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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals[(1)], and in particular Article 17(2), Articles 22 and 25 and Article 61(3) thereof,

Whereas:

(1) Directive 2006/88/EC lays down the animal health requirements to be applied for the placing on the market and the import and the transit through the Community of aquaculture animals and products thereof. Directive 2006/88/EC repeals and replaces Council Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products[(2)] from 1 August 2008.

(2) According to Directive 2006/88/EC aquaculture animal means any aquatic animal, including ornamental aquatic animals, at all its life stages, including eggs and sperm/ gametes, reared in a farm or mollusc farming area, including any aquatic animal from the wild intended for a farm or mollusc farming area. Aquatic animals mean fish, molluscs and crustaceans.

(3) Commission Decision 1999/567/EC of 27 July 1999 laying down the model of the certificate referred to in Article 16(1) of Directive 91/67/EEC[(3)] and Commission Decision 2003/390/EC of 23 May 2003 establishing special conditions for placing on the market of aquaculture animals species considered not susceptible to certain diseases and the products thereof[(4)] lay down certain rules for the placing on the market of aquaculture animals, including certification requirements. Commission Decision 2003/804/EC of 14 November 2003 laying down the animal health conditions and certification requirements for imports of molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption[(5)], Commission Decision 2003/858/EC of 21 November 2003 laying down the animal health conditions and

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 1251/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

certification requirements for introduction of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption[(6)] and Commission Decision 2006/656/EC of 20 September 2006 laying down the animal health conditions and certification requirements for imports of fish for ornamental purpose[(7)] lay down conditions for imports of aquaculture animals into the Community. Those Decisions implement Directive 91/67/EEC.

(4) Directive 2006/88/EC provides that the placing on the market of aquaculture animals is to be subject to animal health certification when the animals are introduced into a Member State, zone or compartment declared disease-free in accordance with that Directive or subject to a surveillance or eradication programme. Accordingly, it is appropriate to lay down certification requirements and harmonised model animal health certificates in this Regulation to replace the certification requirements laid down under Directive 91/67/EEC and the Decisions implementing that Directive.

(5) 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[(8)] lays down specific rules on the hygiene of food of animal origin for food business operators, including packaging and labelling requirements. The animal health certification requirements provided for in the present Regulation for the placing on the market and import of aquaculture animals and products thereof intended for further processing before human consumption should not apply to those animals and products packed and labelled in accordance with Regulation (EC) No 853/2004, subject to certain conditions.

(6) Directive 2006/88/EC provides that Member States are to ensure that the placing on the market of ornamental aquatic animals does not jeopardise the health status of aquatic animals with regard to non-exotic diseases listed in Part II of Annex IV thereto.

(7) Ornamental aquatic animals placed on the market in the Community and intended for facilities without any direct contact with natural waters, namely closed ornamental facilities, do not pose the same risks to other sectors of Community aquaculture or to wild stocks. Accordingly, animal health certification should not be required under this Regulation for such animals.

(8) In order to provide Member States, where the entire territory, or certain zones or compartments thereof, are declared free of one of more of the non-exotic diseases for which ornamental aquatic animals are susceptible, with information on the movements into their territory of ornamental aquatic animals intended for closed ornamental facilities, it is appropriate that such movements are notified through the Traces system as provided for in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market[(9)] and introduced by Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system[(10)].

(9) Movements within the Community from closed ornamental facilities to open ornamental facilities or into the wild, may represent a high risk to other sectors of Community aquaculture, and should not be allowed without the authorisation of the competent authorities of the Member States.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 1251/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(10) Directive 2006/88/EC provides that Member States are to take certain minimum control measures in the event of confirmation of an exotic or non-exotic disease listed in Part II of Annex IV thereto in aquaculture animals or wild aquatic animals or in the case of emerging diseases. In addition, that Directive provides that Member States are to ensure that the placing on the market of aquaculture animals is subject to animal health certification when the animals are allowed to leave an area subject to those control measures.

(11) Accordingly, this Regulation should lay down animal health conditions and certification requirements for consignments of aquaculture animals and products thereof leaving Member States, zones or compartments subject to disease control measures.

(12) Directive 2006/88/EC provides that Member States are to ensure that aquaculture animals and products thereof are introduced into the Community only from third countries or parts thereof that appear on a list drawn up in accordance with that Directive.

(13) Imports into the Community of aquaculture animals should only be permitted from third countries that have animal health legislation and control system equivalent to those in the Community. Accordingly, this Regulation should establish a list of third countries, territories, zones or compartments, from which Member States are permitted to introduce into the Community aquaculture animals for farming, relaying areas, put and take fisheries and open ornamental facilities. However, the import into the Community of certain ornamental fish, molluscs and crustaceans intended for closed ornamental facilities should be permitted from third countries that are members of the World Organisation for Animal Health (OIE).

(14) Third countries and territories which are allowed to export to the Community aquaculture animals for human consumption based on public health considerations should also be allowed to export to the Community under the animal health provisions of this Regulation. Aquaculture animals and products thereof intended for human consumption should therefore only be imported into the Community from third countries, territories, zones or compartments which are included on a list drawn up in accordance with Article 11(1) of 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[(11)].

(15) Such lists are set out in Annexes I and II to Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted[(12)] and, for a transitional period until 31 December 2009, by Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[(13)]. In the interest of consistency of Community legislation, those lists should be taken into account in this Regulation.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 1251/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(16) Directive 2006/88/EC provides that import of aquaculture animals and products thereof are to be accompanied by a document containing an animal health certificate upon their entry into the Community. It is necessary to lay down in this Regulation in detail the animal health conditions for imports of aquaculture animals into the Community, including model animal health certificates, which should replace the import conditions laid down under Directive 91/67/EEC.

(17) 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[(14)] lays down model health certificates for import of fishery products and of live bivalve molluscs intended for human consumption. In the interests of coherency of Community legislation, this Regulation should provide that those model health certificates accompany import of products covered by this Regulation.

(18) Ornamental aquatic animals, including fish, molluscs and crustaceans, are to a large extent introduced into the Community from third countries and territories. To protect the animal health status of ornamental facilities within the Community, it is necessary to lay down certain animal health requirements for the import of such animals.

(19) It is important to ensure that the animal health status of aquaculture animals imported into the Community is not jeopardised during transport to the Community.

(20) The release of imported aquaculture animals into the wild in the Community poses a particularly high risk to the animal health status of the Community, since the control and eradication of diseases in natural waters are difficult. Accordingly, such release should require a specific authorisation from the competent authority and only be authorised under the condition that appropriate measures are taken to secure the animal health status at the place of release.

(21) Aquaculture animals intended for transiting through the Community should comply with the same requirements as aquaculture animals intended for import into the Community.

(22) Specific conditions for transit via the Community of consignments to and from Russia should be provided for owing to the geographical situation of Kaliningrad which affects only Latvia, Lithuania and Poland. In the interests of consistency of Community legislation, Commission Decision 2001/881/EC of 7 December 2001 drawing up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and updating the detailed rules concerning the checks to be carried out by the experts of the Commission[(15)] and Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries[(16)] should be taken into account in this Regulation.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 1251/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(23) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products[17] which lays down the rules to be observed in issuing veterinary certificates, should apply to animal health certificates issued under this Regulation.

(24) Article 17 of Directive 2006/88/EC provides that where scientific data or practical experience substantiates that species other than the susceptible species referred to in Part II of Annex IV to that Directive may be responsible for the transmission of a specific disease by acting as vector species, Member States are to ensure that where those species are introduced for farming or restocking purposes into a Member State, zone or compartment declared free of that specific disease, certain requirements provided for in the Directive are to be complied with. Article 17 of Directive 2006/88/EC also provides for the drawing up of a list of vector species. A list of vector species should therefore be adopted.

(25) The European Food Safety Authority (EFSA) has delivered three opinions on that issue: Scientific Opinion of the Panel on Animal Health and Welfare on a request from the European Commission on possible vector species and live stages of susceptible species not transmitting disease as regards certain fish diseases[18], Scientific Opinion of the Panel on Animal Health and Welfare on a request from the European Commission on possible vector species and live stages of susceptible species not transmitting disease as regards certain mollusc diseases[19], and Scientific Opinion of the Panel on Animal Health and Welfare on a request from the European Commission on possible vector species and live stages of susceptible species not transmitting disease as regards certain crustacean diseases[20].

(26) According to those scientific opinions, the likelihood of the transfer and establishment of the diseases listed in Directive 2006/88/EC by the potential vector species or groups of vector species assessed ranked from negligible/extremely low to moderate, under certain conditions. That assessment covered aquatic species which are used in aquaculture and traded for the purpose of farming.

(27) In drawing up the list of vector species, the EFSA opinions should be taken into account. In deciding which species should be included in that list, an appropriate level of protection of the animal health status of aquaculture animals in the Community should be ensured, while at the same time avoiding the introduction of unnecessary trade restrictions. Consequently, species which pose a moderate risk of disease transmission, according to those opinions, should be included in the list.

(28) Many of the species identified as possible vectors for certain diseases in the EFSA opinions, should only be regarded as such when they originate from an area where species susceptible to the disease in question are present and are intended for an area where those same susceptible species are also present. Accordingly, aquaculture animals of possible vector species should only be regarded as vector species for the purposes of Article 17 of Directive 2006/88/EC under such conditions.

(29) In the interest of clarity and coherence of Community legislation, Decisions 1999/567/EC, 2003/390/EC, 2003/804/EC, 2003/858/EC and 2006/656/EC should be repealed and replaced by this Regulation.