

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 II

**AQUACULTURE PRODUCTION BUSINESSES AND
AUTHORISED PROCESSING ESTABLISHMENTS**

Article 4

Authorisation of aquaculture production businesses and processing establishments

1 Member States shall ensure that each aquaculture production business is duly authorised by the competent authority in accordance with Article 5.

Where appropriate, such authorisation may cover several aquaculture production businesses for molluscs in a mollusc farming area.

However, dispatch centres, purification centres or similar businesses located inside a mollusc farming area shall have an individual authorisation.

2 Member States shall ensure that each processing establishment slaughtering aquaculture animals for disease control purposes in accordance with Article 33 of Chapter V is duly authorised by the competent authority in accordance with Article 5.

3 Member States shall ensure that each aquaculture production business and authorised processing establishment has a unique authorisation number.

4 By way of derogation from the authorisation requirement in paragraph 1, Member States may require only the registration by the competent authority of the following:

- a installations other than aquaculture production businesses, where aquatic animals are kept without the intention of being placed on the market;
- b put and take fisheries;
- c aquaculture production businesses which place aquaculture animals on the market solely for human consumption in accordance with of Article 1(3)(c) of Regulation (EC) No 853/2004.

In those cases, the provisions of this Directive shall apply *mutatis mutandis*, taking into account the nature, characteristics and situations of the installation, put and take fishery or business concerned and the risk of spreading aquatic animal diseases to other populations of aquatic animals as a result of its operation.

5 In the case of non-compliance with the provisions of this Directive, the competent authority shall act in accordance with Article 54 of Regulation (EC) No 882/2004.

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Article 5

Authorisation conditions

1 Member States shall ensure that authorisations, as provided for in Article 4(1) and (2), are only granted by the competent authority if the aquaculture production business operator or authorised processing establishment operator:

- a fulfils the relevant requirements of Articles 8, 9 and 10;
 - b has a system in place which enables the operator to demonstrate to the competent authority that those relevant requirements are being fulfilled;
- and
- c remains under the supervision of the competent authority, which shall perform the duties laid down in Article 54(1).

2 Authorisation shall not be granted if the activity in question were to lead to an unacceptable risk of spreading diseases to farms, mollusc farming areas or to wild stocks of aquatic animals in the vicinity of the farm or mollusc farming area.

However, before a decision to refuse authorisation is taken, consideration shall be given to risk-mitigation measures, including possible alternative siting of the activity in question.

3 Member States shall ensure that the aquaculture production business operator or authorised processing establishment operator submits all relevant information in order to allow the competent authority to assess that the conditions for authorisation are fulfilled, including the information required in accordance with Annex II.

Article 6

Register

The Member States shall establish, keep up to date and make publicly available a register of aquaculture production businesses and authorised processing establishments containing at least the information set out in Annex II.

Article 7

Official controls

1 In accordance with Article 3 of Regulation (EC) No 882/2004, official controls on aquaculture production businesses and authorised processing establishments shall be carried out by the competent authority.

2 The official controls provided for in paragraph 1 shall at least consist of regular inspections, visits, audits, and where appropriate, sampling, for each aquaculture production business, taking account of the risk the aquaculture production business and authorised processing establishment poses in relation to the contracting and spreading of diseases. Recommendations for the frequencies of such controls, depending on the health status of the concerned zone or compartment, are laid down in Part B of Annex III.

3 Detailed rules for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 62(2).

Article 8

Recording obligations - Traceability

- 1 Member States shall ensure that aquaculture production businesses keep a record of:
 - a all movements of aquaculture animals and products thereof into and out of the farm or mollusc farming area;
 - b the mortality in each epidemiological unit as relevant for the type of production;and
 - c the results of the risk-based animal health surveillance scheme provided for in Article 10.
- 2 Member States shall ensure that authorised processing establishments keep a record of all movement of aquaculture animals and products thereof into and out of such establishments.
- 3 Member States shall ensure that when aquaculture animals are transported, transporters keep a record of:
 - a mortality during transport, as practicable for the type of transport and the species transported;
 - b farms, mollusc farming areas and processing establishments visited by the means of transport;and
 - c any water exchange during transport, in particular the sources of new water and site of release of water.
- 4 Without prejudice to specific provisions on traceability, Member States shall ensure that all movements of animals recorded by the aquaculture production business operators as provided for in paragraph 1(a) are registered in such a way that the tracing of the place of origin and destination can be guaranteed. Member States may require such movements to be recorded on a national register and kept in a computerised form.

Article 9

Good hygiene practice

Member States shall ensure that aquaculture production businesses and authorised processing establishments implement good hygiene practice, as relevant for the activity concerned, to prevent the introduction and spreading of diseases.

Article 10

Animal health surveillance scheme

- 1 Member States shall ensure that a risk-based animal health surveillance scheme is applied in all farms and mollusc farming areas, as appropriate for the type of production.

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2 The risk-based animal health surveillance scheme referred to in paragraph 1 shall aim at the detection of:

a any increased mortality in all farms and mollusc farming areas as appropriate for the type of production;

and

b the diseases listed in Part II of Annex IV, in farms and mollusc farming areas where species susceptible to those diseases are present.

3 Recommendations for the frequencies of such animal health surveillance schemes, depending on the health status of the concerned zone or compartment, are laid down in Part B of Annex III. This surveillance shall apply without prejudice to the sampling and surveillance carried out in accordance with Chapter V or Article 49(3), Article 50(4) and Article 52.

4 The risk-based animal health surveillance scheme referred to in paragraph 1 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2).

5 In the light of the outcome of official controls carried out in accordance with Article 7 and of the outcome of Community controls carried out in accordance with Article 58, and of any other relevant information, the Commission shall submit to the Council a report on the overall operation of risk-based animal health surveillance in Member States. This report may, where appropriate, be accompanied by an appropriate proposal, in accordance with the procedure referred to in Article 62(2) laying down detailed rules for the implementing of this Article.