

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

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Whereas:

- (1) Aquaculture animals and products fall under the scope of Annex I to the Treaty as live animals, fish, molluscs and crustaceans. The breeding, rearing and the placing on the market of aquaculture animals and products thereof constitutes an important source of income for persons working in this sector.
- (2) In the context of the internal market, specific animal health rules were laid down for the placing on the market and introduction from third countries of the products concerned by 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⁽²⁾.
- (3) Outbreaks of diseases in aquaculture animals could cause severe losses to the industry concerned. Minimum measures to be applied in case of outbreaks of the most important diseases in fish and molluscs were established by Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases⁽³⁾ and Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs⁽⁴⁾.
- (4) Existing Community legislation was drafted mainly to take into account the farming of salmon, trout and oysters. Since that legislation was adopted, the Community aquaculture industry has developed significantly. A number of additional fish species, particularly marine species, are now used in aquaculture. New types of farming practices involving other fish species have also become increasingly common, particularly following the recent enlargement of the Community. Furthermore, farming of crustaceans, mussels, clams and abalones is becoming increasingly important.

- (5) All disease control measures have an economic impact on aquaculture. Inadequate controls may lead to a spread of pathogens, which may cause major losses and compromise the animal health status of fish, molluscs and crustaceans used in Community aquaculture. On the other hand, over-regulation could place unnecessary restrictions on free trade.
- (6) The Communication from the Commission to the Council and the European Parliament dated 19 September 2002 sets out a strategy for the sustainable development of European aquaculture. That Communication outlined a series of measures designed to create long-term employment in the aquaculture sector, including promoting high animal health and welfare standards, and environmental actions to ensure a sound industry. Those measures should be taken into account.
- (7) Since the adoption of Directive 91/67/EEC, the Community has ratified the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE). The animal health requirements for placing live aquaculture animals and products thereof on the market within the Community set out in Directive 91/67/EEC are more stringent than those standards. Therefore, this Directive should take into account the Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aquatic Animals of the OIE.
- (8) In order to ensure the rational development of the aquaculture sector and to increase productivity, aquatic animal health rules should be laid down at Community level. These rules are necessary, *inter alia*, in order to contribute to the completion of the internal market and to avoid the spread of infectious diseases. Legislation should be flexible to take into account the continuing developments in and diversity of the aquaculture sector, as well as the health status of aquatic animals within the Community.
- (9) This Directive should cover aquaculture animals, and those environments which may affect the health status of such animals. In general the provisions of this Directive should only apply to wild aquatic animals where the environmental situation may impinge on the health status of aquaculture animals, or where necessary in order to fulfil the purpose of other Community legislation, such as Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora⁽⁵⁾ or to protect species referred to in the list drawn up by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). This Directive should not prejudice the adoption of more stringent rules on the introduction of non-native species.
- (10) The competent authorities designated for the purpose of this Directive should perform their functions and duties in accordance with the general principles laid down in Regulation (EC) No 854/2004 of European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption⁽⁶⁾ and 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⁽⁷⁾.

- (11) It is necessary for the development of aquaculture in the Community to increase the awareness and preparedness of the competent authorities and aquaculture production business operators with respect to the prevention, control and eradication of aquatic animal diseases.
- (12) The competent authorities of Member States should have access to and apply state-of-the-art techniques and knowledge in the fields of risk analysis and epidemiology. This is of increasing importance because international obligations now focus on risk analysis in relation to the adoption of sanitary measures.
- (13) It is appropriate to introduce at Community level a system of authorisation of aquaculture production businesses. Such authorisation would enable the competent authorities to establish a complete overview of the aquaculture industry, which would assist in the prevention, control and eradication of aquatic animal diseases. Furthermore, authorisation allows the laying down of specific requirements that should be fulfilled by the aquaculture production business in order to operate. Such authorisation should, where possible, be combined with or included in an authorisation regime which the Member States may already have established for other purposes, for example under environmental legislation. Such authorisation should therefore not be an extra burden to the aquaculture industry.
- (14) Member States should refuse to issue an authorisation if the activity in question would pose an unacceptable risk of spreading diseases to other aquaculture animals or to wild stocks of aquatic animals. Before deciding to refuse an authorisation, consideration should be given to risk mitigation measures or alternative siting of the activity in question.
- (15) The rearing of aquaculture animals for the purpose of human consumption is defined as primary production in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽⁸⁾. Obligations imposed on individual aquaculture production businesses under this Directive, such as record keeping, and internal systems enabling the aquaculture production business to demonstrate to the competent authority that the relevant requirements of this Directive are being fulfilled, should, where possible, be combined with the obligations laid down in Regulation (EC) No 852/2004.
- (16) More attention should be paid to preventing disease occurrence than to controlling the disease once it has occurred. It is therefore appropriate to lay down minimum measures of disease prevention and risk mitigation which should be applied to the whole production chain in aquaculture, from fertilisation and hatching of eggs to the processing of aquaculture animals for human consumption, including transportation.
- (17) In order to improve general animal health and assist in the prevention and control of animal disease through improved traceability, the movement of aquaculture animals should be recorded. Where appropriate, such movements should also be subject to animal health certification.
- (18) In order to have an overview of the disease situation, to facilitate a rapid reaction in the case of a suspicion of disease and to protect farms or mollusc farming areas having a

high animal health standard, a risk-based animal health surveillance should be applied in all such farms and mollusc farming areas.

- (19) It is necessary to ensure that the main aquatic animal diseases at Community level do not spread. Harmonised animal health provisions for placing on the market should therefore be laid down with specific provisions applicable to species susceptible to those diseases. Therefore a list of such diseases and species susceptible thereto should be laid down.
- (20) The prevalence of such aquatic animal diseases is not the same throughout the Community. Reference should therefore be made to the concept of Member States declared disease free, and when dealing with parts of the territory concerned, to the concept of zones or compartments. General criteria and procedures for the granting, maintenance, suspension, restoration and withdrawal of such status should be laid down.
- (21) Without prejudice to 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⁽⁹⁾, in order to maintain and improve the general aquatic animal health status in the Community, Member States, zones or compartments declared free of one or more of the diseases listed should be protected against the introduction of such disease.
- (22) Where necessary, Member States may take interim protective measures in accordance with Article 10 of Directive 90/425/EEC and Article 18 of 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⁽¹⁰⁾.
- (23) In order to avoid the creation of unnecessary trade restrictions, the exchange of aquaculture animals between Member States, zones or compartments where one or more of such diseases are present should be allowed, provided that appropriate risk mitigation measures are taken, including during transport.
- (24) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread the disease, *inter alia* as a result of the discharge of effluents containing pathogens from processing plants. It is therefore necessary for the Member States to have access to processing establishments that have been duly authorised to undertake such slaughter and processing without jeopardising the health status of farmed and wild aquatic animals, including in respect of the discharge of effluents.
- (25) The designation of Community and national reference laboratories should contribute to the high quality and uniformity of diagnostic results. That objective can be achieved by activities such as the application of validated diagnostic tests and the organisation of comparative testing and training of staff from laboratories.
- (26) Laboratories involved in the examination of official samples should work in accordance with internationally approved procedures or criteria based on performance standards and should use diagnostic methods that have, as far as possible, been validated. For a number of activities related to such examination, the European Committee

for Standardisation (CEN), and International Organisation for Standardisation (ISO) have developed European Standards (EN Standards) and International Standards (ISO Standards) respectively, appropriate for the purpose of this Directive. Such standards relate in particular to the operation and assessment of laboratories and to the operation and accreditation of control bodies.

- (27) In order to ensure early detection of any possible outbreak of an aquatic animal disease, it is necessary to oblige those in contact with aquatic animals of susceptible species to notify any suspect case of disease to the competent authority. Routine inspections should be carried out in the Member States to ensure that aquaculture production business operators are familiar with, and apply, the general rules on disease control and biosecurity laid down in this Directive.
- (28) It is necessary to prevent the spread of non-exotic but serious diseases in aquaculture animals as soon as an outbreak occurs by carefully monitoring movements of live aquaculture animals and products thereof, and the use of equipment liable to be contaminated. The choice of the measures to be used by the competent authorities should depend on the epidemiological situation in the Member State concerned.
- (29) In order to advance the animal health status of the Community, it is appropriate that epidemiologically based programmes to control and eradicate certain diseases are submitted by Member States for recognition at Community level.
- (30) For diseases not subject to Community measures, but which are of local importance, the aquaculture industry should, with the assistance of the competent authorities of the Member States, take more responsibility for preventing the introduction of or controlling such diseases through self regulation and the development of 'codes of practice'. However, it may be necessary for the Member States to implement certain national measures. Such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect the trade between the Member States unless this is necessary in order to prevent the introduction of or to control the disease, and should be approved and regularly reviewed at Community level. Pending the establishment of such measures under this Directive, the additional guarantees granted in Commission Decision 2004/453/EC of 29 April 2004 implementing Council Directive 91/67/EEC as regards measures against certain diseases in aquaculture animals⁽¹¹⁾ should remain in force.
- (31) There is a continuous development in knowledge with respect to hitherto unknown diseases in aquatic animals. It may therefore be necessary for a Member State to apply control measures in the case of such emerging disease. Such measures should be swift and adapted to each individual case, but should not be maintained longer than necessary to achieve their goal. As such emerging diseases may also affect other Member States, all Member States and the Commission should be informed of the presence of an emerging disease and any control measures taken.
- (32) It is necessary and appropriate for the achievement of the basic objective of maintaining and, in the event of an outbreak, returning to a disease-free status in Member States, to lay down rules on the measures to increase disease preparedness. Outbreaks should be controlled as speedily as possible, if necessary by emergency vaccination, in order

to limit the adverse effects on the production of, and trade in, live aquaculture animals and products thereof.

- (33) Directive of the European Parliament and of the Council 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products⁽¹²⁾ and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁽¹³⁾ require that, with only minor exceptions, all veterinary medicinal products that are placed on the market within the Community are to hold a marketing authorisation. In general, all vaccines used in the Community should have a marketing authorisation. However, the Member States may permit the use of a product without a marketing authorisation in the event of a serious epidemic subject to certain conditions, in accordance with Regulation (EC) No 726/2004. Vaccines against exotic and emerging diseases in aquaculture animals may qualify for such derogation.
- (34) This Directive should lay down provisions to ensure the necessary level of preparedness to effectively tackle the emergency situations related to one or more outbreaks of serious exotic or emerging diseases affecting aquaculture, in particular by drawing up contingency plans to combat them. Such contingency plans should be reviewed and updated regularly.
- (35) Where the control of a serious aquatic animal disease is subject to harmonised Community eradication measures, Member States should be allowed to make use of financial contribution from the Community under Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund⁽¹⁴⁾. Any application for Community support should be subject to scrutiny as regards compliance with control provisions laid down in this Directive.
- (36) Live aquaculture animals and products thereof imported from third countries should not present an animal health hazard for aquatic animals in the Community. To that end, this Directive should set out measures for the prevention of the introduction of epizootic diseases.
- (37) It is necessary in order to safeguard the aquatic animal health situation in the Community to further ensure that consignments of live aquaculture animals transiting through the Community comply with the relevant animal health requirements applicable to the species concerned.
- (38) The placing on the market of ornamental aquatic animals involves a wide variety of species, often tropical species, solely for ornamental purposes. Those ornamental aquatic animals are normally kept in private aquariums or ponds, garden centres, or in exhibition aquariums, not in direct contact with Community waters. Consequently, ornamental aquatic animals held under such conditions do not pose the same risk to other sectors of Community aquaculture or to wild stocks. It is therefore appropriate to lay down special provisions applicable to the placing on the market, transit and import of ornamental aquatic animals, kept under such conditions.

- (39) However, where ornamental aquatic animals are kept outside closed systems or aquariums, in direct contact with the natural waters of the Community, they could pose a significant risk to Community aquaculture or wild stocks. That is particularly the case for the populations of carp (*Cyprinidae*), as popular ornamental fish such as koi carp are susceptible to some diseases affecting other carp species farmed in the Community or found in the wild. In such cases, the general provisions of this Directive should apply.
- (40) The setting up of electronic means of information exchange is vital for simplification, for the benefit of the aquaculture industry and of the competent authorities. In order to meet that obligation, common criteria need to be introduced.
- (41) Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (42) In accordance with paragraph 34 of the Interinstitutional agreement on better law-making⁽¹⁵⁾, Member States are encouraged to draw up, for themselves and in the interest of the Community, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures and to make them public.
- (43) Since the objectives of this Directive, namely to provide for the approximation of the concepts, principles and procedures forming a common basis for aquatic animal health legislation in the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of this Directive, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (44) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽¹⁶⁾.
- (45) It is appropriate to update Community animal health legislation concerning aquaculture animals and products thereof. Accordingly, Directives 91/67/EEC, 93/53/EEC and 95/70/EC should be repealed and replaced by this Directive,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

- 1 This Directive lays down:

- a the animal health requirements to be applied for the placing on the market, the importation and the transit of aquaculture animals and products thereof;
- b minimum preventive measures aimed at increasing the awareness and preparedness of the competent authorities, aquaculture production business operators and others related to this industry, for diseases in aquaculture animals;
- c minimum control measures to be applied in the event of a suspicion of, or an outbreak of certain diseases in aquatic animals.

2 Member States shall remain free to take more stringent measures in the field covered by Article 13 of Chapter II, and Chapter V, provided that such measures do not affect trade with other Member States.

Article 2

Scope

- 1 This Directive shall not apply to:
- a ornamental aquatic animals reared in non-commercial aquaria;
 - b wild aquatic animals harvested or caught for direct entry into the food chain;
 - c aquatic animals caught for the purpose of production of fishmeal, fish feed, fish oil and similar products.
- 2 Chapter II, Sections 1 to 4 of Chapter III, and Chapter VII shall not apply where ornamental aquatic animals are kept in pet shops, garden centres, garden ponds, commercial aquaria, or with wholesalers:
- a without any direct contact with natural waters in the Community;
 - or
 - b which are equipped with an effluent treatment system reducing the risk of transmitting diseases to the natural waters to an acceptable level.
- 3 This Directive shall apply without prejudice to provisions on the conservation of species or the introduction of non-native species.

Article 3

Definitions

- 1 For the purposes of this Directive, the following definitions shall apply:
- a 'aquaculture' means the rearing or cultivation of aquatic organisms using techniques designed to increase the production of those organisms beyond the natural capacity of the environment and where the organisms remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting;
 - b 'aquaculture animal' means any aquatic animal at all its life stages, including eggs and sperm/gametes, reared in a farm or mollusc farming area, including any aquatic animal from the wild intended for a farm or mollusc farming area;
 - c 'aquaculture production business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to the rearing, keeping or cultivation of aquaculture animals;

- d 'aquaculture production business operator' means any natural or legal person responsible for ensuring that the requirements of this Directive are met within the aquaculture production business under their control;
 - e 'aquatic animal' means:
 - (i) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes* and *Osteichthyes*;
 - (ii) mollusc belonging to the Phylum *Mollusca*;
 - (iii) crustacean belonging to the Subphylum *Crustacea*;
 - f 'authorised processing establishment' means any food business approved in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽¹⁷⁾, for processing aquaculture animals for food purposes, and authorised in accordance with Articles 4 and 5 of this Directive;
 - g 'authorised processing establishment operator' means any natural or legal person responsible for ensuring that the requirements of this Directive are met within the authorised processing establishment under their control;
 - h 'farm' means any premises, enclosed area, or installation operated by an aquaculture production business in which aquaculture animals are reared with a view to their being placed on the market, with the exception of those where wild aquatic animals harvested or caught for the purpose of human consumption are temporarily kept awaiting slaughter without being fed;
 - i 'farming' means the rearing of aquaculture animals in a farm or in a mollusc farming area;
 - j 'mollusc farming area' means a production area or relaying area in which all aquaculture production businesses operate under a common biosecurity system;
 - k 'ornamental aquatic animal' means an aquatic animal which is kept, reared, or placed on the market for ornamental purposes only;
 - l 'placing on the market' means the sale, including offering for sale or any other form of transfer, whether free of charge or not, and any form of movement of aquaculture animals;
 - m 'production area' means any freshwater, sea, estuarine, continental or lagoon area containing natural beds of molluscs or sites used for the cultivation of molluscs, and from which molluscs are taken;
 - n 'put and take fisheries' means ponds or other installations where the population is maintained only for recreational fishing by restocking with aquaculture animals;
 - o 'relaying area' means any freshwater, sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live molluscs;
 - p 'wild aquatic animal' means an aquatic animal which is not an aquaculture animal.
- 2 For the purposes of this Directive, the following definitions shall also apply:
- a the technical definitions laid down in Annex I;
 - b as appropriate, the definitions laid down respectively in:
 - (i) Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽¹⁸⁾;

- (ii) Article 2 of Regulation (EC) No 852/2004;
- (iii) Article 2 of Regulation (EC) No 853/2004;
- (iv) Article 2 of Regulation (EC) No 882/2004.

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.

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.

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.

CHAPTER III

ANIMAL HEALTH REQUIREMENTS FOR PLACING ON THE MARKET OF AQUACULTURE ANIMALS AND PRODUCTS THEREOF

SECTION 1

General Provisions

Article 11

Scope

1 Unless otherwise provided, this Chapter shall apply only to the diseases and the species susceptible thereto listed in Part II of Annex IV.

2 Member States may allow the placing on the market for scientific purposes of aquaculture animals and products thereof, which do not comply with this Chapter under the strict supervision of the competent authority.

The competent authority shall ensure that such placing on the market does not jeopardise the health status with regard to the diseases listed in Part II of Annex IV of aquatic animals at the place of destination or at places of transit.

Any such movements between Member States shall not take place without prior notification of the competent authorities of the Member States concerned.

Article 12

General requirements for the placing of aquaculture animals on the market

1 Member States shall ensure that the placing on the market of aquaculture animals and products thereof does not jeopardise the health status of aquatic animals at the place of destination with regard to the diseases listed in Part II of Annex IV.

2 Detailed rules on the movement of aquaculture animals are laid down in this Chapter, in particular relating to movements between Member States, zones and compartments with different health statuses, as referred to in Part A of Annex III.

Article 13

Disease prevention requirements in relation to transport

1 Member States shall ensure that:

- a the necessary disease prevention measures are applied during the transport of aquaculture animals in order not to alter the health status of those animals during transport, and to reduce the risk of spreading diseases;

and

- b aquaculture animals are transported under conditions which neither alter their health status nor jeopardise the health status of the place of destination, and where appropriate, of places of transit.

This paragraph shall also apply to diseases and the species susceptible thereto not listed in Part II of Annex IV.

2 Member States shall ensure that any water exchanges during transport are carried out at places and under conditions which do not jeopardise the health status of:

- a the aquaculture animals being transported;
- b any aquatic animals at the place of water exchange;

and

- c aquatic animals at the place of destination.

Article 14

Animal health certification

1 Member States shall ensure that the placing on the market of aquaculture animals is subject to animal health certification when the animals are introduced into a Member State, zone or compartment declared disease-free in accordance with Articles 49 and 50 or subject to surveillance, or eradication programme in accordance with Article 44(1) or (2) for:

- a farming and restocking purposes;

or

- b further processing before human consumption, unless:

- (i) as regards fish, they are slaughtered and eviscerated before dispatch;

- (ii) as regards molluscs and crustaceans, they are dispatched as unprocessed or processed products.

2 Member States shall also ensure that the placing on the market of aquaculture animals is subject to animal health certification when the animals are allowed to leave an area subject to the control provisions provided for in Sections 3, 4, 5 and 6 of Chapter V.

This paragraph shall also apply to diseases and the species susceptible thereto not listed in Part II of Annex IV.

3 The following movements shall be subject to notification under the computerised system provided for in Article 20(1) of Directive 90/425/EEC:

- a movements of aquaculture animals between Member States where animal health certification is required in accordance with paragraphs 1 or 2 of this Article;

and

- b all other movements of live aquaculture animals for farming or restocking purposes between Member States where no animal health certification is required under this Directive.

4 Member States may decide to use the computerised system provided for in paragraph 3 to trace movements taking place entirely within their territory.

SECTION 2

Aquaculture animals intended for farming and restocking

Article 15

General requirements for the placing of aquaculture animals on the market for farming and restocking

1 Without prejudice to the provisions laid down in Chapter V, Member States shall ensure that aquaculture animals placed on the market for farming are:

- a clinically healthy;

and

- b do not come from a farm or mollusc farming area where there is any unresolved increased mortality.

This paragraph shall also apply in relation to diseases and the species susceptible thereto not listed in Part II of Annex IV.

2 By way of derogation from paragraph 1(b), Member States may allow such placing on the market, based on an assessment of risk, provided that the animals originate from a part of the farm or mollusc farming area independent of the epidemiological unit where the increased mortality has occurred.

3 Member States shall ensure that aquaculture animals intended for destruction or slaughter in accordance with the disease control measures provided for in Chapter V are not placed on the market for farming and restocking purposes.

4 Aquaculture animals may only be released into the wild for restocking purposes or into put and take fisheries if they:

- a comply with the requirements in paragraph 1;
- and
- b come from a farm or mollusc farming area with a health status as referred to in Part A of Annex III, at least equivalent to the health status of the waters in which they are to be released.

However, Member States may decide that the aquaculture animals shall come from a zone or compartment declared disease-free in accordance with Articles 49 or 50. Member States may also decide to apply this paragraph to programmes drawn up and applied in accordance with Article 43.

Article 16

Introduction of aquaculture animals of species susceptible to a specific disease into areas free of that disease

1 In order to be introduced for farming or restocking into a Member State, zone or compartment declared free of a specific disease in accordance with Articles 49 or 50, aquaculture animals of species susceptible thereto shall originate from another Member State, zone or compartment also declared free of that disease.

2 Where it can be scientifically justified that species susceptible to the specific disease at certain life stages do not transmit that disease, paragraph 1 shall not apply to those life stages.

A list of species and life stages to which the first subparagraph may apply shall be adopted and when necessary amended to take account of scientific and technological developments in accordance with the procedure referred to in Article 62(2).

Article 17

Introduction of live aquaculture animals of vector species into disease-free areas

1 Where scientific data or practical experience substantiates that species other than those referred to in Part II of Annex IV may be responsible for the transmission of a specific disease by acting as vector species, Member States shall ensure that where introduced for farming or restocking purposes into a Member State, zone or compartment declared free of that specific disease in accordance with Articles 49 or 50, such vector species shall:

- a originate from another Member State, zone or compartment declared free of that specific disease;
- or
- b be held in quarantine facilities 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.

2 A list of vector species and life stages of such species to which this Article applies and, where appropriate, the conditions under which those species can transmit a disease shall be adopted, and when necessary amended taking into account scientific and technological developments in accordance with the procedure referred to in Article 62(2).

3 Pending the possible inclusion of a species on the list referred to in paragraph 2, the Commission may decide in accordance with the procedure referred to in Article 62(3), to allow Member States to apply the provisions provided for in paragraph 1.

SECTION 3

Aquaculture animals and products thereof intended for human consumption

Article 18

Aquaculture animals and products thereof placed on the market for further processing before human consumption

1 Member States shall ensure that aquaculture animals of species susceptible to one or more of the non-exotic diseases listed in Part II of Annex IV, and products thereof, may only be placed on the market for further processing in a Member State, zone or compartment declared free of those diseases in accordance with Articles 49 or 50, if they comply with one of the following conditions:

- a they originate from another Member State, zone or compartment declared free of the disease in question;
 - b they are processed in an authorised processing establishment under conditions which prevent the spreading of diseases;
 - c as regards fish, they are slaughtered and eviscerated before dispatch;
- or
- d as regards molluscs and crustaceans, they are dispatched as unprocessed or processed products.

2 Member States shall ensure that live aquaculture animals of species susceptible to one or more of the non-exotic diseases listed in Part II of Annex IV which are placed on the market for further processing in a Member State, zone or compartment declared free of those diseases in accordance with Articles 49 or 50, may only be temporarily stored at the place of processing if:

- a they originate from another Member State, zone, or compartment declared free of the disease in question;
- or
- b they are temporarily kept in dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.

Article 19

Aquaculture animals and products thereof placed on the market for human consumption without further processing

1 This section shall not apply where aquaculture animals of species susceptible to one or more of the diseases listed in Part II of Annex IV, or products thereof, are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for packaging and labelling provided for in Regulation (EC) No 853/2004.

2 Where live molluscs and crustaceans of species susceptible to one or more of the diseases listed in Part II of Annex IV are temporarily relayed in Community waters, or introduced into dispatch centres, purification centres or similar businesses, they shall comply with Article 18(2).

SECTION 4

Wild aquatic animals

Article 20

Release of wild aquatic animals in Member States, zones or compartments declared disease-free

1 Wild aquatic animals of species susceptible to one or more of the diseases listed in Part II of Annex IV caught in a Member State or zone or compartment not declared disease-free in accordance with Articles 49 or 50 shall be placed 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, before they may be released into a farm or mollusc farming area situated in a Member State, zone, or compartment declared free from that disease in accordance with Articles 49 or 50.

2 The Member States may allow traditional extensive lagoon aquaculture practice, without the quarantine provided for in paragraph 1, provided a risk assessment is undertaken and that the risk is considered not higher than what is expected from the application of paragraph 1.

SECTION 5

Ornamental aquatic animals

Article 21

Placing on the market of ornamental aquatic animals

1 Member States shall ensure that the placing on the market of ornamental aquatic animals does not jeopardise the health status of aquatic animals with regard to the diseases listed in Part II of Annex IV.

2 This Article shall apply also in relation to diseases not listed in Part II of Annex IV.

CHAPTER IV

INTRODUCTION OF AQUACULTURE ANIMALS AND PRODUCTS THEREOF INTO THE COMMUNITY FROM THIRD COUNTRIES

Article 22

General requirements for introduction of aquaculture animals and products thereof from third countries

Member States shall ensure that aquaculture animals and products thereof are introduced into the Community only from third countries or parts of third countries that appear on a list drawn up and updated in accordance with the procedure referred to Article 62(2).

Article 23

Lists of third countries and parts of third countries from which introduction of aquaculture animals and products thereof is permitted

1 A third country, or a part of a third country, shall appear on the list provided for in Article 22 only if a Community assessment of that country, or that part of a third country, has demonstrated that the competent authority provides appropriate guarantees as regards compliance with the relevant animal health requirements of Community legislation.

2 The Commission may decide if an inspection as referred to in Article 58(2) is necessary to complete the assessment of the third country, or part of the third country, provided for in paragraph 1.

3 When drawing up or updating the lists provided for in Article 22, particular account shall be taken of:

- a the legislation of the third country;
- b the organisation of the competent authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and the means at their disposal, including staff capacity, to apply their legislation effectively;
- c the aquatic animal health requirements in force that apply to the production, manufacture, handling, storage and dispatch of live aquaculture animals intended for the Community;
- d the assurances which the competent authority of the third country may give regarding compliance or equivalence with the relevant aquatic animal health conditions;
- e any experience of marketing live aquaculture animals from the third country and the results of any import controls carried out;
- f the results of the Community assessment, in particular the results of the assessment carried out by the competent authorities of the third country concerned or, where the Commission so requests, the report submitted by the competent authorities of the third country on any inspections carried out;
- g the health status of farmed and wild aquatic animals in the third country, with particular regard to exotic animal diseases and any aspects of the general aquatic animal health situation in the country which might pose a risk to aquatic animal health in the Community;
- h the regularity, speed and accuracy with which the third country supplies information on the existence of infectious or contagious aquatic animal diseases in its territory,

particularly the notifiable diseases, listed by the World Organisation for Animal Health (OIE);

and

- i the rules on the prevention and control of aquatic animal diseases in force in the third country and their implementation, including rules on imports from other countries.

4 The Commission shall arrange for all lists to be drawn up or updated in accordance with Article 22 and made available to the public.

5 Lists drawn up in accordance with Article 22 may be combined with other lists drawn up for animal and public health purposes.

Article 24

Documents

1 All consignments of aquaculture animals and products thereof shall be accompanied by a document containing an animal health certificate upon their entry into the Community.

2 The animal health certificate shall certify that the consignment satisfies:

- a the requirements laid down for such commodities under this Directive;

and

- b any special import conditions established in accordance with Article 25(a).

3 The document may include details required under other provisions of Community public and animal health legislation.

Article 25

Detailed rules

Where necessary, detailed rules for the application of this Chapter may be established in accordance with the procedure referred to in Article 62(2). These rules may concern in particular:

- (a) special import conditions for each third country, parts thereof or group of third countries;
 - (b) the criteria for classifying third countries and parts thereof with regard to aquatic animal diseases;
 - (c) the use of electronic documents;
 - (d) model animal health certificates and other documents;
- and
- (e) procedures and certification for transit.

CHAPTER V

NOTIFICATION AND MINIMUM MEASURES FOR CONTROL OF DISEASES OF AQUATIC ANIMALS

SECTION 1

Disease notification

Article 26

National notification

- 1 Member States shall ensure that:
 - a when there are any reasons to suspect the presence of a disease listed in Part II of Annex IV, or the presence of such disease is confirmed in aquatic animals, the suspicion and/or the confirmation is immediately notified to the competent authority;
 - and
 - b when increased mortality occurs in aquaculture animals, the mortality is immediately notified to the competent authority or a private veterinarian for further investigations.
- 2 Member States shall ensure that the obligations to notify the matters referred to in paragraph 1 are imposed on:
 - a the owner and any person attending aquatic animals;
 - b any person accompanying aquaculture animals during transport;
 - c veterinary practitioners and other professionals involved in aquatic animal health services;
 - d official veterinarians, senior staff of veterinary or other official or private laboratories;
 - and
 - e any other person with an occupational relationship to aquatic animals of susceptible species or to products of such animals.

Article 27

Notification of the other Member States, the Commission and EFTA Member States

Member States shall notify the other Member States, the Commission and EFTA Member States within 24 hours in case of confirmation of:

- (a) an exotic disease listed in Part II of Annex IV;
- (b) a non-exotic disease listed in Part II of Annex IV where the Member State concerned, zone, or compartment has been declared free of that disease.

SECTION 2

Suspicion of a listed disease – Epizootic investigation*Article 28***Initial control measures**

Member States shall ensure that, in the case of a suspicion of an exotic disease listed in Part II of Annex IV or, in the case of suspicion of a non-exotic disease listed in Part II of Annex IV in Member States, zones or compartments with a health status of either category I or III as referred to in Part A of Annex III, for that disease:

- (a) appropriate samples are taken and examined in a laboratory designated in accordance with Article 57;
- (b) pending the result of the examination provided for in point (a):
 - (i) the farm, or mollusc farming area, in which the disease is suspected, is placed under official surveillance and relevant control measures are implemented to prevent the spreading of the disease to other aquatic animals;
 - (ii) no aquaculture animals are allowed to leave or enter the affected farm or mollusc farming area in which the disease is suspected, unless authorised by the competent authority;
 - (iii) the epizootic investigation provided for in Article 29 is initiated.

*Article 29***Epizootic investigation**

1 Member States shall ensure that the epizootic investigation initiated in accordance with Article 28(b)(iii) is carried out where the examination provided for in Article 28(a) shows the presence of:

- a an exotic disease listed in Part II of Annex IV in any Member State;
- or
- b a non-exotic disease listed in Part II of Annex IV in Member States, zones or compartments with a health status of either category I or III, as referred to in Part A of Annex III, for the disease in question.

2 The epizootic investigation provided for in paragraph 1 shall be aimed at:

- a determining the possible origin and means of contamination;
- b investigating whether aquaculture animals have left the farm or mollusc farming area during the relevant period preceding the notification of the suspicion provided for in Article 26(1);
- c investigating whether other farms have been infected.

3 Where the epizootic investigation provided for in paragraph 1 shows that the disease may have been introduced into one or more farms, mollusc farming areas or unenclosed waters, the Member State concerned shall ensure that the measures provided for in Article 28 are applied in such farms, mollusc farming areas or unenclosed waters.

In the case of extensive water catchment areas or coastal areas, the competent authority may decide to limit the application of Article 28 to a less extensive area in the vicinity of the farm or the mollusc farming area suspected of being infected, where it considers that such less extensive area is sufficiently large to guarantee that the disease does not spread.

4 Where necessary, the competent authority of neighbouring Member States or third countries shall be informed of the suspected case of disease.

In that event, the competent authorities of the Member States involved shall take appropriate action to apply the measures provided for in this Article within their territory.

Article 30

Lifting restrictions

The competent authority shall lift the restrictions provided for in Article 28(b) where the examination provided for in point (a) of that Article fails to demonstrate the presence of the disease.

SECTION 3

Minimum control measures in the case of confirmation of exotic diseases in aquaculture animals

Article 31

Introductory provision

This Section shall apply in the case of confirmation of an exotic disease listed in Part II of Annex IV in aquaculture animals.

Article 32

General measures

Member States shall ensure that:

- (a) the farm or mollusc farming area is officially declared infected;
- (b) a containment area appropriate to the disease in question is established, including a protection zone and surveillance zone, around the farm or mollusc farming area declared infected;
- (c) no restocking takes place and no aquaculture animals are moved into, within, and out of the containment area unless authorised by the competent authority;
- and
- (d) any additional measures necessary to prevent the further spread of the disease are implemented.

Article 33

Harvesting and further processing

- 1 Aquaculture animals which have reached commercial size and show no clinical sign of disease may be harvested under the supervision of the competent authority for human consumption, or for further processing.
- 2 Harvesting, introduction into dispatch centres or purification centres, further processing and any other related operations involved in the preparation of the aquaculture animals for entry into the food chain shall be carried out under conditions which prevent the spread of the pathogen responsible for causing the disease.
- 3 Dispatch centres, purification centres or similar businesses shall be equipped with an effluent treatment system inactivating the pathogen responsible for causing the disease, or the effluent shall be subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.
- 4 Further processing shall be performed in authorised processing establishments.

Article 34

Removal and disposal

- 1 Member States shall ensure that dead fish and crustaceans, as well as live fish and crustaceans showing clinical signs of disease, are removed and disposed of under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽¹⁹⁾, as soon as possible in accordance with the contingency plan provided for in Article 47 of this Directive.
- 2 Aquaculture animals which have not reached commercial size and do not show clinical signs of disease shall, in an appropriate timeframe taking into account the type of production and the risk such animals pose for further spread of the disease, be removed and disposed of under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002, and the contingency plan provided for in Article 47 of this Directive.

Article 35

Fallowing

Where possible, infected farms or mollusc farming areas shall undergo an appropriate period of fallowing after being emptied and, where appropriate, cleansed and disinfected.

For farms or mollusc farming areas rearing aquaculture animals not susceptible to the disease in question, decisions on fallowing shall be based on a risk assessment.

Article 36

Protection of aquatic animals

Member States shall take the necessary measures to prevent the spreading of diseases to other aquatic animals.

Article 37

Lifting measures

The measures provided for in this Section shall be maintained until:

- (a) the eradication measures provided for in this Section have been carried out;
- (b) sampling and surveillance as appropriate for the disease in question and the types of aquaculture production businesses affected has been carried out in the containment area with negative results.

SECTION 4

Minimum control measures in the case of confirmation of non-exotic diseases in aquaculture animals

Article 38

General provisions

1 In the case of confirmation of a non-exotic disease listed in Part II of Annex IV in a Member State, zone or compartment declared free of that disease, the Member State concerned shall either:

- a apply the measures provided for in Section 3 in order to regain such disease-free status,
- or
- b draw up an eradication programme in accordance with Article 44(2).

2 By way of derogation from Article 34(2), where a Member State decides to apply the measures provided for in Section 3, it may allow clinically healthy animals to be raised to market size before slaughter for human consumption or to be moved to another infected zone or compartment. In such cases, measures shall be taken to reduce and as far as possible, prevent the further spreading of the disease.

3 Where the Member State concerned does not wish to regain disease-free status, Article 39 shall apply.

Article 39

Containment measures

In the case of confirmation of a non-exotic disease listed in Part II of Annex IV in a Member State, zone or compartment not declared free of that disease, the Member State concerned shall take measures to contain the disease.

Those measures shall at least consist of:

- (a) declaring the farm or mollusc farming area to be infected;
- (b) establishing a containment area appropriate to the disease in question, including a protection zone and surveillance zone around the farm or mollusc farming area declared infected;
- (c) restricting the movement of aquaculture animals from the containment area to the effect that such animals may only be:
 - (i) introduced into farms or mollusc farming areas in accordance with Article 12(2);
 - or
 - (ii) harvested and slaughtered for human consumption in accordance with Article 33(1);
- (d) the removal and disposal of dead fish and crustaceans, under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002, in an appropriate timeframe taking into account the type of production and the risk such dead animals pose for further spread of the disease.

SECTION 5

Minimum control measures in the case of confirmation of diseases listed in Part II of Annex IV in wild aquatic animals

Article 40

Control of diseases listed in Part II of Annex IV in wild aquatic animals

1 Where wild aquatic animals are infected or suspected of being infected with exotic diseases listed in Part II of Annex IV, the Member State concerned shall monitor the situation, and take measures to reduce and, as far as possible, to prevent the further spreading of the disease.

2 Where wild aquatic animals are infected or suspected of being infected with non-exotic diseases listed in Part II of Annex IV in a Member State, zone or compartment declared free of that disease, the Member State shall also monitor the situation and take measures to reduce, and as far as possible, to prevent the further spreading of the disease.

3 Member States shall inform the Commission and the other Member States within the Committee referred to in Article 62(1) of the measures they have taken in accordance with paragraphs 1 and 2.

SECTION 6

Control measures in case of emerging diseases

Article 41

Emerging diseases

1 Member States shall take appropriate measures to control an emerging disease situation and prevent that disease from spreading, where the emerging disease in question has the potential to jeopardise the health situation of aquatic animals.

2 In the case of an emerging disease situation, the Member State concerned shall inform the Member States, the Commission and EFTA Member States without delay thereof, where the findings are of epidemiological significance to another Member State.

3 Within four weeks of informing the other Member States, the Commission and EFTA Member States as required in paragraph 2, the matter shall be brought to the attention of the Committee referred to in Article 62(1). The measures taken by the Member State concerned pursuant to paragraph 1 of this Article may be extended, amended or repealed in accordance with the procedure referred to in Article 62(2).

4 Where appropriate, the list set out in Part II of Annex IV shall be amended in accordance with the procedure referred to in Article 62(2) to include the emerging disease in question or a new susceptible host species to a disease already listed in that Annex.

SECTION 7

Alternative measures and national provisions

Article 42

Procedure for adoption of ad hoc epidemiological measures for diseases listed in Part II of Annex IV

A decision may be adopted in accordance with the procedure referred to in Article 62(2) to authorise the implementation of ad hoc measures for a limited period of time, under conditions appropriate to the epidemiological situation where:

- (a) the measures provided for in this chapter are found not to be suited to the epidemiological situation;
- or
- (b) the disease appears to be spreading despite the measures taken in accordance with this chapter.

Article 43

Provisions for limiting the impact of diseases not listed in Part II of Annex IV

1 Where a disease not listed in Part II of Annex IV constitutes a significant risk for the animal health situation of aquaculture or wild aquatic animals in a Member State, the Member State concerned may take measures to prevent the introduction of or to control that disease.

Member States shall ensure that these measures do not exceed the limits of what is appropriate and necessary to prevent the introduction of or to control the disease.

2 Member States shall notify to the Commission any measures referred to in paragraph 1 that may affect trade between Member States. Those measures shall be subject to approval in accordance with the procedure referred to in Article 62(2).

3 Approval referred to in paragraph 2 shall only be granted where the establishment of intra-Community trade restrictions is necessary to prevent the introduction of or to control the disease, and shall take into account the provisions laid down in Chapters II, III, IV and V.

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.

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;
- 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.

CHAPTER VII

DISEASE-FREE STATUS

Article 49

Disease-free Member State

1 A Member State shall be declared free of one or more of the non-exotic diseases listed in Part II of Annex IV in accordance with the procedure referred to in Article 62(2), if paragraph 2 of this Article is complied with and:

- a none of the species susceptible to the disease(s) in question is present in its territory;
- or
- b the pathogen is known not to be able to survive in the Member State, and in its water source;
- or
- c the Member State meets the conditions laid down in Part I of Annex V.

2 Where neighbouring Member States, or water catchment areas shared with neighbouring Member States, are not declared disease-free, the Member State shall establish appropriate buffer zones in its territory. The demarcation of buffer zones shall be such that they protect the disease-free Member State from passive introduction of the disease.

3 The specific requirements for surveillance, buffer zones, sampling and diagnostic methods that shall be used by Member States to grant disease-free status in accordance with this Article shall be adopted in accordance with the procedure referred to in Article 62(2).

Article 50

Disease-free zone or compartment

1 A Member State may declare a zone or a compartment within its territory free of one or more of the non-exotic diseases listed in Part II of Annex IV, where:

- a none of the species susceptible to the disease(s) in question is present in the zone or compartment, and where relevant in its water source;
- or

- b the pathogen is known not to be able to survive in the zone or compartment, and where relevant in its water source;
- or
- c the zone or compartment complies with the conditions laid down in Part II of Annex V.

2 A Member State shall submit the declaration referred to in paragraph 1 to the Standing Committee on Food Chain and Animal Health in accordance with the following procedure:

- a the declaration shall be supported by evidence in a form to be determined in accordance with the procedure referred to in Article 62(2) and be accessible by electronic means to the Commission and Member States, in accordance with the requirements of Article 59;
- b the Commission shall add the notification of the declaration to the agenda of the next meeting of the Committee referred to in Article 62(1) as an information point. The declaration shall take effect 60 days after the date of the meeting;
- c within this period, the Commission or Member States may seek clarification or additional information on the supporting evidence from the Member State making the declaration;
- d where written comments are made by at least one Member State, or the Commission, within the period referred to in point (b) indicating significant objective concerns related to the supporting evidence, the Commission and the Member States concerned shall together examine the submitted evidence in order to resolve the concerns. In that case, the period referred to in point (b) may be prolonged for 30 days. Such comments shall be submitted to the declaring Member State and to the Commission;
- e if the arbitration referred to in point (d) fails, the Commission may decide to make an on-the-spot inspection in accordance with Article 58 to verify the compliance of the declaration submitted with the criteria set out in paragraph 1, unless the declaring Member State withdraws its declaration;
- f where necessary in the light of the results achieved, a decision in accordance with the procedure referred to in Article 62(2) shall be taken, to suspend the self-declaration of the disease-free status of the zone or compartment concerned.

3 Where the zone(s) or compartment(s) referred to in paragraph 1 comprise more than 75 % of the territory of the Member State, or if the zone or compartment consists of a water catchment area shared by another Member State or third country, the procedure referred to in paragraph 2 shall be replaced by the procedure referred to in Article 62(2).

4 The specific requirements of the surveillance, sampling and diagnostic methods used by Member States to obtain disease-free status in accordance with this Article shall be laid down in accordance with the procedure referred to in Article 62(2).

Article 51

Lists of disease-free Member States, zones or compartments

1 Each Member State shall establish and maintain an updated list of zones and compartments declared disease-free in accordance with Article 50(2). Such lists shall be made publicly available.

2 The Commission shall draw up and update a list of Member States, zones or compartments declared disease-free in accordance with Articles 49 or 50(3), and shall make the list publicly available.

Article 52

Maintenance of disease-free status

A Member State that is declared free from one or more non-exotic diseases listed in Part II of Annex IV in accordance with Article 49 may discontinue targeted surveillance and maintain its disease-free status provided that the conditions conducive to clinical expression of the disease in question exist, and the relevant provisions of this Directive are implemented.

However, for disease-free zones or compartments in Member States not declared disease-free, and in all cases where conditions are not conducive to clinical expression of the disease in question, targeted surveillance shall be continued in accordance with the methods provided for in Articles 49(3) or 50(4) as appropriate, but at a level commensurate with the degree of risk.

Article 53

Suspension and restoration of disease-free status

1 Where a Member State has reason to believe that any of the conditions for maintaining its status as a disease-free Member State, zone or compartment have been breached, that Member State shall immediately suspend trade in susceptible species and vector species to other Member States, zones or compartments with a higher health status for the disease in question as laid down in Part A of Annex III and apply the provisions of Sections 2 and 4 of Chapter V.

2 Where the epizootic investigation provided for in Article 29(1) confirms that the suspected breach has not taken place, the disease-free status of the Member State, zone or compartment shall be restored.

3 Where the epizootic investigation confirms a significant likelihood that infection has occurred, the disease-free status of the Member State, zone or compartment shall be withdrawn, in accordance with the procedure under which that status was declared. The requirements laid down in Annex V shall be complied with before the disease-free status is restored.

CHAPTER VIII

COMPETENT AUTHORITIES AND LABORATORIES

Article 54

General obligations

1 Each Member State shall designate its competent authorities for the purposes of this Directive and notify the Commission thereof.

The competent authorities shall operate and perform their duties in accordance with Regulation (EC) No 882/2004.

2 Each Member State shall ensure that effective and continuous cooperation based on the free exchange of information relevant to the implementation of this Directive is established

between the competent authorities it designates for the purposes of this Directive and any of its other authorities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin.

Information shall also, to the extent necessary, be exchanged between the competent authorities of the different Member States.

3 Each Member State shall ensure that the competent authorities have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology, and that there is a free exchange of any information relevant to the implementation of this Directive between the competent authorities and laboratories.

Article 55

Community reference laboratories

1 Community reference laboratories for the aquatic animal diseases relevant to this Directive shall be designated in accordance with the procedure referred to in Article 62(2) for a period to be defined in accordance with that procedure.

2 Community reference laboratories for aquatic animal diseases shall comply with the functions and duties laid down in Part I of Annex VI.

3 The Commission shall review the designation of the Community reference laboratories by the end of the period referred to in paragraph 1 at the latest, in the light of their compliance with the functions and duties referred to in paragraph 2.

Article 56

National reference laboratories

1 Member States shall arrange for the designation of a national reference laboratory for each of the Community reference laboratories referred to in Article 55.

Member States may designate a laboratory situated in another Member State or EFTA Member State, and a single laboratory may be the national reference laboratory for more than one Member State.

2 Member States shall communicate the name and address of each designated national reference laboratory to the Commission, the relevant Community reference laboratory and other Member States, including any updates hereto.

3 The national reference laboratory shall liaise with the relevant Community reference laboratory provided for in Article 55.

4 In order to ensure an efficient diagnostic service throughout the territory of a Member State in accordance with the requirements of this Directive, the national reference laboratory shall collaborate with any laboratory designated in accordance with Article 57 situated in the territory of the same Member State.

5 Member States shall ensure that any national reference laboratory on their territory is adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with this Directive and to comply with the functions and duties laid down in Part II of Annex VI.

Article 57

Diagnostic services and methods

Member States shall ensure that:

- (a) laboratory examinations for the purposes of this Directive are carried out in laboratories designated for such purpose by the competent authority;
 - (b) laboratory examinations in the case of suspicion and to confirm the presence of the diseases listed in Part II of Annex IV are carried out by diagnostic methods to be established in accordance with the procedure referred to in Article 62(2);
- and
- (c) laboratories designated for diagnostic services in accordance with this Article shall comply with the functions and duties laid down in Part III of Annex VI.

CHAPTER IX

INSPECTIONS, ELECTRONIC MANAGEMENT AND PENALTIES

Article 58

Community inspections and audits

1 Experts from the Commission may carry out on-the-spot inspections, including audits, in cooperation with the competent authorities of the Member States, insofar as they are necessary for the uniform application of this Directive.

The Member States in the territory of which such inspections and audits are made shall provide the experts with all the assistance necessary for carrying out their duties.

The Commission shall inform the competent authority of the results of any such inspections and audits.

2 Experts from the Commission may also carry out on-the-spot inspections, including audits, in third countries, in cooperation with the competent authorities of the third country concerned, in order to verify conformity with or equivalence to Community aquatic animal health rules.

3 Where a serious animal health risk is identified during a Commission inspection, the Member State concerned shall immediately take all measures necessary to safeguard animal health.

Where such measures are not taken, or where they are considered to be insufficient, the measures necessary to safeguard animal health shall be adopted in accordance with the procedure referred to in Article 62(3) and the Member State concerned shall be informed thereof.

Article 59

Electronic management

1 Member States shall, by 1 August 2008 at the latest, ensure that all procedures and formalities relating to making the information provided for in Article 6, Article 50(2) Article 51(1) and Article 56(2) available by electronic means are in place.

2 The Commission shall, in accordance with the procedure referred to in Article 62(2), adopt detailed rules for the implementation of paragraph 1 in order to facilitate the interoperability of information systems and use of procedures by electronic means between Member States.

Article 60

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 65(1) at the latest and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER X

AMENDMENTS, DETAILED RULES AND COMMITTEE PROCEDURE

Article 61

Amendments and detailed rules

1 Article 50(2) may be amended in accordance with the procedure referred to in Article 62(2).

2 The Annexes to this Directive may be amended in accordance with the procedure referred to in Article 62(2).

3 The measures necessary for the implementation of this Directive shall be adopted in accordance with the procedure referred to in Article 62(2).

Article 62

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health (hereinafter referred to as the Committee).

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

4 The Committee shall adopt its Rules of Procedure.

CHAPTER XI

TRANSITIONAL AND FINAL PROVISIONS

Article 63

Repeal

1 Directives 91/67/EEC, 93/53/EEC and 95/70/EC shall be repealed as from 1 August 2008.

2 References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table laid down in Annex VIII.

3 However, Commission Decision 2004/453/EC shall continue to apply for the purpose of this Directive pending the adoption of the necessary provisions in accordance with Article 43 of this Directive, which shall be adopted not later than 3 years after the entry into force of this Directive.

Article 64

Transitional provisions

Transitional provisions may be adopted in accordance with the procedure referred to in Article 62(2) for a period of four years from 14 December 2006.

Article 65

Transposition

1 Member States shall adopt and publish, not later than 1 May 2008, the laws, regulations and administrative provisions necessary to comply with this Directive before 14 December 2008. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 August 2008.

When they are adopted by Member States, these measures 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 reference shall be laid down by Member States.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Status: This is the original version (as it was originally adopted).

Article 66

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 67

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 24 October 2006.

For the Council

The President

J. KORKEAOJA

ANNEX I

DEFINITIONS

In addition to the definitions in Article 3, the following technical definitions shall apply:

- (a) 'compartment' means one or more farms under a common biosecurity system containing an aquatic animal population with a distinct health status with respect to a specific disease;
- (b) 'common biosecurity system' means that the same aquatic animal health surveillance, disease prevention, and disease control measures are applied;
- (c) 'containment area' means an area around an infected farm or mollusc farming area where disease control measures are applied with the purpose of preventing the spread of the disease;
- (d) 'disease' means a clinical or non-clinical infection with one or more aetiological agents in aquatic animals;
- (e) 'disease-free zones or compartments' means zones or compartments declared disease-free in accordance with Articles 49 or 50;
- (f) 'emerging disease' means a newly identified serious disease, the cause of which may or may not yet be established, that has the potential to be spread within and between populations, such as by way of trade in aquatic animals and/or aquatic animal products. It also means a listed disease identified in a new host species not yet included in Part II of Annex IV as a susceptible species;
- (g) 'epidemiological unit' means a group of aquatic animals that share approximately the same risk of exposure to a disease agent within a defined location. This risk may be because they share a common aquatic environment, or because management practices make it likely that a disease agent in one group of animals would quickly spread to another group of animals;
- (h) 'fallowing' means, for disease management purposes, an operation where a farm is emptied of aquaculture animals susceptible to the disease of concern or known to be capable of transferring the disease agent, and, where feasible, of the carrying water;
- (i) 'further processing' means processing of aquaculture animals before human consumption by any type of measures and techniques affecting anatomical wholeness, such as bleeding, gutting/evisceration, heading, slicing and filleting, which produces waste or by-products and could cause a risk of spreading diseases;
- (j) 'increased mortality' means unexplained mortalities significantly above the level of what is considered to be normal for the farm or mollusc farming area in question under the prevailing conditions. What is considered to be increased mortality shall be decided in cooperation between the farmer and the competent authority;
- (k) 'infection' means the presence of a multiplying, or otherwise developing, or latent disease agent in, or on, a host;
- (l) 'infected zone or compartment' means zones or compartments where the infection is known to occur;
- (m) 'quarantine' means maintaining a group of aquatic animals in isolation with no direct or indirect contact with other aquatic animals, in order to undergo observation for

a specified length of time and, where appropriate, testing and treatment, including proper treatment of the effluent waters;

- (n) 'susceptible species' means any species in which infection by a disease agent has been demonstrated by natural cases or by experimental infection that mimics the natural pathways;
- (o) 'vector' means a species that is not susceptible to a disease but which is capable of spreading infection by conveying pathogens from one host to another;
- (p) 'zone' means a precise geographical area with a homogeneous hydrological system comprising part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area, an entire water catchment area from its source(s) to its estuary, or more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

ANNEX II

Information required in the official register of aquaculture
production businesses and authorised processing establishments

PART I

Authorised aquaculture production business

1. The following minimum information on each aquaculture production business shall be kept by the competent authority in a register, as provided for in Article 6:
 - (a) the name and addresses of the aquaculture production business, and contact details (telephone, facsimile, e-mail);
 - (b) the registration number and particulars of the authorisation delivered, (i.e. dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisation(s));
 - (c) the geographical position of the farm defined by a suitable system of coordinates of all farm-sites (if possible, GIS coordinates);
 - (d) the purpose, type (i.e. type of culture system, or facilities such as land-based facilities, sea cages, earth ponds) and maximum volume of production where this is regulated;
 - (e) for continental farms, dispatch centres and purification centres, details on the farm's water supply and discharges;
 - (f) the species of aquaculture animals reared at the farm (for multi-species farms or ornamental farms, it shall as a minimum be registered whether any of the species are known to be susceptible to diseases listed in Part II of Annex IV, or known vectors of such diseases);
 - (g) updated information on the health status (i.e. if the farm is disease-free (located in a Member State, zone or compartment), where the farm is under

a programme with a view of achieving such status, or where the farm is declared infected by a disease referred to in Annex IV).

2. Where an authorisation is granted to a mollusc farming area in accordance with the second subparagraph of Article 4(1), the data required pursuant to point 1(a) of this part shall be recorded for all aquaculture production businesses which operate within the mollusc farming area. The data required pursuant to points 1(b) to 1(g) of this part shall be recorded at mollusc farming area level.

PART II

Authorised processing establishments

The following minimum information on each authorised processing establishment shall be kept by the competent authority in a register, as provided for in Article 6:

- (a) the name and addresses of the authorised processing establishment, and contact details (telephone, facsimile, e-mail);
- (b) the registration number and particulars of the authorisation delivered (i.e. dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisation(s));
- (c) the geographical position of the processing establishment defined by a suitable system of coordinates (if possible GIS coordinates);
- (d) details on the authorised processing establishment's water effluent treatment systems;
- (e) the species of aquaculture animals handled in the authorised processing establishment.

ANNEX III

PART A

Health status of aquaculture zones or compartments to be considered for the application of Article 12

Aquaculture animals for farming and restocking

| Category | Health status | May introduce animals from | Health certification | | May dispatch animals to |
|----------|----------------------------------|----------------------------|----------------------|-----------------------------------------|-------------------------|
| | | | Introduction | Dispatching | |
| I | Disease-free (Articles 49 or 50) | Only category I | YES | NO when dispatched to category III or V | All categories |
| | | | | YES when dispatched | |

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|-----|----------------------------------------------------------------------------------------------------------|--------------------------|-----|---------------------------|----------------------|
| | | | | to categories I, II or IV | |
| II | Surveillance Programme (Article 44(1)) | Only category I | YES | NO | Categories III and V |
| III | Undetermined (not known to be infected but not subject to a programme for achieving disease-free status) | Categories I, II, or III | NO | NO | Categories III and V |
| IV | Eradication Programme (Article 44(2)) | Only category I | YES | YES | Only category V |
| V | Infected (Article 39) | All categories | NO | YES | Only category V |

PART B

Recommended surveillance and inspections on farms and mollusc-farming areas

| Species present | Health status as referred to in Part A | Risk level | Surveillance | Recommended inspection frequency by the competent authority (Article 7) | Recommended inspection frequency by qualified aquatic animal health services (Article 10) | Specific requirements for inspections, sampling and surveillance necessary to maintain the health status | Comments |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------|--------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| No species susceptible to the diseases listed in Annex IV | Category I Declared disease-free in accordance with Article 49(1)(a) or (b) or Article 50(1)(a) or (b). | Low | Passive | 1 every 4 years | 1 every 4 years | Specific requirements for the maintenance of the disease-free status in accordance with Article 52. | The recommended inspection frequencies shall apply without prejudice to the specific requirements mentioned |

| | | | | | | | |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------|-----------------------------|-----------------|-----------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Species susceptible to one or more of the diseases listed in Annex IV | Category I Declared disease-free in accordance with of Article 49(1)(c) or of Article 50(1)(c). | High | Active, targeted or passive | 1 every year | 1 every year | | for each health status. However, where possible, such inspections and sampling should be combined with the inspections required pursuant to Articles 7 and 10. The aim of inspections by the competent authority is to check compliance with this Directive in accordance with Article 7. The aim of inspections by qualified aquatic animal health services is to check the health status of the animals, to advise the aquaculture production |
| | | Medium | | 1 every 2 years | 1 every 2 years | | |
| | | Low | | 1 every 4 years | 1 every 2 years | | |
| | Category II Not declared disease-free but subject to a surveillance programme approved in accordance with Article 44(1). | High | Targeted | 1 every year | 1 every year | Specific requirements in accordance with Article 44(1) | |
| | | Medium | | 1 every 2 years | 1 every 2 years | | |
| | | Low | | 1 every 4 years | 1 every 2 years | | |
| | Category III Not known to be infected but not subject to surveillance programme for achieving disease-free status. | High | Active | 1 every year | 3 every year | | |
| | | Medium | | 1 every year | 2 every year | | |
| | | Low | | 1 every 2 years | 1 every year | | |
| | Category IV Known to be infected but subject to an eradication programme approved in accordance | High | Targeted | 1 every year | 1 every year | Specific requirements in accordance with Article 44(2) | |
| | | Medium | | 1 every 2 years | 1 every 2 years | | |
| | | Low | | 1 every 4 years | 1 every 2 years | | |

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| | | | | | | |
|-------------------------------------------------------------------------------------------------------|--------|---------|-----------------|-----------------|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| with Article 44(2). | | | | | | business operator on aquatic animal health issues, and where necessary, undertake the necessary veterinary measures. |
| Category V Known to be infected. Subject to minimum control measures as provided for in Chapter V. | High | Passive | 1 every 4 years | 1 every year | Specific requirements in accordance with Chapter V. | |
| | Medium | | 1 every 4 years | 1 every 2 years | | |
| | Low | | 1 every 4 years | 1 every 4 years | | |

Risk levels

A high-risk farm or mollusc farming area is a farm or mollusc farming area which:

- (a) has a high risk of spreading diseases to or contracting diseases from other farms or wild stocks;
- (b) operates under farming conditions which could increase the risk of disease outbreaks (high biomass, low water quality), taking into account the species present;
- (c) sells live aquatic animals for further farming or restocking.

A medium-risk farm or mollusc farming area is a farm or mollusc farming area which:

- (a) has medium risk of spreading diseases to or contracting diseases from other farms or wild stocks;
- (b) operates under farming conditions which would not necessarily increase the risk of disease outbreaks (medium biomass and water quality), taking into account the species present;
- (c) sells live aquatic animals mainly for human consumption.

A low-risk farm or mollusc farming area is a farm or mollusc farming area which:

- (a) has a low risk of spreading diseases to or contracting diseases from other farms or wild stocks;
- (b) operates under farming conditions which would not increase the risk of disease outbreaks (low biomass, good water quality), taking into account the species present;
- (c) sells live aquatic animals for human consumption only.

Types of health surveillance

Passive surveillance shall include mandatory immediate notification of the occurrence or suspicion of specified diseases or of any increased mortalities. In such cases investigation in accordance with Section 2 of Chapter V shall be required.

Active surveillance shall include:

- (a) routine inspection by the competent authority or by other qualified health services on behalf of the competent authorities;
- (b) examination of the aquaculture animal population on the farm or in the mollusc farming area for clinical disease;
- (c) diagnostic samples to be collected on suspicion of a listed disease or observed increased mortality during inspection;
- (d) mandatory immediate notification of occurrence or suspicion of specified diseases or of any increased mortalities.

Targeted surveillance shall include:

- (a) routine inspection by the competent authority or by other qualified health services on behalf of the competent authorities;
- (b) prescribed samples of aquaculture animals to be taken and tested for specific pathogen(s) by specified methods;
- (c) mandatory immediate notification of occurrence or suspicion of specified diseases or of any increased mortalities.

ANNEX IV

Disease listing

PART I

Criteria for listing diseases

- A. Exotic diseases shall meet the following criteria laid down in point 1 and either point 2 or 3.
 - 1. The disease is exotic to the Community, i.e. the disease is not established in Community aquaculture, and the pathogen is not known to be present in Community waters.
 - 2. It has potential for significant economic impact if introduced into the Community, either by production losses in Community aquaculture or by restricting the potential for trade in aquaculture animals and products thereof.
 - 3. It has potential for detrimental environmental impact if introduced into the Community, to wild aquatic animal populations of species, which are an asset worth protecting by Community law or international provisions.
- B. Non-exotic diseases shall meet the following criteria laid down in points 1, 4, 5, 6, 7, and 2 or 3.
 - 1. Several Member States, or regions in several Member States, are free of the specific disease.
 - 2. It has potential for significant economic impact if introduced into a Member State free of the disease, either by production losses, and annual costs

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associated with the disease and its control exceeding 5 % of the value of the production of the susceptible aquaculture animal species production in the region, or by restricting the possibilities for international trade in aquaculture animals and products thereof.

3. The disease has shown, where it occurs, to have a detrimental environmental impact if introduced into a Member State free of the disease, to wild aquatic animal populations of species that is an asset worth protecting under Community law or international provisions.
4. The disease is difficult to control and contain at farm or mollusc farming area level without stringent control measures and trade restrictions.
5. The disease may be controlled at Member State level, experience having shown that zones or compartments free of the disease may be established and maintained, and that this maintenance is cost-beneficial.
6. During placing on the market of aquaculture animals, there is a risk that the disease will establish itself in a previously uninfected area.
7. Reliable and simple tests for infected aquatic animals are available. The tests must be specific and sensitive and the testing method harmonised at Community level.

PART II

Listed diseases

| EXOTIC DISEASES | | |
|-----------------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | DISEASE | SUSCEPTIBLE SPECIES |
| FISH | Epizootic haematopoietic necrosis | Rainbow trout (<i>Oncorhynchus mykiss</i>) and redfin perch (<i>Perca fluviatilis</i>) |
| | Epizootic ulcerative syndrome | Genera: <i>Catla</i> , <i>Channa</i> , <i>Labeo</i> , <i>Mastacembelus</i> , <i>Mugil</i> , <i>Puntius</i> and <i>Trichogaster</i> . |
| MOLLUSCS | Infection with <i>Bonamia exitiosa</i> | Australian mud oyster (<i>Ostrea angasi</i>) and Chilean flat oyster (<i>O. chilensis</i>) |
| | Infection with <i>Perkinsus marinus</i> | Pacific oyster (<i>Crassostrea gigas</i>) and Eastern oyster (<i>C. virginica</i>) |
| | Infection with <i>Microcytos mackini</i> | Pacific oyster (<i>Crassostrea gigas</i>), Eastern oyster (<i>C. virginica</i>), Olympia flat oyster (<i>Ostrea conchaphila</i>) and European flat oyster (<i>O. edulis</i>) |

| | | |
|-------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CRUSTACEANS | Taura syndrome | Gulf white shrimp (<i>Penaeus setiferus</i>), Pacific blue shrimp (<i>P. stylirostris</i>), and Pacific white shrimp (<i>P. vannamei</i>) |
| | Yellowhead disease | Gulf brown shrimp (<i>Penaeus aztecus</i>), Gulf pink shrimp (<i>P. duorarum</i>), Kuruma prawn (<i>P. japonicus</i>), black tiger shrimp (<i>P. monodon</i>), Gulf white shrimp (<i>P. setiferus</i>), Pacific blue shrimp (<i>P. stylirostris</i>), and Pacific white shrimp (<i>P. vannamei</i>) |

NON-EXOTIC DISEASES

| | DISEASE | SUSCEPTIBLE SPECIES |
|------|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FISH | Spring viraemia of carp (SVC) | Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>C. carassius</i>), grass carp (<i>Ctenopharyngodon idellus</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), sheatfish (<i>Silurus glanis</i>) and tench (<i>Tinca tinca</i>) |
| | Viral haemorrhagic septicaemia (VHS) | Herring (<i>Clupea spp.</i>), whitefish (<i>Coregonus spp.</i>), pike (<i>Esox lucius</i>), haddock (<i>Gadus aeglefinus</i>), Pacific cod (<i>G. macrocephalus</i>), Atlantic cod (<i>G. morhua</i>), Pacific salmon (<i>Oncorhynchus spp.</i>) rainbow trout (<i>O. mykiss</i>), rockling (<i>Onos mustelus</i>), brown trout (<i>Salmo trutta</i>), turbot (<i>Scophthalmus maximus</i>), sprat (<i>Sprattus sprattus</i>) and grayling (<i>Thymallus thymallus</i>) |
| | Infectious haematopoietic necrosis (IHN) | Chum salmon (<i>Oncorhynchus keta</i>), coho salmon (<i>O. kisutch</i>), Masou salmon (<i>O. masou</i>), rainbow or steelhead trout (<i>O. mykiss</i>), sockeye salmon (<i>O. nerka</i>), pink salmon (<i>O. rhodurus</i>) chinook |

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|-------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | salmon (<i>O. tshawytscha</i>), and Atlantic salmon (<i>Salmo salar</i>) |
| | Koi herpes virus (KHV) disease | Common carp and koi carp (<i>Cyprinus carpio</i>). |
| | Infectious salmon anaemia (ISA) | Rainbow trout (<i>Oncorhynchus mykiss</i>), Atlantic salmon (<i>Salmo salar</i>), and brown and sea trout (<i>S. trutta</i>). |
| MOLLUSCS | Infection with <i>Marteilia refringens</i> | Australian mud oyster (<i>Ostrea angasi</i>), Chilean flat oyster (<i>O. chilensis</i>), European flat oyster (<i>O. edulis</i>), Argentinian oyster (<i>O. puelchana</i>), blue mussel (<i>Mytilus edulis</i>) and Mediterranean mussel (<i>M. galloprovincialis</i>) |
| | Infection with <i>Bonamia ostreae</i> | Australian mud oyster (<i>Ostrea angasi</i>), Chilean flat oyster (<i>O. chilensis</i>), Olympia flat oyster (<i>O. conchaphila</i>), Asiatic oyster (<i>O. denselammellosa</i>), European flat oyster (<i>O. edulis</i>), and Argentinian oyster (<i>O. puelchana</i>). |
| CRUSTACEANS | White spot disease | All decapod crustaceans (order <i>Decapoda</i>). |

ANNEX V

Requirements for declaring a Member State, zone or compartment disease-free

PART I

Disease-free Member State

1. On historical grounds
 - 1.1. A Member State where susceptible species are present, but where there has not been any observed occurrence of the disease for at least for a period of 10 years before the date of application for the disease-free status despite conditions that are conducive to its clinical expression may be considered disease-free where:

- (a) basic biosecurity measure conditions have been in place continuously for at least a period of 10 years before the date of application for the disease-free status;
- (b) infection is not known to be established in wild populations;
- (c) the implementation of trade and imports conditions to prevent the introduction of the disease into the Member State is effective.

A Member State wishing to benefit from a disease-free status, shall submit an application in accordance with Article 49 before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

- 1.2. The basic biosecurity measures referred to in point 1.1(a) shall consist, as a minimum, of the following:

- (a) the disease is compulsorily notifiable to the competent authority, including notification of suspicion;
- (b) an early detection system is in place throughout the Member State, enabling the competent authority to undertake effective disease investigation and reporting, and ensuring in particular:
 - (i) the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or molluscs farming areas, and in the wild;
 - (ii) the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay.

- 1.3. The early detection system referred to in point 1.2(b) shall include at least the following:

- (a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians or aquatic animal health specialists in detecting and reporting unusual disease occurrence;
- (b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- (c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

2. Based on targeted surveillance

A Member State where the last known clinical occurrence was within 10 years before the date of application for the disease-free status or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free of the specific disease where:

- (a) the Member State meets the basic disease control conditions laid down in point 1.2;

and

- (b) targeted surveillance in accordance with methods adopted pursuant to Article 49(3), has been in place for at least a period of two years without detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.

Where there are parts of the Member State in which the number of farms, or mollusc farming areas is limited, and consequently targeted surveillance in these parts do not provide sufficient epidemiological data, but in which there are wild populations of any of the susceptible species, those wild populations shall be included in the targeted surveillance.

PART II

Disease-free zone or compartment

1. Zones

1.1. A zone may comprise:

- (a) an entire water catchment area from its source to its estuary;
or
- (b) part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area;
or
- (c) more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

The geographical demarcation of the zone shall be clearly identified on a map.

- 1.2. Where a zone extends over more than one Member State, it may not be declared a disease-free zone unless the conditions outlined in points 1.3, 1.4 and 1.5 apply to all areas of that zone. In that case both Member States concerned shall apply for approval for the part of the zone situated in their territory.

- 1.3. A zone where susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of application for the disease-free status, despite conditions that are conducive to its clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.1.

A Member State wishing to benefit from a disease-free status shall notify its intention in accordance with Article 50(2) before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

- 1.4. A zone where the last known clinical occurrence was within a period of 10 years before the date of application for the disease-free status or where

the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free where it complies *mutatis mutandis* with the requirements laid down in Part I.2.

- 1.5. A buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease.
2. Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status regarding that disease of surrounding natural waters
 - 2.1. A compartment may comprise one or more farms, a group or cluster of farms or a mollusc farming area that may be considered as one epidemiological unit due to its geographical localisation and distance from other groups or clusters of farms or mollusc farming areas, provided that all farms comprising the compartment fall within a common biosecurity system. The geographical demarcation of a compartment shall be clearly identified on a map.
 - 2.2. A compartment where susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of application for the disease-free status despite conditions that are conducive to its clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements in Part I.1 of this Annex.

Member States wishing to benefit from this provision shall notify their intention in accordance with Article 50(2) before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.
 - 2.3. A compartment where the last known clinical occurrence was within 10 years before the date of application for the disease-free status, or where the infection status in the compartment or in the waters surrounding the compartment prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.2.
 - 2.4. Each farm or mollusc farming area in a compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring programme is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.
3. Compartments comprising one or more individual farms where the health status regarding a specific disease is independent of the health status regarding that disease of the surrounding natural waters.
 - 3.1. A compartment may comprise:
 - (a) an individual farm which may be considered a single epidemiological unit, as it is not influenced by the animal health status in the surrounding waters;

or

- (b) more than one farm where each farm in the compartment complies with the criteria laid down in point 3.1(a) and points 3.2 to 3.6, but, due to extensive movement of animals between farms, shall be considered as a single epidemiological unit, provided that all farms are under a common biosecurity system.

3.2. A compartment shall be supplied with water:

- (a) through a water treatment plant inactivating the relevant pathogen in order to reduce the risk of the introduction of the disease to an acceptable level;

or

- (b) directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water shall be supplied directly to the farm, and be channelled through a pipe.

3.3. There shall be natural or artificial barriers that prevent aquatic animals from entering each farm in a compartment from the surrounding watercourses.

3.4. The compartment shall, where appropriate, be protected against flooding and infiltration of water from the surrounding watercourses.

3.5. The compartment shall comply, *mutatis mutandis*, with the requirements laid down in Part I.2.

3.6. A compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.

3.7. Implementing measures concerning point 3.2(a) shall be laid down in accordance with the procedure referred to in Article 62(2).

4. Special provisions for individual farms which commence or recommence their activities

4.1. A new farm, which meets the requirements referred to in points 3.1(a) and 3.2 to 3.6, but which commences its activities with aquaculture animals from a compartment declared disease-free may be considered disease-free without undergoing the sampling required for approval.

4.2. A farm which recommences its activities after a break with aquaculture animals from a compartment declared disease-free, and meets the requirements referred to in points 3.1(a) and 3.2 to 3.6, may be considered disease-free without undergoing the sampling required for approval, provided that:

- (a) the health history of the farm over the last four years of its operation is known to the competent authority; however, if the farm concerned has been in operation for less than four years, the actual period in which it has been in operation will be taken into account;

- (b) the farm has not been subject to animal-health measures in respect of the diseases listed in Part II of Annex IV and there have been no antecedents of those diseases on the farm;
- (c) prior to the introduction of the aquaculture animals, eggs or gametes, the farm is cleaned and disinfected, followed, as necessary, by a period of fallowing.

ANNEX VI

Functions and duties of laboratories

PART I

Community reference laboratories

1. In order to be designated as a Community reference laboratory in accordance with Article 55, laboratories shall fulfil the following requirements. They must:
 - (a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence, including trained personnel available for emergency situations occurring within the Community;
 - (b) possess the equipment and products needed to carry out the tasks assigned to them;
 - (c) have an appropriate administrative infrastructure;
 - (d) ensure that their staff respect the confidential nature of certain subjects, results or communications;
 - (e) have sufficient knowledge of international standards and practices;
 - (f) have available, as appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;
 - (g) take account of research activities at national and Community level.
2. However, the Commission may designate only laboratories that operate and are assessed and accredited in accordance with the following European Standards, account being taken of the criteria for different testing methods laid down in this Directive:
 - (a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
 - (b) EN 45002 on 'General criteria for the assessment of testing laboratories';
 - (c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.
3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4. For one or more of the diseases under their responsibility, the Community reference laboratories may take advantage of the skills and capacity of laboratories in other Member States or EFTA Member States, provided that the laboratories concerned comply with the requirements laid down in points 1, 2 and 3 of this Annex. Any intention to take advantage of such cooperation shall be part of the information provided as a basis for the designation in accordance with Article 55(1). However, the Community reference laboratory shall remain the contact point for the National reference laboratories in the Member States, and for the Commission.
5. The Community reference laboratories shall:
 - (a) coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
 - (i) typing, storing and, where appropriate, supplying strains of the pathogen of the relevant disease to facilitate the diagnostic service in the Community,
 - (ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in each Member State, where serological tests are required,
 - (iii) organising periodic comparative tests (ring tests) of diagnostic procedures at Community level with the national reference laboratories designated by the Member States, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (iv) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;
 - (b) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;
 - (c) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Community;
 - (d) collaborate, as regards methods of diagnosing animal diseases falling within their areas of competence, with the competent laboratories in third countries where those diseases are prevalent;
 - (e) collaborate with the relevant OIE reference laboratories with regard to exotic diseases listed in Part II of Annex IV under their responsibility;
 - (f) collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture.

PART II

National reference laboratories

1. The national reference laboratories designated pursuant to Article 56 shall be responsible for coordinating the diagnostic standards and methods within their field of responsibility in the Member State concerned. These national reference laboratories shall:

- (a) undertake to notify, without delay, the competent authority whenever the laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;
 - (b) coordinate, in consultation with the relevant Community reference laboratory, the methods employed in Member States for diagnosing the diseases concerned under their responsibility;
 - (c) assist actively in the diagnosis of outbreaks of the relevant disease by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;
 - (d) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Member State;
 - (e) ensure confirmation of positive results of all outbreaks of exotic diseases listed in Part II of Annex IV, and of primary outbreaks of non-exotic diseases listed in that Annex;
 - (f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in accordance with Article 57, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Member State;
 - (g) cooperate with the Community reference laboratory referred to in Article 55 and participate in the comparative tests organised by the Community reference laboratories;
 - (h) ensure a regular and open dialogue with their national competent authorities;
 - (i) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:
 - (i) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
 - (ii) EN 45002 on 'General criteria for the assessment of testing laboratories';
 - (iii) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.
2. The accreditation and assessment of testing laboratories referred to in point 1(i) may relate to individual tests or groups of tests.
3. The Member States may designate national reference laboratories which do not comply with the requirements referred to in point 1(i)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided the laboratory operates under quality assurance in line with the guidelines in ISO 9001.
4. Member States may authorise a national reference laboratory situated on their territory to take advantage of the skills and capacity of other laboratories designated pursuant to Article 57, for one or more of the diseases under their responsibility, provided that these laboratories comply with the relevant requirements of this Part. However, the national reference laboratory shall remain the contact point for the central competent authority of the Member State, and for the Community reference laboratory.

PART III

Designated laboratories in Member States

1. The competent authority of a Member State shall designate only laboratories for diagnostic services pursuant to Article 57 that fulfil the following requirements. They must:
 - (a) undertake to notify, without delay, the competent authority whenever a laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;
 - (b) undertake to participate in comparative tests (ring-tests) of diagnostic procedures arranged by the national reference laboratory;
 - (c) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:
 - (i) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
 - (ii) EN 45002 on 'General criteria for the assessment of testing laboratories';
 - (iii) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.
2. The accreditation and assessment of testing laboratories referred to in paragraph 1(c) may relate to individual tests or groups of tests.
3. The Member States may designate laboratories which do not comply with the requirements referred to in point 1(c)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided that the laboratory operates under quality assurance in line with the guidelines in ISO 9001.
4. The competent authority shall cancel the designation where the conditions referred to in this Annex are no longer fulfilled.

ANNEX VII

CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

Member States shall ensure that contingency plans meet at least the following requirements:

1. Provision must be made to ensure the legal powers needed to implement contingency plans and put into effect a rapid and successful eradication campaign;
2. Provision must be made to ensure access to emergency funds, budgetary means and financial resources in order to cover all aspects of the fight against exotic diseases listed in Part II of Annex IV;
3. A chain of command must be established to guarantee a rapid and effective decision-making process for dealing with exotic diseases listed in Annex IV or emerging

- diseases. A central decision-making unit must be in charge of the overall direction of control strategies;
4. Detailed plans must be available for Member States to be prepared for the immediate establishment of local disease control centres in the event of an outbreak of exotic diseases listed in Part II of Annex IV or emerging diseases and to implement disease control and environment protection measures at a local level;
 5. Member States must ensure cooperation between the competent authorities and competent environmental authorities and bodies in order to ensure that actions on veterinary and environmental safety issues are properly coordinated;
 6. Provision must be made for adequate resources to ensure a rapid and effective campaign, including personnel, equipment and laboratory capacity;
 7. An up-to-date operations manual must be available, with a detailed, comprehensive and practical description of all the actions, procedures, instructions and control measures to be employed in handling exotic diseases listed in Part II of Annex IV or emerging diseases;
 8. Detailed plans must be available for emergency vaccination, where appropriate;
 9. Staff must be regularly involved in training in clinical signs, epidemiological enquiry and control of epizootic diseases, in real-time alert exercises, and in training in communication skills to provide ongoing disease awareness campaigns for authorities, farmers and veterinarians;
 10. Contingency plans must be prepared that take into account the resources needed to control a large number of outbreaks occurring within a short period of time;
 11. Without prejudice to the veterinary requirements laid down in Regulation (EC) No 1774/2002, contingency plans must be prepared to ensure that, in the event of an outbreak of diseases, any mass disposal of aquatic animal carcasses and aquatic animal waste is done without endangering animal and human health, using processes or methods which prevent damage to the environment and in particular:
 - (i) with minimum risk to soil, air, surface and groundwater, and to plants and animals;
 - (ii) with minimum nuisance caused by noise or odours;
 - (iii) with minimum adverse effects on the nature or places of special interest;
 12. Such plans must include the identification of appropriate sites and undertakings for the treatment or disposal of animal carcasses and animal waste in the event of an outbreak in accordance with Regulation (EC) No 1774/2002.

ANNEX VIII

CORRELATION TABLE

| This Directive | Repealed Directives | | |
|-----------------|---------------------|-----------|----------|
| | 91/67/EEC | 93/53/EEC | 95/70/EC |
| Article 1(1)(a) | Article 1, | — | — |

Status: This is the original version (as it was originally adopted).

| | first subparagraph | | |
|------------------|-----------------------------------|---------------|---------------|
| Article 1(1)(b) | — | — | — |
| Article 1(1)(c) | — | Article 1 | Article 1 |
| Article 1(2) | — | Article 20(2) | Article 12(2) |
| Article 2(1) | — | — | — |
| Article 2(2) | — | — | — |
| Article 2(3) | Article 1, second subparagraph | — | — |
| Article 3 | Article 2 | Article 2 | Article 2 |
| Article 4 | — | — | — |
| Article 5 | — | — | — |
| Article 6 | — | — | — |
| Article 7 | — | — | — |
| Article 8(1) | — | Article 3(2) | Article 3(2) |
| Article 8(2) | — | — | — |
| Article 8(3) | — | — | — |
| Article 8(4) | — | — | — |
| Article 9 | — | — | — |
| Article 10 | — | — | Article 4 |
| Article 11 | — | — | — |
| Article 12 | — | — | — |
| Article 13(1) | Article 4, first paragraph | — | — |
| Article 13(2) | Article 4, second paragraph | — | — |
| Article 14(1)(a) | Article 7(1), Article 8(1) | — | — |
| Article 14(1)(b) | — | — | — |
| Article 14(2) | Article 16(1) | — | — |
| Article 14(3) | Article 16(1), | — | — |
| Article 14(4) | — | — | — |
| Article 15(1) | Article 3(1)(a) and (2) | — | — |
| Article 15(2) | — | — | — |
| Article 15(3) | Article 3(1)(b) and (2) | — | — |

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|---------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Article 15(4) | — | — | — |
| Article 16(1) | Article 7(1)(a), first sentence Article 7(1)(b) Article 8(1)(a) Article 8(1)(b) | — | — |
| Article 16(2) | — | — | — |
| Article 17 | — | — | — |
| Article 18(1) | Article 9 | — | — |
| Article 18(2) | — | — | — |
| Article 19(1) | — | — | — |
| Article 19(2) | Article 9(2) | — | — |
| Article 20 | Article 14(3) | — | — |
| Article 21 | — | — | — |
| Article 22 | Article 19(1) | — | — |
| Article 23(1) | — | — | — |
| Article 23(2) | Article 22 | — | — |
| Article 23(3) | Article 19(2) | — | — |
| Article 23(4) | Article 19(3) | — | — |
| Article 23(5) | — | — | — |
| Article 24 | Article 21 | — | — |
| Article 25(a) | Article 20 | — | — |
| Article 25(b) | — | — | — |
| Article 25(c) | — | — | — |
| Article 25(d) | Article 21(2) | — | — |
| Article 25(e) | — | — | — |
| Article 26 | — | Article 4 | Article 5(1) |
| Article 27 | — | — | Article 5(5) |
| Article 28(a) | — | Article 5(1) Article 10(1)(a) | Article 5(2)(a) |
| Article 28(b) | — | Article 5(2)(b) Article 10(1)(c) | Article 5(2)(b) |
| Article 29(1) | — | Article 5 (2)(h) Article 6(a), seventh indent Article 8(1) Article 9(1), first sentence | Article 4(1), third subparagraph, third indent Article 5(4), first and fourth subparagraph |

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| | | | |
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| | | Article 10(1)b | |
| Article 29(2) | — | Article 5(2)(i) | Article 5(4), second and fourth subparagraph |
| Article 29(3) | — | Article 6(b) Article 6(d) Article 8(2) Article 8(3) Article 9(2) | — |
| Article 29(4) | — | Article 5(2)(i), second indent | — |
| Article 30 | — | Article 5(4) | Article 5(3) |
| Article 31 | — | — | — |
| Article 32 | — | Article 5(2), Article 6 | Article 4(1), third subparagraph, second indent, Article 5(2)(b), Article 5(4), third and fourth subparagraph |
| Article 33(1) | Article 3(3) | Article 6(a) fourth indent | — |
| Article 33(2) | — | Article 6(a), fourth indent | — |
| Article 33(3) | — | — | — |
| Article 33(4) | — | — | — |
| Article 34(1) | — | Article 5(2)(c) Article 6(a), first and third indent | — |
| Article 34(2) | — | Article 6(a), fourth indent | — |
| Article 35 | — | Article 6(a), second, fifth and sixth indent | — |
| Article 36 | — | — | — |
| Article 37(a) | — | — | — |
| Article 37(b) | — | — | Article 5(3) |
| Article 38(1) | — | Article 9(1), second sentence | — |
| Article 38(2) | — | Article 9(3) | — |
| Article 38(3) | — | — | — |
| Article 39(a) | — | Article 10(1)(c) | Article 4(1), third paragraph, first indent |

| | | | |
|---------------|------------------------------|------------------------------------------|---|
| Article 39(b) | — | — | — |
| Article 39(c) | — | Article 10(1)(c) | — |
| Article 39(d) | — | — | — |
| Article 40 | — | Article 7 | — |
| Article 41 | — | — | — |
| Article 42 | — | — | — |
| Article 43 | — | — | — |
| Article 44(1) | Article 10 | Article 10(2) | — |
| Article 44(2) | Article 10 | Article 10(2) | — |
| Article 45 | Article 10(1) | — | — |
| Article 46 | — | — | — |
| Article 47 | — | Article 6(a), first indent Article 15 | — |
| Article 48(1) | — | Article 14(1) | — |
| Article 48(2) | — | Article 14(1) | — |
| Article 48(3) | — | — | — |
| Article 48(4) | — | — | — |
| Article 49(1) | Article 5(1) | — | — |
| Article 49(2) | — | — | — |
| Article 49(3) | Article 15 | — | — |
| Article 50(1) | Article 5(1) Article 6(1) | — | — |
| Article 50(2) | — | — | — |
| Article 50(3) | Article 5(1) | — | — |
| Article 50(4) | Article 15 | — | — |
| Article 51(1) | — | — | — |
| Article 51(2) | Article 5(2) | — | — |
| Article 52 | — | — | — |
| Article 53(1) | — | — | — |
| Article 53(2) | — | — | — |
| Article 53(3) | — | Article 9(1), second sentence | — |
| Article 54(1) | — | — | — |
| Article 54(2) | — | Article 6(d) Article 8(3) | — |

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|---------------|-------------------------------|--------------------------------|----------------------------------------------------------------------|
| Article 54(3) | — | — | — |
| Article 55(1) | — | Article 13(1) | Article 7(1) |
| Article 55(2) | — | Article 13(2) | Article 7(2) |
| Article 55(3) | — | — | — |
| Article 56(1) | — | Article 12(1) Article 12(4) | Article 6(2) Article 6(3) |
| Article 56(2) | — | — | — |
| Article 56(3) | — | Article 12(6) | Article 6(5) |
| Article 56(4) | — | — | — |
| Article 56(5) | — | Article 12(1) Article 12(3) | Article 6(2) |
| Article 57(a) | — | Article 11(2) | — |
| Article 57(b) | — | Article 11(1) | Article 6(1) |
| Article 57(c) | — | — | — |
| Article 58(1) | Article 17 | Article 16 | Article 8 |
| Article 58(2) | Article 22 | — | — |
| Article 58(3) | Article 17 | — | — |
| Article 59 | — | — | — |
| Article 60 | — | — | — |
| Article 61(1) | — | — | — |
| Article 61(2) | Article 25 | Article 18 | Article 9 |
| Article 61(3) | Article 9(3) Article 17(2) | Article 18a | Article 4(2) Article 5(4), fourth subparagraph Article 8(4) |
| Article 62 | Article 26 Article 27 | Article 19 | Article 10 |
| Article 63 | — | — | — |
| Article 64 | — | — | — |
| Article 65 | Article 29 | Article 20 | Article 12 |
| Article 66 | — | — | Article 13 |
| Article 67 | Article 30 | Article 21 | Article 14 |

- (1) [OJ C 88, 11.4.2006, p. 13.](#)
- (2) [OJ L 46, 19.2.1991, p. 1.](#) Directive as last amended by Regulation (EC) No 806/2003 ([OJ L 122, 16.5.2003, p. 1.](#)).
- (3) [OJ L 175, 19.7.1993, p. 23.](#) Directive as last amended by the 2003 Act of Accession.
- (4) [OJ L 332, 30.12.1995, p. 33.](#) Directive as last amended by the 2003 Act of Accession.
- (5) [OJ L 206, 22.7.1992, p. 7.](#) Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1.](#)).
- (6) [OJ L 139, 30.4.2004, p. 206,](#) corrected by [OJ L 226, 25.6.2004, p. 83.](#) Regulation as last amended by Commission Regulation (EC) No 2076/2005 ([OJ L 338, 22.12.2005, p. 83.](#)).
- (7) [OJ L 165, 30.4.2004, p. 1,](#) corrected by [OJ L 191, 28.5.2004, p. 1.](#) Regulation as last amended by Commission Regulation (EC) No 776/2006 ([OJ L 136, 24.5.2006, p. 3.](#)).
- (8) [OJ L 139, 30.4.2004, p. 1,](#) corrected by [OJ L 226, 25.6.2004, p. 3.](#)
- (9) [OJ L 224, 18.8.1990, p. 29](#) Directive as last amended by Directive 2002/33/EC of the European Parliament and of the Council ([OJ L 315, 19.11.2002, p. 14.](#)).
- (10) [OJ L 268, 24.9.1991, p. 56.](#) Directive as last amended by the 2003 Act of Accession.
- (11) [OJ L 156, 30.4.2004, p. 5,](#) as corrected by [OJ L 202, 7.6.2004, p. 4.](#) Decision as last amended by Commission Decision 2006/272/EC ([OJ L 99, 7.4.2006, p. 31.](#)).
- (12) [OJ L 311, 28.11.2001, p. 1.](#) Directive as last amended by Directive 2004/28/EC ([OJ L 136, 30.4.2004, p. 58.](#)).
- (13) [OJ L 136, 30.4.2004, p. 1.](#)
- (14) [OJ L 223, 15.8.2006, p. 1.](#)
- (15) [OJ C 321, 31.12.2003, p. 1.](#) Corrected version in [OJ C 4, 8.1.2004, p. 7.](#)
- (16) [OJ L 184, 17.7.1999, p. 23.](#) Decision as last amended by Decision 2006/512/EC ([OJ L 200, 22.7.2006, p. 11.](#)).
- (17) [OJ L 139, 30.4.2004, p. 55.](#)
- (18) [OJ L 31, 1.2.2002, p. 1.](#)
- (19) [OJ L 273, 10.10.2002, p. 1.](#) Regulation as last amended by Commission Regulation (EC) No 208/2006 ([OJ L 36, 8.2.2006, p. 25.](#)).