>The requirements set out in part II.7 shall not apply to consignments intended for a quarantine facility complying with the requirements at least equivalent to those laid down in Decision 2008/946/EC.</p>		
<p>Official veterinarian or official inspector</p> <p>Name (in capital letters):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp: ' _____</p> <p>Qualification and title:</p> <p>LVU No:</p> <p>Signature:</p>		

(2) Part C is replaced by the following:

PART C

List of species susceptible to diseases for which national measures are approved under Decision 2010/221/EU

Disease	Susceptible species
Spring Viraemia of Carp (SVC)	Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), grass carp (<i>Ctenopharyngodon idellus</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), sheatfish (<i>Silurus glanis</i>), and tench (<i>Tinca tinca</i>), Orfe (<i>Leuciscus idus</i>)
Bacterial kidney disease (BKD)	Family: <i>Salmonidae</i>
Infectious pancreatic necrosis virus (IPN)	Rainbow trout (<i>Oncorhynchus mykiss</i>), brook trout (<i>Salvelinus fontinalis</i>), brown trout (<i>Salmo trutta</i>), Atlantic salmon (<i>Salmo salar</i>) and (<i>Oncorhynchus spp.</i>), whitefish (<i>Coregonus lavaretus</i>)
Infection with salmonid alphavirus (SAV)	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), brown trout (<i>Salmo trutta</i>)
Infection with <i>Gyrodactylus salaris</i>	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), Arctic char (<i>Salvelinus alpinus</i>), North American brook trout (<i>Salvelinus fontinalis</i>), grayling (<i>Thymallus thymallus</i>), North American lake trout (<i>Salvelinus namaycush</i>) and brown trout (<i>Salmo trutta</i>).
Ostreid herpesvirus 1 μ var (OsHV-1 μ var)	Pacific oyster (<i>Crassostrea gigas</i>)