

# COMMISSION

## 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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC <sup>(1)</sup>, and in particular the second subparagraph of Article 10(3) and the first subparagraph of Article 10(4) 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 <sup>(2)</sup>, and in particular Articles 25 and 61(3) thereof,

Whereas:

(1) Pursuant to Article 16(1) of Directive 2006/88/EC aquaculture animals of species susceptible to diseases listed in Part II of Annex IV to that Directive which are to be introduced for farming or restocking into a Member State, zone or compartment declared free of a specific disease must originate from a Member State, zone or compartment also declared free of that disease. Pursuant to Article 44(4) of that Directive, the same is to apply to areas subject to a surveillance or eradication programme with regard to a specific disease.

(2) Pursuant to Article 17(1) of Directive 2006/88/EC vector species to diseases listed in Part II of Annex IV to that

Directive which are to be introduced for farming or restocking purposes into a Member State, zone or compartment declared free of a specific disease must either originate from another Member State, zone or compartment declared free of that disease or be held in quarantine in water free of the pathogen in question, for an appropriate period of time, where, in the light of the scientific data or practical experience provided, this proves to be sufficient to reduce the risk of transmission of the specific disease to a level acceptable for preventing the transmission of the disease concerned. Pursuant to Article 44(4) of Directive 2006/88/EC, the same is to apply to areas subject to a surveillance or eradication programme with regard to a specific disease.

(3) A list of possible vector species to the diseases listed in Part II of Annex IV to Directive 2006/88/EC, including the conditions under which those species are to be regarded as vectors for the purpose of Article 17 of that Directive, is set out in Annex I to Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species <sup>(3)</sup>.

(4) Article 20(1) of Directive 2006/88/EC provides, by way of derogation from Article 16 of that Directive, that the release of wild aquatic animals of species susceptible to diseases listed in Part II of Annex IV to that Directive, caught in a Member State, zone or compartment not declared free of a specific disease, in a Member State, zone or compartment declared free of that disease is subject to the placing of the wild aquatic animals in quarantine under the supervision of the competent authority in suitable facilities, for a period of time sufficient to reduce to an acceptable level the risk of transmission of the disease. Pursuant to Article 44(4) of Directive 2006/88/EC, the same is to apply to areas subject to a surveillance or eradication programme with regard to a specific disease.

<sup>(1)</sup> OJ L 268, 24.9.1991, p. 56.

<sup>(2)</sup> OJ L 328, 24.11.2006, p. 14.

<sup>(3)</sup> See page 41 of this Official Journal.

(5) Pursuant to Articles 10 and 11 of Regulation (EC) No 1251/2008 animals of vector species and wild aquatic animals intended for farming, relaying areas, put and take fisheries and open ornamental facilities, and ornamental aquatic animals of susceptible species intended for closed ornamental facilities may be imported into a Member State, zone or compartment declared free of a specific disease or into areas subject to a surveillance or eradication programme with regard to a specific disease without having to originate from disease free areas if they have been subject to quarantine, as provided for in Directive 2006/88/EC, for an appropriate period of time. According to Article 10(1) first indent of Directive 91/496/EEC, the quarantine may be carried out in a third country.

(6) To ensure that the quarantine is carried out in a manner that reduces the risk of transmission of diseases listed in Part II of Annex IV to Directive 2006/88/EC to an acceptable level, detailed rules on quarantine should be laid down.

(7) Quarantine facilities in the Community are covered by the definition of 'aquaculture production businesses' in Article 3(1)(c) of Directive 2006/88/EC. In the interest of the animal health situation within the Community, quarantine facilities in third countries should comply with equivalent requirements as those laid down for aquaculture production businesses in Directive 2006/88/EC.

(8) When quarantine is carried out in the Community it is of vital importance that the transport of the consignments of aquaculture animals to the quarantine facility is monitored to ensure that the animals to be quarantined are transported directly to the quarantine facility in a safe manner.

(9) Quarantine facilities should be constructed and managed in a manner that prevents the spread of diseases between quarantine units and between the quarantine facilities and other aquaculture production businesses.

(10) Certain activities relating to quarantine in the Community fall within the definition of 'official controls' in Article 2(1) of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>(1)</sup>. Costs relating to quarantine in the

Community should therefore be covered by Article 27 of that Regulation, which provides that Member States may collect fees or charges to cover the cost occasioned by official controls.

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

HAS ADOPTED THIS DECISION:

#### 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;

<sup>(1)</sup> OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.

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.

## 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

1. The quarantine must have been carried out in a quarantine facility as referred to in Article 2(1)(c).
2. 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.
3. 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

1. 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.
2. 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.

#### Article 6

#### Suspension and withdrawal of authorisation of quarantine facilities in third countries

1. 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**

1. 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.

3. The attestation provided for in paragraph 1 shall:

- (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 <sup>(1)</sup> ('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.

2. 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;
- (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;

<sup>(1)</sup> OJ L 224, 18.8.1990, p. 29.

(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).

3. 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.

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:

- (a) 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.

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.

*Article 20*

**Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 12 December 2008.

*For the Commission*

Androulla VASSILIOU

*Member of the Commission*

## ANNEX I

**Minimum conditions for quarantine facilities**

## PART A

**Construction and equipment conditions**

1. The quarantine facility must be a premise which is separated from other quarantine facilities, other farms or other mollusc farming areas, by a distance specified by the competent authority on the basis of a risk assessment which takes into account the epidemiology of the relevant listed disease(s). However, a quarantine facility may be located within a farm or mollusc farming area.
2. The quarantine units must be constructed in such a way that water exchanges amongst them are not possible. In addition, the water outlet system of each quarantine unit must be designed to prevent any possible cross-contamination amongst quarantine units or other units of the same farm or mollusc farming area.
3. The water supply of the quarantine units must be free of the relevant listed disease(s).
4. When the draining system of the quarantine units is located in a Member State, zone, compartment or third country or part thereof declared free of a listed disease(s) or subject to a surveillance or eradication programme with regard to a listed disease(s), it must have an effluent treatment system approved by the competent authority. The effluent treatment system must:
  - (a) treat all effluents and wastes generated within the quarantine unit in a manner that effectively inactivates the infectious agent responsible for the relevant listed disease(s);
  - (b) be equipped with fail-safe backup mechanisms to ensure continuous operation and complete containment.
5. The quarantine units must be constructed in such a way that the contact with other animals likely to spread the relevant listed disease(s) is prevented.
6. All equipment must be constructed in such a way that it can be cleansed and disinfected and appropriate equipment must be available for cleansing and disinfection.
7. Hygiene barriers have to be installed at all entrances/exits to the quarantine facility and to its different units.
8. Each quarantine unit of the quarantine facility must have its own equipment in order to avoid cross contamination amongst the different quarantine units.

## PART B

**Management conditions**

1. The aquaculture production business operator of the quarantine facility must secure, by contract or legal instrument, the services of an approved qualified aquatic animal health professional.
2. For each consignment of aquaculture animals quarantined:
  - (a) the quarantine unit must be cleansed and disinfected and then kept free from aquaculture animals for at least seven days before the introduction of a new consignment;
  - (b) the quarantine period shall only start when the last aquaculture animals of the consignment are introduced.
3. Appropriate measures shall be taken to prevent cross-contamination between incoming and outgoing consignments.
4. No unauthorised persons may enter the quarantine facility.
5. Persons entering the quarantine facility must wear protective clothing including footwear.

6. No contacts between personnel or equipment, which may cause contamination between quarantine facilities or quarantine units or between quarantine facilities and farms or mollusc farming areas, shall take place.
7. Upon receipt, transport vehicles and equipment, including tanks, containers and water must be treated in a manner that effectively inactivates the infectious agent responsible for the relevant listed disease(s).
8. Dead aquaculture animals and aquaculture animals showing clinical signs of disease must be clinically inspected by an approved qualified aquatic animal health professional and a representative selection of dead aquaculture animals and aquaculture animals showing clinical signs of disease must be examined in a laboratory designated by the competent authority.
9. The necessary examination, sampling and diagnostic methods must be carried out in consultation with and under the control of the competent authority.
10. In addition to the recording obligations provided for in Article 8 of Directive 2006/88/EC, the quarantine facility must keep a record of:
  - (a) entry/exit time of personnel;
  - (b) treatment of incoming water and of effluent water as appropriate;
  - (c) any abnormal conditions affecting quarantine operation (power cuts, building damage or serious weather conditions);
  - (d) dates and results of samples submitted for testing.

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ANNEX II

**Examination, sampling, testing and diagnosis of aquaculture animals**

1. The examination, sampling, testing and diagnosis of aquaculture animals shall be carried out ensuring that the environmental conditions conducive to the laboratorial detection of the relevant listed disease(s) are present in the quarantine facility during the whole quarantine period.
  2. During quarantine, the following aquaculture animals shall be sampled within 15 days before date of the expiry of the quarantine period:
    - (a) when sentinel aquaculture animals are used, samples from all of them must be taken;
    - (b) when sentinel aquaculture animals are not used, samples must be taken from a relevant number of aquaculture animals ensuring the detection of the relevant listed disease(s) with a 95 % confidence if the design prevalence is 10 % (never less than 10 animals).
  3. Subject to Article 18, testing of samples taken during quarantine must be carried out in laboratories designated by the competent authority using the diagnostic methods to be laid down in accordance with Article 49(3) of Directive 2006/88/EC.
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