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**COUNCIL DIRECTIVE**

**of 28 January 1991**

**concerning the animal health conditions governing the placing on the market of aquaculture animals and products**

(91/67/EEC)

(OJ L 46, 19.2.1991, p. 1)

Amended by:

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▼B**COUNCIL DIRECTIVE****of 28 January 1991****concerning the animal health conditions governing the placing on the market of aquaculture animals and products**

(91/67/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,Having regard to the opinion of the European Parliament<sup>(2)</sup>,Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

Whereas aquaculture animals and products are included in the list in Annex II to the Treaty;

Whereas the breeding and rearing of aquaculture animals, and the placing on the market of aquaculture animals and products constitutes a source of income for persons working in the fisheries sector;

Whereas, in order to ensure the rational development of this sector and to increase productivity, health rules for this sector must be laid down at Community level;

Whereas in this context it is necessary to contribute to the completion of the internal market, avoiding the spread of infectious or contagious diseases;

Whereas the animal health situation for aquaculture animals is not the same throughout the territory of the Community; whereas reference must therefore be made to the concept of zones when dealing with parts of the territory concerned;

Whereas criteria and procedures should be laid down for the grant, maintenance, suspension, restoration and withdrawal of approval of such zones;

Whereas reference should also be made to the concept of farms enjoying a specific animal health status;

Whereas criteria and procedures should be laid down for the grant, maintenance, suspension, restoration and withdrawal of approval of such farms;

Whereas it is necessary to set Community requirements applicable to imports of aquaculture animals and products from third countries; whereas these requirements must provide for adequate protective measures;

Whereas a Community inspection system should be established in order to verify compliance with this Directive;

Whereas scientific studies should be undertaken so as to be able to supplement in the future the rules laid down by this Directive;

Whereas provision should be made for a procedure establishing close and efficient cooperation between the Commission and the Member States within the Standing Veterinary Committee,

<sup>(1)</sup> OJ No C 84, 2. 4. 1990, p. 42.<sup>(2)</sup> OJ No C 19, 28. 1. 1991.<sup>(3)</sup> OJ No C 332, 31. 12. 1990.

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HAS ADOPTED THIS DIRECTIVE:

## CHAPTER 1

**General provisions***Article 1*

This Directive defines the animal health conditions governing the placing on the market of aquaculture animals and products.

This Directive shall apply without prejudice to Community or national provisions on the conservation of species.

*Article 2*

For the purposes of this Directive:

1. 'aquaculture animals' means live fish, crustaceans or molluscs coming from a farm, including those from the wild intended for a farm;
2. 'aquaculture products' means products derived from aquaculture animals, whether intended for farming, such as eggs and gametes, or for human consumption;
3. 'fish, crustaceans or molluscs' means any fish, crustacean or mollusc at any stage of development;
4. 'farm' means any establishment or, in general, any geographically defined installation in which aquaculture animals are reared or kept with a view to their being placed on the market;
5. 'approved farm' means a farm complying, as the case may be, with the requirements of Annex C I, II or III, and approved as such in accordance with Article 6;
6. 'approved zone' means a zone complying, as the case may be, with the provisions of Annex B I, II or III, and approved as such in accordance with Article 5;
7. 'approved laboratory' means a laboratory located in the territory of a Member State, designated by the competent authority, under its responsibility, to carry out the diagnostic tests provided for in this Directive;
8. 'official service' means the veterinary service or any other service of equivalent level designated by the competent authority of the Member State or third country and responsible for carrying out the controls provided for in this Directive;
9. 'health inspection' means a visit by an official service or services for the purpose of conducting health checks on a farm or zone;
10. 'placing on the market' means holding or displaying for sale, offering for sale, selling, delivering, transferring or any other form of placing on the market in the Community, with the exception of retail sale.

## CHAPTER 2

**Placing on the market of Community aquaculture animals and products***Article 3*

1. The placing on the market of aquaculture animals shall be subject to the following general requirements:

- (a) they must show no clinical signs of disease on the day of loading;
- (b) they must not be intended for destruction or slaughter under a scheme for the eradication of a disease listed in Annex A;

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- (c) they must not come from a farm which is subject to a prohibition for animal health reasons and must not have been in contact with

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animals from such a farm, and in particular from a farm which is subject to control measures in the context of Commission Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases<sup>(1)</sup>.

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2. Aquaculture products being placed on the market for breeding purposes (eggs and gametes) must originate from animals which satisfy the requirements laid down in paragraph 1.

3. Aquaculture products being placed on the market for human consumption must originate from animals which satisfy the requirements laid down in paragraph 1 (a).

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4. This Article shall apply without prejudice to the provisions of Directive 93/53/EEC with regard to the control of certain fish diseases, in particular the diseases in list I.

**▼B***Article 4*

Aquaculture animals must be dispatched in the shortest possible period to the place of destination, using means of transport that have been cleaned and, if necessary, disinfected in advance with a disinfectant that is officially authorized in the Member State of dispatch.

If water is used in overland transport, the vehicles shall be designed in such a way that water cannot escape from the vehicle during transport. Transport shall be carried out in such a way as to safeguard effectively the health of the animals, in particular by changing the water. Changes of water must be carried out in places complying with the requirements of Annex D. A list of these places and any subsequent amendments thereto must be notified by each Member State to the Commission, which shall forward that information to the other Member States.

*Article 5***▼M1**

1. In order to obtain, for one or more of the diseases referred to in Annex A, column 1, list II, the status of approved zone, Member States shall submit to the Commission:

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- all appropriate justifications concerning the conditions laid down, as the case may be, in Annex B under I B, II B or III B,
- the national rules ensuring compliance with the conditions laid down, as the case may be, in Annex B under I C, II C or III C.

**▼M1**

2. The Commission shall scrutinize the information referred to in paragraph 1. The Commission shall use such information as a basis for approving zones in accordance with the procedure laid down in Article 26. If, in accordance with Annex B under I.D.5, II.D or III.D.5, the approval of a zone is withdrawn by the official service, the Commission shall revoke the decision concerning its approval. Re-approval of the zone concerned shall occur in accordance with the procedure laid down in Article 26.

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3. The Commission shall draw up the list of approved zones. It shall amend this list in order to take account of new approvals or withdrawal of approvals. The Commission shall forward the list and any amendments thereto to the Member States.

<sup>(1)</sup> OJ No L 175, 19. 7. 1993, p. 23.

**▼B***Article 6***▼M1**

1. In order to obtain, for one or more of the diseases referred to in Annex A, column 1, list II, the status of approved farm situated in a non-approved zone, Member States shall submit to the Commission:

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- all appropriate justifications concerning the conditions set out, as the case may be, in Annex C under I A, II A or III A,
- the national rules ensuring compliance with the conditions set out in Annex C under I B, II B or III B.

2. On receipt of the file relating to the request for approval or re-approval of a farm in a non-approved zone, the Commission shall have a month within which to examine that file. That examination shall be carried out in the light of the information mentioned in paragraph 1 and, where appropriate, of on-site inspections undertaken in accordance with the provisions set out in Article 17.

Should that examination lead to favorable conclusions, the Commission shall forward such conclusions to the Member States. The Member States shall have a period of two weeks within which to make known their remarks.

After expiry of that period, if no remarks have been made or if the Member States' remarks are not contrary to the Commission's conclusions, the Commission shall approve or re-approve the farm.

Should there exist major differences between the Commission's conclusions and the Member States' remarks, or should the Commission, after examining the file, consider that the approval or re-approval ought not be granted, the Commission shall have two months within which to refer the matter to the Standing Veterinary Committee and obtain its opinion. In that case, the approval or re-approval shall be granted in accordance with the procedure laid down in Article 26.

If in accordance with Annex C under I C, II C or III C, the approval of a farm is withdrawn by the official service, the Commission shall revoke the approval decision.

3. The Commission shall draw up the list of approved farms. It shall amend that list in order to take account of new approvals or withdrawal of approvals. The Commission shall forward the list and any amendments thereto to the Member States.

*Article 7***▼M1**

1. The placing on the market of live fish belonging to the susceptible species referred to in Annex A, column 2, list II, their eggs or gametes, shall be subject to the following additional guarantees:

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- (a) where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 1 or 2, certifying that they come from an approved zone or an approved farm. Pending the outcome of the review provided for in Article 28, additional guarantees to be met for the introduction into an approved zone of fish coming from an approved farm situated in a non-approved zone shall be fixed in accordance with the procedure laid down in Article 26. Pending that decision, national rules shall continue to apply subject to compliance with the general provisions of the Treaty;
- (b) where they are to be introduced into a farm which, although not situated in an approved zone, fulfils the conditions set out in Annex C I, they must in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 1 or 2, certifying that they come respectively from an approved zone or from a farm of the same health status as the farm of destination.

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2. The Commission may, in accordance with the procedure laid down in Article 26, adapt or delete the additional guarantees referred to in paragraph 1, depending on the evolution of the animal health situation in the Community, in particular in order to take account of the results of the eradication measures for the disease referred to in Annex A, column 1 of list I.

*Article 8***▼M1**

1. The placing on the market of live molluscs referred to in Annex A, column 2, list II, shall be subject to the following additional guarantees:

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- (a) if they are to be relaid in an approved coastal zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 3 or 4, certifying that they come from an approved coastal zone or from an approved farm in a non-approved coastal zone, as the case may be;
- (b) if they are to be relaid in a farm which although not situated in an approved coastal zone fulfils the conditions set out in Annex C III, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 3 or 4, certifying that they come from an approved coastal zone or from a farm of the same health status as the farm of destination.

2. The Commission may, in accordance with the procedure laid down in Article 26, adapt or delete the additional guarantees referred to in paragraph 1, on the basis of the animal health situation existing in the Community.

*Article 9*

The placing on the market in an approved zone of aquaculture animals and products for human consumption originating in a non-approved zone shall be subject to the following requirements:

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1. Fish susceptible to the diseases referred to in Annex A, column 1, list II, must be slaughtered and eviscerated prior to dispatch.

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However, pending the outcome of the review provided for in Article 28, the obligation to eviscerate shall not be required, if the fish come from an approved farm in a non-approved zone. Derogations from this principle may be adopted under the procedure provided for in Article 26.

Pending that decision, national rules shall continue to apply subject to compliance with the general provisions of the Treaty.

**▼M1**

2. Live molluscs susceptible to the diseases referred to in Annex A, column 1, list II, must be delivered either for direct human consumption or to the preserving industry; they shall not be relaid unless:

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- they originate in an approved farm in a non-approved coastal zone, or
- they are temporarily immersed in storage ponds or purification centres which are specially equipped and approved for that purpose by the competent authority and include in particular a system for the treatment and disinfection of residual water. The conditions for such approval will be determined by the Commission in accordance with the procedure laid down in Article 26.

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3. The Commission shall, in accordance with the procedure provided for in Article 26, take, if necessary, appropriate measures to ensure uniform compliance with this Article.

*Article 10*

1. Where a Member State draws up or has drawn up a programme designed to enable it subsequently to initiate the procedures provided for in Article 5 (1) and Article 6 (1), it shall submit its programme to the Commission specifying in particular:

- the geographical zone and farm or farms concerned,
- the measures to be taken by the official services to ensure that the programme is properly carried out,
- the procedures followed by the approved laboratories, their number and location,
- the prevalence of the disease or diseases listed in Annex A, column 1 of lists I and II,
- the measures laid down to combat these diseases where detected.

2. The Commission shall scrutinize the programmes submitted by the Member States. The programmes shall be approved in accordance with the procedure laid down in Article 26. After the adoption of the programmes, the introduction of aquaculture animals and products into zones or farms covered by the programmes shall be subject to the rules set out in Articles 7 and 8.

3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 26. Under the same procedure the Commission may approve an amendment or addition to a programme which has been approved or to guarantees provided for by the rules referred to in paragraph 2.

*Article 11*

1. The movement documents referred to in Articles 7 and 8 must be drawn up by the official service at the place of origin within 48 hours before loading, in the official language or languages of the place of destination. They must be drawn up on a single sheet of paper, be made out for a single consignee. They shall be valid for 10 days.

2. Each consignment of aquaculture animals and products must be clearly identified in order to be able to trace back to the farm of origin, and to verify where appropriate the correlation of the animals or products with the information contained in the accompanying movement document. This information may figure directly on the container or on a label fixed to it or on the movement document.

*Article 12*

1. Where a Member State draws up or has drawn up a voluntary or compulsory control programme for one of the diseases referred to in Annex A, column 1 of list III, it shall submit the programme to the Commission, outlining in particular:

- the distribution of the disease in the Member States,
- the justification of the programme, taking into account, the importance of the disease and the programme's likely benefit in relation to its cost,
- the geographical area in which the programme will be implemented,
- the status of farms to be established, and the standards which must be achieved by the farms in each category, including test procedures,
- the rules applicable for entry of animals of a lower health status into the farm,
- the action to be taken if, for any reason, a farm loses its status,
- the procedures under which the programme is to be monitored.

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2. The Commission shall scrutinize the programme presented by the Member States. These programmes may be approved in accordance with the procedure laid down in Article 26. The additional guarantees, general or specific, which may be required for the introduction of aquaculture animals and products into officially checked zones or farms shall be defined in accordance with the same procedure.

3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 26. Under the same procedure, the Commission may approve an amendment or addition to a programme which has been approved or to guarantees which have been defined in accordance with paragraph 2.

*Article 13*

1. Where a Member State considers that its territory or part of its territory is free from one of the diseases listed in Annex A, column 1 of list III, it shall submit to the Commission appropriate justifications, setting out in particular:

- the name of the disease and the previous history of its occurrence in that Member State,
- the results of surveillance testing based on serological, virological, microbiological or pathological findings, as appropriate, and on the fact that the disease is compulsorily notifiable to the competent authorities,
- the period over which the surveillance was carried out,
- the control arrangements for verifying that the area concerned remains free from the disease.

2. The Commission shall examine such justifications. The additional guarantees, general or specific, which may be required for the introduction of aquaculture animals and products into certain areas or farms shall be defined in accordance with the procedure provided for in Article 26.

3. The Member State concerned shall notify the Commission of any change in the particulars specified in paragraph 1 which relate to the disease. The guarantees defined as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn in accordance with the procedure provided for in Article 27.

**▼M1***Article 14*

1. Without prejudice to the requirements for diseases referred to in Annex A, column 1, list III, established in accordance with Articles 12 and 13, the placing on the market of live farmed fish not belonging to the susceptible species referred to in Annex A, column 2, list II, as well as their eggs and gametes shall be subject to the following additional requirements:

- (a) where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from a zone of the same health status, from an approved farm in a non-approved zone or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Annex A, column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters.

However, pending the outcome of the review provided for in Article 28, Member States may, under the procedure laid down in Article 26, request a derogation from the preceding subparagraph, in particular so as to prohibit the introduction into an approved zone of fish referred to in this paragraph originating in an approved farm situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Annex A, column 2, list II, and is not connected with a watercourse



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or with coastal or estuarial waters. In order to ensure uniform compliance with that provision, appropriate conditions and measures shall be fixed under the same procedure. Pending those decisions, the relevant national rules shall continue to apply subject to compliance with the general provisions of the Treaty;

- (b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Annex C, they must, in accordance with Article 11, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from an approved zone, from a farm of the same health status or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Annex A, column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters.

2. The requirements laid down in paragraph 1 shall apply to the placing on the market of farmed molluscs not belonging to the susceptible species referred to in Annex A, column 2, list II.

3. Without prejudice to the requirements for diseases referred to in Annex A, column 1, list III established in accordance with Articles 12 and 13, the placing on the market of wild fish, molluscs or crustaceans, their eggs or gametes, shall be subject to the following additional requirements:

- (a) where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from a zone of the same health status;
- (b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Annex C, they must, in accordance with Article 11, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from an approved zone;
- (c) where such animals are fished in the deep sea and are to be used for breeding in approved zones and approved farms, they must be placed in quarantine under the supervision of the official service in suitable facilities and under appropriate conditions to be determined in accordance with the procedure laid down in Article 26.

4. The requirements laid down in paragraphs 1, 2 and 3 shall not apply where practical experience and/or scientific evidence has shown that there is no passive transmission of the disease when aquaculture animals, their eggs and gametes, not belonging to the susceptible species referred to in Annex A, column 2, list II, are moved from a non-approved zone to an approved zone.

In accordance with the procedure laid down in Article 26, the Commission shall establish the list of aquaculture animals to which the derogation referred to in the first subparagraph shall apply and, where necessary, shall amend that list in the light of scientific and technological developments. The special conditions for placing such animals on the market, including the model of the accompanying document required, shall be established and amended according to the same procedure.

5. This Article shall not apply to ornamental tropical fish kept permanently in aquariums.

▼B*Article 15*

Sampling plans and diagnostic methods to be applied for the detection and confirmation of the presence of the diseases referred to in Annex A, column 1, shall be established in accordance with the procedure laid down in Article 26. These sampling plans must take account of the

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presence of wild fish, crustaceans and molluscs in the aquatic environment.

*Article 16*

1. The rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market<sup>(1)</sup> as regards aquaculture products for human consumption and 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<sup>(2)</sup> as regards aquaculture animals and products placed on the market shall apply, in particular as regards the organization of and the action to be taken following the inspections to be carried out by the Member State of destination, and the protective measures to be implemented.

2. Directive 89/662/EEC is amended as follows:

(a) in Annex A, the following indent is added:

‘— Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1)’;

(b) in Annex B the following indent is deleted:

‘— aquaculture products intended for human consumption.’

3. In Annex A, point I, of Directive 90/425/EEC the following reference is added:

‘Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1)’.

*Article 17*

1. Commission veterinary experts may, where it is necessary for the uniform application of this Directive, carry out on-site inspections in conjunction with the competent authorities. The Member State in whose territory an inspection is carried out shall provide the experts with all the assistance necessary to complete their task. The Commission shall notify the Member States of the outcome of such inspections.

2. General provisions for the application of this Article shall be adopted in accordance with the procedure laid down in Article 26.

The rules to be followed during the inspection provided for in this Article shall be drawn up in accordance with the same procedure.

## CHAPTER 3

**Rules governing imports from third countries***Article 18*

Aquaculture animals and products imported into the Community shall satisfy the conditions laid down in Articles 19, 20 and 21.

*Article 19*

1. Aquaculture animals and products must come from third countries or parts thereof appearing on a list drawn up by the Commission in accordance with the procedure laid down in Article 26. That list may be supplemented or amended in accordance with the same procedure.

<sup>(1)</sup> OJ No L 395, 30. 12. 1989, p. 13.

<sup>(2)</sup> OJ No L 224, 18. 8. 1990, p. 29; as amended by Directive 90/539/EEC (OJ No L 303, 31. 10. 1990, p. 6).

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2. In deciding whether a third country or part thereof may appear on the list referred to in paragraph 1, particular account shall be taken of:
- (a) the state of health of the aquaculture animals, particular attention being paid to exotic diseases and the environmental health situation in the third country which might endanger the health of livestock in the Member States;
  - (b) the regularity and rapidity of the information supplied by the country relating to the existence of infectious or contagious diseases of aquaculture animals in its territory, in particular those diseases mentioned in list B of the International Office of Epizootics;
  - (c) the rules of the third country on the prevention and control of diseases of aquaculture animals;
  - (d) the structure of the official services in the third country and their powers;
  - (e) the organization and implementation of measures to prevent and control infectious or contagious diseases of aquaculture animals;
  - (f) assurances which the third country may provide concerning the rules laid down in this Directive.
3. The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

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4. If by 1 January 1994 no decision has been taken with regard to the drawing up of the list referred to in paragraph 1, the requisite transitional measures may be adopted, in accordance with the procedure laid down in Article 26, for a period of three years.

**▼B***Article 20*

1. For each third country, aquaculture animals and products shall satisfy the health conditions adopted in accordance with the procedure laid down in Article 26.
2. Depending on the animal health situation in the third country concerned, the conditions referred to in paragraph 1 may include in particular:
- restriction to imports from a part of the third country,
  - restriction to certain species at any stage of development,
  - the prescription of a treatment to be applied to the products, such as the disinfection of eggs,
  - prescription of the use to which these animals or products are to be put,
  - the measures to apply following importation, such as quarantine or the disinfection of eggs.

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3. Pending establishment of the import conditions provided for in this Directive, Member States shall ensure that imports of aquaculture animals and products from third countries are subject to conditions at least equivalent to those applying to the production and placing on the market of Community products.

**▼B***Article 21*

1. Aquaculture animals and products shall be accompanied by a certificate drawn up by the official services of the exporting third country. This certificate must:
- (a) be issued on the day of loading of the consignment for dispatch to the Member State of destination;
  - (b) accompany the consignment in the original;

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- (c) attest that the aquaculture animals and certain fishery products meet the requirements of this Directive and those laid down pursuant thereto with regard to importation from the third country;
- (d) be valid for 10 days;
- (e) consist of a single sheet of paper;
- (f) be made out for a single consignee.

2. The certificate referred to in paragraph 1 must comply with a model established in accordance with the procedure laid down in Article 26.

*Article 22*

Inspections shall be carried out on the spot by veterinary experts of the Member States and the Commission to verify whether the provisions of this Directive, and in particular Articles 19 and 20 thereof, are being applied in practice.

The experts from the Member States who are to be entrusted with the task of carrying out these inspections shall be appointed by the Commission, acting on proposals from the Member States.

Those inspections shall be made on behalf of the Community, which shall bear the expenditure incurred in this connection.

The frequency of and the procedures for these inspections shall be determined in accordance with the procedure laid down in Article 26.

*Article 23*

1. The general rules and principles applicable during inspections of aquaculture products imported from third countries shall be those laid down in Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries<sup>(1)</sup>.

2. The general rules and principles applicable during inspections of live aquaculture animals imported from third countries shall be those laid down by Article 7 of Directive 90/425/EEC.

**▼M1***Article 24*

If an infectious or contagious disease of aquaculture animals, likely to endanger the health of livestock in a Member State breaks out or spreads in a third country or if any other animal health reason so justifies, the rules, procedures and measures laid down in Article 19 of Directive 90/675/EEC shall apply as regards aquaculture products and those laid down in Article 18 of Directive 91/496/EEC shall apply as regards aquaculture animals.

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## CHAPTER 4

**Final provisions***Article 25*

Annexes C and E may be amended in accordance with the procedure laid down in Article 26.

Annexes A, B and C shall be amended only by the Council acting by a qualified majority on a proposal from the Commission, with a view in particular to adapting them to technological progress.

<sup>(1)</sup> OJ No L 373, 31. 12. 1990, p. 1.

▼B*Article 26*

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC<sup>(1)</sup>, hereinafter referred to as 'the Committee', either on his own initiative or at the request of the representative of a Member State.

2. (a) The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.

*Article 27*

1. Where the procedure laid down in this Article is to be followed, the Chairman shall without delay, refer the matter to the Committee, either on his own initiative or at the request of the representative of a Member State.

2. (a) The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within two days. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of 15 days from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.

*Article 28*

Before 1 July 1992, in respect of the list of diseases set out in Annex A, and before 1 January 1997, in respect of the health status of approved farms in a non-approved zone, the Council shall, on the basis of a report from the Commission on the experience gained, prepared

<sup>(1)</sup> OJ No L 255, 18. 10. 1968, p. 23.

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following an opinion from the Scientific Veterinary Committee and accompanied by any proposals, on which it will decide by a qualified majority, review the provisions of this Directive and in particular those concerning the marketing of live fish coming from approved farms in non-approved zones.

*Article 29*

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993.
2. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

*Article 30*

This Directive is addressed to the Member States.

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## ANNEX A

**LIESTED DISEASES/PATHOGENS OF FISH, MOLLUSCS AND CRUSTACEA**

1	2
Disease/pathogen	Susceptible species
LIST I	
<b>Fish</b>	
Infectious salmon aneamia (ISA)	Atlantic salmon ( <i>Salmo salar</i> )
LIST II	
<b>Fish</b>	
Viral haemorrhagic septicaemia (VHS)	Salmonid species, Grayling ( <i>Thymallus thymallus</i> ); Whitefish ( <i>Coregonus spp.</i> ); Pike ( <i>Esox lucius</i> ); Turbot ( <i>Scophthalmus maximus</i> );
Infectious haematopoietic necrosis (IHN)	Salmonid species Pike fry ( <i>Esox lucius</i> )
<b>Molluscs</b>	
<i>Bonamia ostreae</i>	Flat oyster ( <i>Ostrea edulis</i> )
<i>Marteilla refringens</i>	Flat oyster ( <i>Ostrea edulis</i> )
LIST III	
<b>Fish</b>	
Infectious pancreatic necrosis (IPN)	To be specified in the programme referred to in Articles 12 and 13'
Spring viraemia of carp (SVC)	
Bacterial kidney disease (BKD) ( <i>Renibacterium salmonidarum</i> )	
Furunculosis ( <i>Aeromonas salmonicida</i> )	
(Enteric redmouth disease) (ERM) ( <i>Yersinia ruckeri</i> )	
<i>Gyrodactylus salaris</i>	
<b>Crustaceans</b>	
Crayfish plague ( <i>Aphanomyces astaci</i> )	

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## ANNEX B

## APPROVED ZONES

I. **Continental zones for fish** (column 2 of ►M1 list ◀ II in Annex A)A. *Definition of continental zones*

A continental zone consists of

- a part of the territory comprising an entire catchment area from the sources of the waterways to the estuary, or more than one catchment area, in which fish is reared, kept or caught, or
- a part of a catchment area from the sources of the waterways to a natural or artificial barrier preventing fish migrating from downstream of that barrier.

The size and the geographical situation of a continental zone must be such that possibilities for recontamination, e.g. by migrating fish, are reduced to a minimum. That may require the establishment of a buffer-zone in which a monitoring programme is carried out without obtaining the status of approved zone.

B. *Grant of appeal*

In order to obtain approved status, a continental zone must meet the following requirements:

1. all fish are free for at least four years from any clinical or other sign of one or more of the diseases referred to in Annex A, column 1 of ►M1 list ◀ II;
2. all farms in the continental zone are placed under the supervision of the official services. Two health inspections per year for four years must have been carried out.

The health inspection must have been made at the times of year when the water temperature favours the development of these diseases.

The health inspection must consist at least of:

- an inspection of fish showing abnormalities,
- the taking of samples which are to be sent as quickly as possible to the approved laboratory to be tested for the pathogens in question.

However, zones having a historical record of absence of the diseases referred to in Annex A, column 1 of ►M1 list ◀ II, may obtain approved status if:

- (a) their geographical situation does not permit easy introduction of diseases;
- (b) an official disease control system has been in place for an extended period of time of at least 10 years during which:
  - there has been regular monitoring of all farms,
  - a disease notification system has been applied,
  - no case of disease has been reported,
  - no live fish from infected zones has been introduced;
3. if there is no farm in a continental zone to be approved, the official services must have subjected fish from the lower part of the catchment area to a health inspection twice a year for four years, in accordance with paragraph 2;
4. the laboratory examinations of fish taken during health inspections have produced negative results as regards the pathogens in question.

C. *Maintenance of approval*

Maintenance of approval is subject to the following requirements:

1. fish introduced into the zone must come from another approved zone or from an approved farm;
2. each farm must undergo two health inspections annually in accordance with point B 2; however, samples will be taken by rotation in 50 % of the fish farms in the continental zone each year;



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3. the results of the laboratory examinations on the fish sampled during the health inspections must have been negative as regards the agents of the diseases referred to in Annex A, column 1 of ►**M1** list ◀ II;
4. a register must be kept by the farmers or the persons responsible for the introducing of fish, containing all the information necessary to enable the state of health of the fish to be monitored constantly.

*D. Suspension, re-establishment and withdrawal of approval*

1. Any abnormal death or other symptom that might constitute grounds for suspecting an outbreak amongst fish of a disease referred to in Annex A, column 1 of ►**M1** list ◀ II must be notified as quickly as possible to the official service. The latter shall immediately suspend the approval of the zone.
2. A sample of at least 10 sick fish must be sent to the approved laboratory in order to be tested for the pathogens in question. The results of the tests must be communicated immediately to the official service.
3. Where the results are negative for the pathogens in question but positive for another cause, the official service shall restore approval.
4. However, when no diagnosis can be made, a further health inspection must be made within 15 days of the first sampling and a sufficient number of sick fish must be taken and forwarded to the approved laboratory in order to be tested for the pathogens in question.

If the results are again negative or if there are no more sick fish, the official service will restore the approval.

5. Where the results are positive, approval must be withdrawn by the official service.
6. Restoration of the approval of a zone is subject to the following requirements:
  - (a) when an outbreak occurs:
    - all fish in the infected farms must have been slaughtered, and infected or contaminated fish must have been destroyed,
    - facilities and equipment must have been disinfected in accordance with a procedure approved by the official services;
  - (b) after elimination of the outbreak, the requirements set up in point B must be again complied with.
7. The central competent authority shall inform the Commission and the other Member States regarding suspension, restoration and withdrawal of the approval of zones.

**II. Coastal zones for fish** (column 2 of ►**M1** list ◀ II of Annex A)

- A. A coastal zone consists of a part of the coast or sea water or an estuary with a precise geographical delimitation which consists of a homogeneous hydrological system.

*B. Grant of approval*

In order to obtain approved status, a coastal zone for fish must meet the requirements laid down for continental zones referred to in point I B.

*C. Maintenance of status*

Maintenance of the approval for a coastal zone is subject to the requirements set out in point I C.

*D. Suspension, restoration and withdrawal of approval*

The rules are identical to those set out in point I D.

**III. Coastal zones for molluscs** (column 2 of ►**M1** list ◀ II of Annex A)

- A. A coastal zone must comply with the definition laid down in point II A.

▼BB. *Grant of approval*

In order to be approved, a coastal zone must meet the following requirements:

1. all molluscs have for at least two years shown no clinical or other sign of one or more of the diseases referred to in Annex A, column 1 of ►M1 list ◀ II;
2. all farms in the coastal zone are placed under the supervision of the official services. Health inspections are carried out at intervals adapted to the development of the pathogens in question.

During these inspections samples are taken and sent without delay to the approved laboratory to be tested for the pathogens in question;

3. if there is no farm in the continental zone, the official service must have submitted molluscs to a health inspection in accordance with point 2, at intervals adapted to the development of the pathogens in question. However, if detailed investigations of fauna show that the zone does not contain any molluscs belonging to vector, carrier or susceptible species, the official service may approve the zone before any molluscs are introduced;
4. laboratory examinations of molluscs taken during health inspections by the official services have produced negative results as regards the pathogens in question.

For zones having a historical record of absence of the diseases referred to in Annex A, column 1 of ►M1 list ◀ II, this information may be taken into account for the grant of approval.

C. *Maintenance of approval*

Maintenance of approval is subject to the following requirements:

1. molluscs introduced into the coastal zone must come from other approved coastal zones or from approved farms in non-approved coastal zones;
2. each farm must undergo a health inspection in accordance with point B 2 at intervals adapted to the development of the pathogens in question;
3. the results of the laboratory examinations on the molluscs sampled during the health inspections must have been negative as regards the agents of the diseases referred to in Annex A, column 1 of ►M1 ————— ◀ II;
4. a register must be kept by the farmers or the persons responsible for the introduction of molluscs, containing all information necessary to enable the state of health of the molluscs to be monitored constantly.

D. *Suspension, restoration and withdrawal of approval*

1. Any abnormal death or other symptom that might constitute grounds for suspecting an outbreak amongst molluscs of a disease, referred to in Annex A, column 1 of list II, must be notified as quickly as possible to the official service. The latter shall immediately suspend approval of the zone.
2. A sample of sick molluscs must be sent to the approved laboratory in order to be tested for the pathogens in question.

The results of the tests must be communicated immediately to the official service.

3. Where the results are negative for the pathogens in question, but positive for another cause, approval shall be restored.
4. However, when no diagnosis can be made, a further health inspection must be made within 15 days of the first taking of samples and a sufficient number of sick molluscs must be taken and forwarded to the approved laboratory in order to be tested for the pathogens in question. If the results are again negative or if there are no longer any sick molluscs, the official service will restore approval.
5. Where the results are positive, approval must be withdrawn by the official service.
6. Restoration of approval of a zone is subject to the following requirements:

(a) when an outbreak occurs:

- infected or contaminated molluscs must have been destroyed,

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- facilities and equipment must have been disinfected in accordance with a procedure approved by the official service;
  - (b) after elimination of the outbreak, the requirements set out in point B must again be complied with.
7. The central competent authority shall inform the Commission and the other Member States regarding suspension, restoration and withdrawal of the approval of zones.

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## ANNEX C

## APPROVED FARMS IN A NON-APPROVED ZONE

- I. **Continental farms for fish** (Column 2 of ►M1 list ◀ II of Annex A)
- A. *Grant of approval*
- In order to be approved, a farm must meet the following requirements:
1. Water must be supplied by a well or a borehole.
  2. There must be a natural or artificial barrier for anadromic fish situated downstream.
  3. It must comply with the relevant requirements set out in Annex B I B.
- B. *Maintenance of approval*
- Maintenance of approval shall be subject to the requirements set out in Annex B I C. However, sampling must be carried out once a year.
- C. *Suspension, restoration and withdrawal of approval*
- The requirements set out in Annex B I D shall apply.
- II. **Coastal farms for fish** (Column 2 of ►M1 list ◀ II of Annex A)
- A. *Grant of approval*
- In order to be approved, a farm must meet the following requirements:
1. It must be supplied with water by means of a system which allows the destruction of the agents of the diseases referred to in Annex A, column 1 of ►M1 list ◀ II.
  2. It must comply, *mutatis mutandis*, with the requirements laid down in Annex B II B.
- B. *Maintenance of approval*
- Maintenance of approval shall, *mutatis mutandis*, be subject to the requirements laid down in Annex B II C.
- C. *Suspension, restoration and withdrawal of approval*
- The requirements laid down in Annex B II D shall apply *mutatis mutandis*.
- III. **Coastal farms for molluscs** (Column 2 of ►M1 list ◀ II of Annex A)
- A. *Grant of approval*
- In order to be approved, a farm must meet the following requirements:
1. It must be supplied with water by means of a system which allows the destruction of the agents of diseases referred to in Annex A, column 1 of ►M1 list ◀ II.
  2. It must comply, *mutatis mutandis*, with the requirements as set out in Annex B III B, points 1, 2 and 4.
- B. *Maintenance of approval*
- Maintenance of approval shall, *mutatis mutandis*, be subject to the guarantees laid down in Annex B III C, points 1 to 4.
- C. *Suspension, restoration and withdrawal of approval*
- The requirements set out in Annex B III D shall apply *mutatis mutandis*.

**▼B***ANNEX D***RENEWAL OF WATER**

Renewal of water during the transportation of aquaculture animals shall be carried out in facilities which are approved by the Member States and meet the following requirements:

1. The hygienic properties of the water available for changing must be such as not to alter the health situation of the species transported with regard to the agents of the diseases referred to in Annex A, column 1 of ►**MI** list ◀ II.
2. These facilities shall contain devices designed to prevent any contamination of the host environment:
  - either by facilitating disinfection of the water, or
  - by ensuring that release of this water does not under any circumstances entail direct discharge into the open sea or free-flowing waterways.

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## ANNEX E

## Models of movement documents

## CHAPTER 1

## MOVEMENT DOCUMENT FOR LIVE FISH, EGGS AND GAMETES FROM AN APPROVED ZONE

I. Country of origin: .....

Approved zone: .....

II. Farm of origin (name and address): .....

III. Animals or products: .....

	Live fish	Eggs	Gametes
Family (common name and scientific name)			
Species (common name and scientific name)			
Quantity    Number Total weight Average weight			

IV. Destination

Country of destination: .....

Consignee (name and address): .....

V. Means of transport (nature and identification): .....

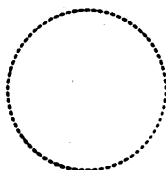
VI. Health attestation

I, the undersigned, hereby certify that the animals or goods forming the present consignment originate from an approved zone and that they satisfy the requirements of Directive 90/67/EEC.

Done at ....., on .....

Name of official service:

Stamp of official service

.....  
Name (in capitals).....  
Function of signing officer.....  
Signature

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## CHAPTER 2

## MOVEMENT DOCUMENT FOR LIVE FISH, EGGS OR GAMETES FROM AN APPROVED FARM

I. Country of origin: .....

II. Farm of origin (name and address): .....

III. Animals or products: .....

	Live fish	Eggs	Gametes
Family (common name and scientific name)			
Species (common name and scientific name)			
Quantity			
Number			
Total weight			
Average weight			

## IV. Destination

Country of destination: .....

Consignee (name and address): .....

V. Means of transport (nature and identification): .....

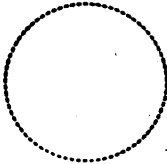
## VI. Health attestation

I, the undersigned, hereby certify that the animals or products forming the present consignment originate from an approved farm and that they satisfy the requirements of Directive 91/67/EEC.

Done at ....., on .....

Name of official service:

Stamp of official service

.....  
Name (in capitals).....  
Function of signing officer.....  
Signature

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CHAPTER 3

MOVEMENT DOCUMENT FOR MOLLUSCS FROM AN APPROVED COASTAL ZONE

I. **Country of origin:** .....  
 Approved zone: .....

II. **Farm of origin (name and address):** .....  
 .....

III. **Animals:** .....

		Molluscs
Family (common name and scientific name)		
Species (common name and scientific name)		
Quantity	Number Total weight Average weight	

IV. **Destination**  
 Country of destination: .....  
 Consignee (name and address): .....  
 .....

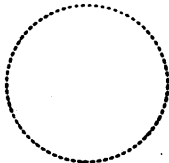
V. **Means of transport (nature and identification):** .....  
 .....

VI. **Health certification**  
 I, the undersigned, hereby certify that the animals forming the present consignment originate from an approved coastal zone and that they satisfy the requirements of Directive 91/67/EEC.

Done at ....., on .....

Name of official service:

Stamp of official service



.....  
 Name (in capitals)  
 .....

.....  
 Function of signing officer  
 .....

.....  
 Signature



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## CHAPTER 4

## MOVEMENT DOCUMENT FOR MOLLUSCS FROM AN APPROVED FARM

I. Country of origin: .....

II. Farm of origin (name and address): .....

III. Animals: .....

		Molluscs
Family (common name and scientific name)		
Species (common name and scientific name)		
Quantity	Number Total weight Average weight	

## IV. Destination

Country of origin: .....

Consignee (name and address): .....

V. Means of transport (nature and identification): .....

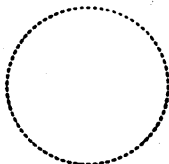
## VI. Health certification

I, the undersigned, hereby certify that the animals forming the present consignment originate from an approved farm and that they satisfy the requirements of Directive 91/67/EEC.

Done at ....., on .....

Name of official service:

Stamp of official service

.....  
Name (in capitals).....  
Function of signing officer.....  
Signature