Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

CHAPTER 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[(1)], 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[(2)];

(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 were 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[(3)], 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.

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

(**1**) OJ L 139, 30.4.2004, p. 55.

(**2**) OJ L 31, 1.2.2002, p. 1.

(**3**) 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).