Commission Decision of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals (notified under document number C(2008) 7905) (Text with EEA relevance) (2008/946/EC)

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

This Decision lays down the requirements for the quarantine, which is provided for in:

- (a) Articles 17 and 20 of Directive 2006/88/EC; and
- (b) Chapter IV of Regulation (EC) No 1251/2008 and the model certificates set out in Annex IV to that Regulation.

Article 2

Definitions

For the purposes of this Decision, the following definitions shall apply:

- 1. 'quarantine facility' means a facility:
 - (a) in which quarantine of aquaculture animals is carried out;
 - (b) which contains one or more quarantine units; and
 - (c) which is authorised and registered by a competent authority, within the meaning of Article 2(4) of Regulation (EC) No 882/2004, as a quarantine facility in accordance with Articles 4 and 6 of Directive 2006/88/EC, and which complies with the minimum conditions for quarantine facilities set out in Annex I to this Decision;
- 2. 'quarantine unit' means an operationally and physically separated unit of a quarantine facility, which only contains aquaculture animals of the same consignment, with the same health status, and, when appropriate, sentinel aquaculture animals;
- 3. 'sentinel aquaculture animals' means aquaculture animals which are to be used as a diagnostic aid during quarantine;
- 4. 'listed diseases' means the diseases listed in Part II of Annex IV to Directive 2006/88/EC;
- 5. 'approved qualified aquatic animal health professional' means a qualified aquatic animal health professional designated by the competent authority to carry out specific official controls on quarantine facilities on its behalf.

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CHAPTER II

QUARANTINE OF AQUACULTURE ANIMALS IN THIRD COUNTRIES

Article 3

Conditions for imports

Where quarantine is a condition for imports into the Community of consignments of aquaculture animals in accordance with Chapter IV of Regulation (EC) No 1251/2008, such consignments shall only be imported into the Community if the conditions laid down in this Chapter are complied with.

Article 4

Quarantine conditions in third countries

- The quarantine must have been carried out in a quarantine facility as referred to in Article 2(1)(c).
- The quarantine facility must be under the control of the competent authority and that authority must:
 - a visit the premises of the quarantine facility at least once a year;
 - b ensure that the quarantine facility meets the conditions set out in this Decision;
 - c audit the activity of the approved qualified aquatic animal health professional; and
 - d verify that the conditions under which the authorisation was granted remain fulfilled.
- The aquaculture animals must have been subject to the quarantine provisions laid down in the following Articles:
 - a in the case of susceptible species, Articles 13, 14 and 15;
 - b in the case of vector species, Articles 16 and 17.
- 4 The aquaculture animals must only be released from quarantine on written authorisation by the competent authority.

Article 5

Authorisation of quarantine facilities in third countries

- In order to be authorised by the competent authority, quarantine facilities must comply with:
 - a provisions which are at least equivalent to the authorisation conditions laid down in Article 5 of Directive 2006/88/EC;
 - b the minimum conditions for quarantine facilities set out in Annex I to this Decision.
- Each authorised quarantine facility must be assigned a registration number.
- 3 A list of authorised quarantine facilities must be drawn up and communicated to the Commission.

CĤAPTER III

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Article 6

Suspension and withdrawal of authorisation of quarantine facilities in third countries

- Where the competent authority has received notification that the presence of listed disease(s) is suspected in a quarantine facility, it must:
 - a immediately suspend the authorisation of that facility;
 - b ensure that the measures necessary to confirm or rule out the suspicion are taken in accordance with point 3 of Annex II.
- 2 A suspension pursuant to paragraph 1 must not be removed until:
 - a the suspicion of the relevant listed disease(s) has been officially ruled out; or
 - b the eradication of the relevant listed disease(s) in the quarantine facility is successfully completed and the relevant quarantine units are cleansed and disinfected.
- 3 The authorisation of a quarantine facility must be immediately withdrawn by the competent authority where the facility no longer complies with the conditions set out in Article 5(1).

The Commission must be immediately informed thereof.

Article 7

Lists of quarantine facilities

The Commission shall provide the Member States with any new and updated lists of quarantine facilities that it receives in accordance with Article 5(3) and shall make them available to the public.

CHAPTER III

QUARANTINE OF AQUACULTURE ANIMALS IN THE COMMUNITY

Article 8

Attestation

- Where consignments of aquaculture animals imported into the Community are intended for quarantine in the Community, the importer or his agent shall provide a written attestation signed by the person responsible for the quarantine facility confirming that the aquaculture animals will be accepted for quarantine.
- 2 The attestation provided for in paragraph 1 shall:
 - a be drawn up in at least one official language of the Member State of the border inspection post where the veterinary checks are carried out; however, that Member State may instead permit another official language of the Community to be used, accompanied, if necessary, by an official translation into one of its official languages;
 - b include the registration number of the quarantine facility.
- The attestation provided for in paragraph 1 shall:

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- a reach the border inspection post before the arrival of the consignment; or
- b be presented to the border inspection post by the importer or his agent before the aquaculture animals are released from that post.

Article 9

Direct transport of aquaculture animals to quarantine facilities

Where consignments of aquaculture animals imported into the Community are intended for quarantine in the Community, they shall be transported directly from the border inspection post to the quarantine facility.

When vehicles are used for that transport they shall be sealed by the official veterinarian of the border inspection post with a tamper proof seal.

Article 10

Monitoring of transport of aquaculture animals

- 1 Where consignments of aquaculture animals imported into the Community are intended for quarantine in the Community:
 - a the official veterinarian of the border inspection post shall notify the competent authority of the quarantine facility within one working day of the date of arrival of the consignment at the border inspection post, of the place of origin and the place of destination of the consignment via the computerised system provided for in Article 20(1) of Council Directive 90/425/EEC⁽¹⁾ ('the Traces system');
 - b the person responsible for the quarantine facility shall notify, within one working day of the date of arrival of the consignment at the quarantine facility, the competent authority of that facility of the arrival of the consignment;
 - c the competent authority of the quarantine facility shall notify via the Traces system, within three working days of the date of arrival of the consignment at that facility, the official veterinarian of the border inspection post which notified it of the shipment of the consignment as referred to in point (a), of the arrival of the consignment.
- If confirmation is provided to the competent authority of the border inspection post, that the aquaculture animals declared as being intended for a quarantine facility in the Community have not arrived at their destination within three working days of the estimated date of arrival, the competent authority shall take appropriate measures.

Article 11

Quarantine conditions in the Community

Where quarantine in the Community is a condition for the placing on the market of consignments of aquaculture animals in accordance with Article 17 or 20 of Directive 2006/88/EC or for imports of such consignments into the Community in accordance with Chapter IV of Regulation (EC) No 1251/2008, the consignments shall comply with the following conditions:

(a) the quarantine period must be carried out in the same quarantine facility in the Community;

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- (b) the aquaculture animals must be subject to the quarantine provisions laid down in the following Articles:
 - (i) in the case of susceptible species, Articles 13, 14 and 15;
 - (ii) in the case of vector species, Articles 16 and 17;
- (c) the aquaculture animals must only be released from quarantine on written authorisation by the competent authority.

Article 12

Measures in case of suspicion or confirmation of listed disease(s)

- 1 If during quarantine, the presence of disease(s) is suspected in the quarantine facility, the competent authority shall:
 - a take and analyse appropriate samples in accordance with point 3 of Annex II;
 - b ensure that, pending the laboratorial results, no aquaculture animals are moved into or out of the quarantine facility.
- 2 If during quarantine, the presence of the relevant listed disease(s) is confirmed, the competent authority shall ensure that:
 - a all aquaculture animals in the quarantine units concerned are removed and disposed of, taking into account the risk of spreading the relevant listed disease(s);
 - b the quarantine units concerned are cleansed and disinfected;
 - c no aquaculture animals are moved into the quarantine units concerned during a period of 15 days following the final cleansing and disinfection;
 - d water in the quarantine units concerned is treated in a manner that effectively inactivates the infectious agent responsible for the relevant listed disease(s).
- By way of derogation from paragraph 2(a), the competent authority may authorise the placing on the market of the aquaculture animals kept in the quarantine facility and products thereof provided that the health status of the aquatic animals at the place of destination with regard to the relevant listed disease(s) is not jeopardised.
- 4 Member States shall inform the Commission of any measures taken pursuant to this Article.

CHAPTER IV

QUARANTINE PROVISIONS

SECTION 1

Susceptible species

Article 13

Duration of quarantine for susceptible species

1 Fish shall be quarantined for at least 60 days.

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- 2 Crustaceans shall be quarantined for at least 40 days.
- 3 Molluscs shall be quarantined for at least 90 days.

Article 14

Examination, sampling, testing and diagnosis

- 1 To demonstrate the absence of the relevant listed disease(s), the examination, sampling, testing and diagnosis referred to in Annex II shall be carried out with negative results.
- 2 Sentinel aquaculture animals may be used for the examination, sampling, testing and diagnosis, except where species susceptible to infection with *Marteilia refringens* are quarantined.
- 3 The competent authority shall determine the number of sentinel aquaculture animals to be used, taking into account the number of aquaculture animals kept, the size of the quarantine unit, and the characteristics of the relevant listed disease(s) and species.
- 4 Sentinel aquaculture animals shall be:
 - a of species susceptible to the relevant listed disease(s) and, where possible and taking into account their living conditions, being at the most susceptible life stages;
 - b sourced from a Member State, zone or compartment, or from a third country or part thereof declared free of the relevant listed disease(s);
 - c unvaccinated against the relevant listed disease(s);
 - d placed in the quarantine unit immediately before or upon arrival of the aquaculture animals to be quarantined and kept in contact with those animals and under the same zootechnical and environmental conditions.

Article 15

Inspection

The competent authority shall inspect the conditions of the quarantine at least at the beginning and the end of the quarantine period of each consignment of aquaculture animals.

When the competent authority carries out such inspections, it shall:

- ensure that the environmental conditions conducive to the laboratorial detection of the relevant listed disease(s) are present;
- (b) examine the mortality records during the quarantine;
- (c) where relevant, check the aquaculture animals in the quarantine units.

CHAPTER V

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SECTION 2

Vector species

Article 16

Quarantine provisions applicable to vector species

- 1 Vector species shall be quarantined for at least 30 days.
- 2 The water of the quarantine unit shall be exchanged at least once a day.

Article 17

Inspection

The competent authority shall inspect the conditions of the quarantine at least at the beginning and the end of the quarantine period of each consignment of aquaculture animals.

When the competent authority carries out such inspections, it shall:

- (a) examine the mortality records during the quarantine;
- (b) where relevant, check the aquaculture animals in the quarantine units.

CHAPTER V

FINAL PROVISIONS

Article 18

Transitional provision

Pending the adoption of the diagnostic methods to be laid down in accordance with Article 49(3) of Directive 2006/88/EC, testing of samples taken to demonstrate the absence of the relevant listed disease(s) during quarantine shall be carried out in accordance with the diagnostic methods laid down in the corresponding chapter to each listed disease(s) of the last version of the Manual of diagnostic tests for aquatic animals of the World Organisation for Animal Health (OIE).

Article 19

Date of application

This Decision shall apply from 1 January 2009.

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Article 20

Adressees

This Decision is addressed to the Member States.

Done at Brussels, 12 December 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

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(1) OJ L 224, 18.8.1990, p. 29.