

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

CHAPTER VI

CONTROL PROGRAMMES AND VACCINATION

SECTION 1

Surveillance and eradication programmes

Article 44

Drawing up and approval of surveillance and eradication programmes

1 Where a Member State not known to be infected but not declared free (category III as referred to in Part A of Annex III) of one or more of the non-exotic diseases listed in Part II of Annex IV draws up a surveillance programme for achieving disease-free status for one or more of those diseases, it shall submit that programme for approval in accordance with the procedure referred to in Article 62(2).

Such programmes may also be amended or terminated in accordance with that procedure.

The specific requirements for surveillance, sampling and diagnostic shall be those provided for in Article 49(3).

However, where a programme provided for in this paragraph is to cover individual compartments or zones, which comprise less than 75 % of the territory of the Member State, and the zone or compartment consists of a water catchment area not shared with another Member State or third country, the procedure referred to in Article 50(2) shall apply for any approval, or amendment or termination of such programme.

2 Where a Member State known to be infected (category V as referred to in Part A of Annex III) by one or more of the non-exotic diseases listed in Part II of Annex IV, draws up an eradication programme for one or more of those diseases, it shall submit that programme for approval in accordance with the procedure referred to in Article 62(2).

Such programmes may also be amended or terminated in accordance with that procedure.

3 An overview of the programmes approved in accordance with paragraphs 1 and 2 of this Article shall be made available at Community level in accordance with the procedures provided for in Article 51.

4 From the date of approval of the programmes referred to in this Article, the requirements and measures provided for in Article 14, Sections 2, 3, 4 and 5 of Chapter III, Section 2 of Chapter V, and Article 38(1) in relation to areas declared disease-free shall apply to the areas which are covered by the programmes.

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Article 45

Content of programmes

Programmes shall not be approved unless they contain at least the following:

- (a) a description of the epidemiological situation of the disease before the date of commencement of the programme;
 - (b) an analysis of the estimated costs and the anticipated benefits of the programme;
 - (c) the likely duration of the programme and the objective to be attained by the completion date of the programme;
- and
- (d) a description and demarcation of the geographical and administrative area in which the programme is to be applied.

Article 46

Period of application of programmes

- 1 Programmes shall continue to be applied until:
 - a the requirements laid down in Annex V have been fulfilled, and the Member State, zone or compartment is declared free of the disease;or
 - b the programme is withdrawn, namely if it no longer fulfils its purpose, by the competent authority of the Member State concerned, or by the Commission.
- 2 If the programme is withdrawn as provided for in paragraph 1(b), the Member State concerned shall apply the containment measures in Article 39 from the date of withdrawal of the programme.

SECTION 2

Contingency plan for emerging and exotic diseases

Article 47

Contingency plan for emerging and exotic diseases

- 1 Each Member State shall draw up a contingency plan specifying the national measures required to maintain a high level of disease awareness and preparedness and to ensure environmental protection.
- 2 The contingency plan shall:
 - a provide the competent authority with the authority and means to access all facilities, equipment, personnel and other appropriate materials necessary for the rapid and efficient eradication of an outbreak;

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b ensure coordination and compatibility with neighbouring Member States and encourage cooperation with neighbouring third countries;

and

c where relevant, give a precise indication of the vaccine requirements and vaccination conditions considered necessary in the event of emergency vaccination.

3 Member States shall comply with the criteria and requirements laid down in Annex VII when drawing up contingency plans.

4 Member States shall submit the contingency plans for approval in accordance with the procedure referred to in Article 62(2).

Every five years, each Member State shall update its contingency plan and submit the updated plan for approval in accordance with that procedure.

5 The contingency plan shall be implemented in the event of an outbreak of emerging diseases and of exotic diseases listed in Part II of Annex IV.

SECTION 3

Vaccination

Article 48

Vaccination

1 Member States shall ensure that vaccination against the exotic diseases listed in Part II of Annex IV is prohibited unless such vaccination is approved in accordance with Articles 41, 42 or 47.

2 Member States shall ensure that vaccination against the non-exotic diseases listed in Part II of Annex IV is prohibited in any parts of their territory declared free of the diseases in question in accordance with Article 49 or 50, or covered by a surveillance programme, approved in accordance with Article 44(1).

Member States may allow such vaccination in parts of their territory not declared free from the diseases in question, or where vaccination is a part of an eradication programme approved in accordance with Article 44(2).

3 Member States shall ensure that the vaccines used are authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004.

4 Paragraphs 1 and 2 shall not apply to scientific studies for the purpose of developing and testing vaccines under controlled conditions.

During such studies, Member States shall ensure that the appropriate measures are taken to protect other aquatic animals from any adverse effect of the vaccination carried out within the framework of the studies.