L.N. 24 of 2009

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Requirements for Aquaculture Animals and Products thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals Rules, 2009

IN the exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Resources and Rural Affairs has made the following rules:-

CHAPTER I

Title, Scope and Definitions

Title

1. (1) These rules may be cited as the Animal Health Requirements for Aquaculture Animals and Products thereof, and on the Prevention and Control of certain Diseases in Aquatic Animals Rules, 2009.

(2) The scope of these rules is to implement the rules contained in the European Union Council Directive 2006/88/EC of the 24th October 2006 and in the European Union Commission Directive 2008/53/EC of the 30th April 2008, repealing and replacing the Measures for the Control of Fish Diseases Rules, 2005 and the Bivalve Molluscs (Minimum Measures for the Control of Diseases) Rules, 2005 which implement the rules contained in European Union Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases and the rules contained in European Union Council Directive 95/70/EEC on the introduction of minimum European Community measures for the control of certain disease affecting bivalve molluscs, respectively.

LN 354 of 2005

LN 316 of 2005.

(3) These rules shall define:

(a) the animal health requirements to be applied for

the placing on the market, the importation and the transit of aquaculture animals and the products thereof;

(b) the 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) the minimum control measures to be applied in the event of a suspicion of, or an outbreak of certain diseases in aquatic animals.

Scope

2. (1) These Rules 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 fish-meal, 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 centers, 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) These rules shall apply without prejudice to provisions on the conservation of species or the introduction of non-native species.

Definitions

3. (1) For the purposes of these rules, the following definitions shall apply:

"aquaculture" means the rearing or cultivation of aquatic organisms including fish, molluscs, crustaceans, other

invertebrates and aquatic plants, 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;

"aquaculture animal" means any aquatic animal at all its lifestages, including eggs and sperm or gametes, reared in a farm or mollusc farming area, including any aquatic animal from the wild intended for a farm or mollusc farming area;

"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;

"aquaculture production business operator" means any natural or legal person responsible for ensuring that the requirements of these rules are met within the aquaculture production business under their control;

"aquatic animal" means:

(a) fish belonging to the superclass Agnatha and to the classes Chondrichthyes and Osteichthyes;

(b) mollusc belonging to the Phylum Mollusca;

(c) crustacean belonging to the Subphylum Crustacea;

"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, for processing aquaculture animals for food purposes, and authorised in accordance with rules 4 and 5 hereof;

"authorised processing establishment operator" means any natural or legal person responsible for ensuring that the requirements of these rules are met within the authorized processing establishment under their control;

"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;

"farming" means the rearing of aquaculture animals in a farm or in a mollusc farming area;

"mollusc farming area" means a production area or relaying area in which all aquaculture production businesses operate under a common biosecurity system;

"ornamental aquatic animal" means an aquatic animal which is kept, reared, or placed on the market for ornamental purposes only;

"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;

"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;

"put and take fisheries" means ponds or other installations where the population is maintained only for recreational fishing by restocking with aquaculture animals;

"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;

"wild aquatic animal" means an aquatic animal which is not an aquaculture animal.

(2) For the purposes of these rules, the following definitions shall also apply:

(a) the technical definitions laid down in Schedule 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;

(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

Authorisation of aquaculture production businesses and processing establishments.

4. (1) Each aquaculture production business in the territory of Malta shall ensure that it is duly authorised by the competent authority in accordance with rule 5.

Provided that such authorisation may cover several aquaculture production businesses for molluscs in a mollusc farming area, also dispatch centres, purification centres or similar businesses located inside a mollusc farming area shall have an individual authorisation.

(2) Each processing establishment slaughtering aquaculture animals for disease control purposes in accordance with rule 33 of Chapter V in the territory of Malta shall ensure that it is duly authorised by the competent authority in accordance with rule 5.

(3) Each aquaculture production business and authorised processing establishment in the territory of Malta shall have a unique authorisation number.

(4) By way of derogation from the authorisation requirement in sub-rule (1) hereof, the territory of Malta 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; and

(c) aquaculture production businesses which place aquaculture animals on the market solely for human consumption in accordance with Article 1 (3)(c) of Regulation (EC) No. 853/2004:

Provided that, the provisions of these rules 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 their operation.

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

Authorisation conditions.

5. (1) The competent authority in the territory of Malta shall ensure that authorisations, as provided for in sub-rules 4 (1) and (2), are only granted if the aquaculture production business operator or authorised processing establishment operator:

(a) fulfils the relevant requirements of rules 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 sub-rule 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:

Provided that, 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) The aquaculture production business operator or authorised processing establishment operator shall submit all relevant information to the competent authority in order to allow the competent authority to assess that the conditions for authorisation are fulfilled, including the information required in accordance with Schedule II.

Register

6. The competent authority shall establish, maintain and make publicly available a register of aquaculture production businesses and authorised processing establishments containing the information set out in Schedule II.

Official controls.

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

(2) The official controls provided for in sub-rule (1) hereof shall 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. The frequencies of such controls depend on the health status of the concerned zone or compartment and should be fixed in accordance with the recommendations that are laid down in Part B of Schedule III.

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

Recording obligations – Traceability.

8. (1) Aquaculture production businesses shall 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 rule 10.

(2) Authorised processing establishments shall keep a record of all movement of aquaculture animals and products thereof

into and out of such establishments.

(3) The transporters of aquaculture animals shall keep a record of:

(a) the mortality during transport, as practicable for the type of transport and the species transported;

(b) the 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, the aquaculture production business operators as provided for in sub-rule (1)(a) shall ensure that all movements of animals are recorded and registered in such a way that the tracing of the place of origin and destination can be guaranteed. Such movements have to be submitted to the competent authority and shall be recorded on a national register and kept in a computerised form.

Good hygiene practice.

9. The aquaculture production businesses and authorised processing establishments have to implement good hygiene practice, as relevant for the activity concerned, to prevent the introduction and spreading of diseases, which practice must be approved by the competent authority.

Animal health surveillance scheme.

10. (1) The competent authority shall ensure that a risk-based animal health surveillance scheme shall be 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 sub-rule (1) hereof 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 Schedule IV, in farms and mollusc farming areas were species susceptible to those diseases are present.

(3) Such animal health surveillance schemes, depending

on the health status of the concerned zone or compartment are laid down in accordance with the recommendations listed in Part B of Schedule III. This surveillance shall apply without prejudice to the sampling and surveillance carried out in accordance with Chapter V or sub-rules 49 (3) and 50 (4), and rule 52.

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

(5) A report shall be submitted by the competent authority on the overall operation of risk-based animal health surveillance, in the light of the outcome of official controls carried out in accordance with rule 7 and of the outcome of Community controls carried out in accordance with rule 58, and of any other relevant information. This report may be accompanied by an appropriate proposal, in accordance with the procedure referred to in sub-rule 62 (2).

CHAPTER III

Animal Health Requirements for Placing on the Market of Aquaculture Animals and Products thereof

SECTION 1

General Provisions

Scope

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

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

General requirements for the placing of aquaculture animals on the market.

12. (1) Producers shall ensure that the placing on the market of aquaculture animals and products thereof shall not jeopardize the health status of aquatic animals at the place of destination with regard to the diseases listed in Part II of Schedule IV.

(2) Producers shall ensure that they will follow the detailed rules on the movement of aquaculture animals as 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 Schedule III.

Disease prevention requirements in relation to transport.

13. (1) The competent authority 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 sub-rule shall also apply to diseases and the species susceptible thereto not listed in Part II of Schedule IV.

(2) The transporters must make sure that any water exchanges during transport shall be carried out at places and under conditions that 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.

Animal health certification.

14. (1) The placing on the market of aquaculture animals is subject to animal health certification by the competent authority of the area of origin when the animals are introduced into a zone or compartment within the territory of Malta declared disease-free in accordance with rules 49 and 50 or subject to surveillance, or to the eradication programme in accordance with rule 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) The placing on the market of aquaculture animals is subject to animal health certification by the competent authority 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 Schedule 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 these rules.

(4) The computerised system provided for in sub-rule (3) may be used by the competent authority to trace movements taking place entirely within its territory.

SECTION 2

Aquaculture Animals Intended for Farming and Restocking

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

15. (1) Without prejudice to the provisions laid down in Chapter V, the competent authority 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 Schedule IV.

(2) By way of derogation from sub-rule (1) (b), such placing on the market may be permitted by the competent authority 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) Aquaculture animals intended for destruction or slaughter in accordance with the disease control measures provided for in Chapter V shall not be 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 sub-rule (1); and

(b) come from a farm or mollusc farming area with a health status as referred to in Part A of Schedule III, at least equivalent to the health status of the waters in which they are to be released:

Provided that, aquaculture animals must originate from a zone or compartment declared disease-free in accordance with rules 49 or 50. The competent authority may also decide to apply this paragraph to programmes drawn up and applied in accordance with rule 43.

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

16. (1) Aquaculture animals of species susceptible to a specific disease originating from a zone or compartment within the territory of Malta declared free of that disease may be introduced for farming or restocking into another Member State, zone or compartment declared free of a specific disease in accordance with rules 49 or 50.

(2) Where it can be scientifically justified that species susceptible to the specific disease at certain life stages do not transmit that disease, sub-rule (1) shall not apply to those life stages:

Provided that a list of species and life stages to which

the first sub-rule 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 sub-rule 62 (2).

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

17. (1) Any species other than those referred to in Part II of Schedule IV which may be responsible for the transmission of a specific disease by acting as vector species as sustained by scientific data or practical experience, such species introduced for farming or restocking purposes into a zone or compartment within the territory of Malta declared free of that specific disease in accordance with rules 49 or 50, 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, 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 rule applies and, where appropriate, the conditions under which these 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 sub-rule 62 (2).

(3) In accordance with the procedure referred to in sub-rule 62 (3) together with the possible inclusion of a species on the list referred to in sub-rule (2), the Commission may decide to permit the application of the provisions provided for in sub-rule (1).

SECTION 3

Aquaculture Animals and Products thereof Intended for Human Consumption

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

18. (1) Aquaculture animals of species susceptible to one or more of the non-exotic diseases listed in Part II of Schedule IV, and products thereof, may only be placed on the market for further processing in a zone or compartment within the territory of Malta declared free of those diseases in accordance with rules 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) Live aquaculture animals of species susceptible to one or more of the non-exotic diseases listed in Part II of Schedule IV which are placed on the market for further processing in a zone or compartment within the territory of Malta declared free of those diseases in accordance with rules 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.

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

19. (1) Where aquaculture animals of species susceptible to one or more of the diseases listed in Part II of Schedule IV, or products thereof, are placed on the market for human consumption without further processing, this section shall not apply, 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 Schedule IV are temporarily relayed in Community waters, or introduced into dispatch centres, purification centres or similar businesses, they shall comply with sub-rule 18 (2).

SECTION 4

Wild Aquatic Animals

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

20. (1) Wild aquatic animals of species susceptible to one or more of the diseases listed in Part II of Schedule IV which are caught in a zone or compartment within the territory of Malta not declared disease-free in accordance with rules 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 rules 49 or 50.

(2) Traditional extensive lagoon aquaculture practice without the quarantine provided for in sub-rule (1) hereof may be permitted by the competent authority, provided a risk assessment is undertaken and that the risk is considered not higher than what is expected from the application of sub-rule (1) hereof.

SECTION 5

Ornamental Aquatic Animals

Placing on the market of ornamental aquatic animals.

21. (1) Traders and retailers shall ensure that the placing on the market of ornamental aquatic animals shall not jeopardise the health status of aquatic animals with regard to the diseases listed in Part II of Schedule IV.

(2) This rule shall apply also in relation to diseases not listed in Part II of Schedule IV.

CHAPTER IV

Introduction of Aquaculture Animals and Products thereof into the Community from Third Countries

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

22. Aquaculture animals and products thereof shall be 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 in sub-rule 62 (2).

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

23. (1) A third country, or a part of a third country, shall appear on the list provided for in rule 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) In the completion of the assessment of the third country, or part of the third country, as provided for in sub-rule (1) hereof, the Commission may also request an inspection as referred to in sub-rule 58 (2).

(3) When drawing up or updating the lists provided for in rule 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) All lists shall be drawn up or updated by the Commission in accordance with rule 22 and shall be made available to the public.

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

24. (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. Documents.

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

(a) the requirements laid down for such commodities under these rules; and

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

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

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

(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

National notification.

26. (1) Any person within the territory of Malta shall ensure that:

(a) when there are any reasons to suspect the presence of a disease listed in Part II of Schedule 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) The obligation to notify the matters referred to in sub-rule (1) hereof 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.

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

27. Other Member States, the Commission and EFTA Member States shall be notified within 24 hours in case of confirmation of:

(a) an exotic disease listed in Part II of Schedule IV; and

(b) a non-exotic disease listed in Part II of Schedule 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

Initial control measures.

28. In the case of a suspicion of an exotic disease listed in Part II of Schedule IV or, in the case of suspicion of a non-exotic disease listed in Part II of Schedule IV in the territory of Malta, comprising any zones or compartments with a health status of either category I or III as referred to in Part A of Schedule III, the competent authority shall ensure that for such disease:

(a) appropriate samples are taken and examined in a laboratory designated in accordance with rule 57; and

(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 duly authorised;

(iii) the epizootic investigation provided for in rule 29 is initiated.

Epizootic investigation.

29. (1) The epizootic investigation initiated in accordance with sub-rule 28 (b) (iii) shall be carried out where the examination provided for in sub-rule 28 (a) shows the presence of:

(a) an exotic disease listed in Part II of Schedule IV in any Member State; or

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

(2) The epizootic investigation provided for in sub-rule (1) hereof 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 sub-rule 26 (1);

(c) investigating whether other farms have been infected.

(3) Where the epizootic investigation provided for in sub-rule (1) hereof 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 rule 28 are applied in such farms, mollusc farming areas or unenclosed waters:

Provided that in the case of extensive water catchment areas or coastal areas, the competent authority may decide to limit the application of rule 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 rule within their territory.

Lifting restrictions.

30. The competent authority shall lift the restrictions provided for in sub-rule 28 (b) where the examination provided for in sub-rule 28 (a) fails to demonstrate the presence of the disease.

SECTION 3

Minimum Control Measures in the Case of Confirmation of Exotic Diseases in Aquaculture Animals

Introductory provision.

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

General measures.

32. The competent authority 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.

Harvesting and further processing.

33. (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) Any operations involved in the preparation of the aquaculture animals for entry into the food chain, including harvesting, the introduction into dispatch centres or purification centres, and any further processing, shall be carried out under the 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. In the absence of such system, 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.

Removal and disposal.

34. (1) Dead fish and crustaceans, as well as live fish and crustaceans showing clinical signs of disease, shall be removed and disposed of as soon as possible 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 which lays down health rules concerning animal by-products not intended for human consumption, and the contingency plan provided for in rule 47 of these rules.

(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 rule 47 of these rules.

Fallowing.

35. Infected farms or mollusc farming areas shall undergo an appropriate period of fallowing after being emptied and, where appropriate, cleansed and disinfected:

Provided that with regards to 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.

Protection of aquatic animals.

36. Necessary measures shall be adopted by the competent authority within the territory of Malta to prevent the spreading of diseases to other aquatic animals.

Lifting measures.

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

(a) the eradication measures provided for in this Section have been carried out; and

(b) the 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

General provisions.

38. (1) In the case of confirmation of a non-exotic disease listed in Part II of Schedule IV in any zone or compartment within the territory of Malta declared free of that disease, the competent authority may:

(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 sub-rule 44 (2).

(2) By way of derogation from sub-rule 34 (2), where the competent authority 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 competent authority does not wish to regain disease-free status, rule 39 shall apply.

Containment measures.

39. In the case of confirmation of a non-exotic disease listed in Part II of Schedule IV in a zone or compartment within the territory of Malta not declared free of that disease, the competent authority 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 sub-rule 12 (2); or

(ii) harvested and slaughtered for human consumption in accordance with sub-rule 33 (1); and

(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 time-frame 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 Schedule IV in Wild Aquatic Animals

Control of diseases listed in Part II of Schedule IV in wild aquatic animals.

40. (1) Where wild aquatic animals are infected or suspected of being infected with exotic diseases listed in Part II of Schedule IV, the competent authority 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 Schedule IV in a zone or compartment within the territory of Malta declared free of that disease, the competent authority shall also monitor the situation and take measures to reduce, and as far as possible, to prevent the further spreading of the disease.

(3) The competent authority shall inform the Commission and the other Member States within the Committee referred to in sub-rule 62 (1) of the measures they have taken in accordance with sub-rules (1) and (2) hereof.

SECTION 6

Control Measures in Case of Emerging Diseases

Emerging diseases.

41. (1) Appropriate measures shall be taken by the competent authority 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 competent authority shall inform the other 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 sub-rule (2) hereof, the matter shall be brought to the attention of the Committee referred to in sub-rule 62 (1). The measures taken by the competent authority pursuant to sub-rule (1) hereof may be extended, amended or repealed in accordance with the procedure referred to in sub-rule 62 (2).

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

SECTION 7

Alternative Measures and National Provisions

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

42. A decision may be adopted in accordance with the procedure referred to in sub-rule 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.

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

43. (1) Where a disease not listed in Part II of Schedule IV constitutes a significant risk for the animal health situation of aquaculture or wild aquatic animals in the territory of Malta, the competent authority may take measures to prevent the introduction of or to control that disease:

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

(2) The Commission shall be notified with any measures referred to in sub-rule (1) hereof by the competent authority, which may affect trade between Member States. Those measures shall be subject to approval in accordance with the procedure referred to in sub-rule 62 (2).

(3) The approval referred to in sub-rule (2) hereof 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

Drawing up and approval of surveillance and eradication programmes.

44. (1) Where the territory of Malta is not known to be infected but not declared free (category III as referred to in Part A of Schedule III) of one or more of the non-exotic diseases listed in Part II of Schedule IV, the competent authority shall draw up a surveillance programme for achieving a disease-free status for one or more of those diseases. The competent authority shall submit that programme for approval in accordance with the procedure referred to in sub-rule 62 (2), and these programmes may also be amended or terminated in accordance with that procedure and the specific requirements for surveillance, sampling and diagnostic shall be those provided for in sub-rule 49 (3):

Provided that, where a programme provided for in this paragraph is to cover individual compartments or zones, which

comprise less than 75% of the territory of Malta, 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 sub-rule 50 (2) shall apply for any approval, or amendment or termination of such programme.

(2) If the territory of Malta is known to be infected (category V as referred to in Part A of Schedule III) by one or more of the non-exotic diseases listed in Part II of Schedule IV, the competent authority shall draw up an eradication programme for one or more of those diseases and shall submit that programme for approval in accordance with the procedure referred to in sub-rule 62 (2), and such programmes may also be amended or terminated in accordance with that procedure.

(3) An overview of the programmes approved in accordance with sub-rules (1) and (2) hereof shall be made available at Community level in accordance with the procedures provided for in rule 51.

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

Content of programmes.

45. 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.

Period of application of programmes.

46. (1) Programmes shall continue to be applied until:

(a) the requirements laid down in Schedule V have been fulfilled, and the zone or compartment within the territory of Malta is declared free of the disease; or

(b) the programme is withdrawn, namely if it no longer fulfils its purpose, by the competent authority, or by the Commission.

(2) If the programme is withdrawn as provided for in sub-rule 1 (b) hereof, the competent authority shall apply the containment measures in rule 39 from the date of withdrawal of the programme.

SECTION 2

Contingency Plan for Emerging and Exotic Diseases

Contingency plan for emerging and exotic diseases.

47. (1) A contingency plan shall be drawn up by the competent authority and it shall specify 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 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, it shall give a precise indication of the vaccine requirements and vaccination conditions considered necessary in the event of emergency vaccination.

(3) The competent authority shall comply with the criteria and requirements laid down in Schedule VII when drawing up contingency plans.

(4) The competent authority shall submit the contingency plans for approval in accordance with the procedure referred to in sub-rule 62 (2), and every five years, the competent authority shall

update its contingency plan and it shall 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 Schedule IV.

SECTION 3

Vaccination

Vaccination.

48. (1) Vaccination against the exotic diseases listed in Part II of Schedule IV shall be prohibited unless such vaccination is approved in accordance with rules 41, 42, 44 or 47.

(2) Vaccination against the non-exotic diseases listed in Part II of Schedule IV shall be prohibited in any part of the territory of Malta declared free of the diseases in question in accordance with rules 49 or 50, or covered by a surveillance programme, approved in accordance with sub-rule 44 (1):

Provided that vaccination in parts of the territory of Malta which have not declared free from the diseases in question may be permitted or where vaccination is a part of an eradication programme approved in accordance with sub-rule 44 (2).

(3) The vaccines must be authorised in accordance with Directive 2001/82/EC and Regulation (EC) No. 726/2004.

(4) Sub-rules (1) and (2) hereof shall not apply to scientific studies for the purpose of developing and testing vaccines under controlled conditions and during such studies, the appropriate measures shall be taken to protect other aquatic animals from any adverse effect of the vaccination carried out within the frame-work of the studies.

CHAPTER VII

Disease-Free Status

Disease-free Member State.

49. (1) The territory of Malta shall be declared free of one or more of the non-exotic diseases listed in Part II of Schedule IV in accordance with the procedure referred to in sub-rule 62 (2), if sub-

rule (2) hereof is complied with, and:

(a) none of the species susceptible to the diseases in question is present within its territory; or

(b) the pathogen is known not to be able to survive in its territory, and in its water source; or

(c) the territory of Malta meets the conditions laid down in Part I of Schedule V.

(2) The competent authority shall establish appropriate buffer zones within the territory of Malta where its neighbouring Member States, or water catchment areas shared with its neighbouring Member States are not declared disease-free. The demarcation of buffer zones shall be such that they protect the territory of Malta declared disease-free from any passive introduction of the disease.

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

Disease-free zone or compartment.

50. (1) A zone or a compartment within the territory of Malta may be declared free of one or more of the non-exotic diseases listed in Part II of Schedule IV, where:

(a) none of the species susceptible to the diseases 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 Schedule V.

(2) The competent authority shall submit the declaration referred to in sub-rule (1) hereof 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 sub-rule 62 (2) and be accessible by electronic means to the Commission and to other Member States, in accordance with the requirements of rule 59;

(b) the Commission shall add the notification of the declaration to the agenda of the next meeting of the Committee referred to in sub-rule 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 competent authority making the declaration;

(d) where written comments are made by at least one Member State, or the Commission, within the period referred to in paragraph (b) of sub-rule (2) hereof 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 paragraph (b) of sub-rule (2) hereof may be prolonged for 30 days and such comments shall be submitted to the declaring Member State and to the Commission;

(e) if the arbitration referred to in paragraph (d) of sub-rule (2) hereof fails, the Commission may decide to make an on-the-spot inspection in accordance with rule 58 to verify the compliance of the declaration submitted with the criteria set out in sub-rule (1) hereof, 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 sub-rule 62 (2) shall be taken, to suspend the self-declaration of the disease-free status of the zone or compartment concerned.

(3) Where the zones or compartments referred to in sub-rule (1) hereof comprise more than 75% of the territory of Malta, 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 sub-rule (2) shall be replaced by the procedure referred to in sub-rule 62 (2).

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

Lists of disease-free Member States, zones or compartments.

51. (1) The competent authority shall establish and maintain an updated list of zones and compartments declared disease-free in accordance with sub-rule 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 rules 49 or sub-rule 50 (3), and shall make the list publicly available.

Maintenance of disease-free status.

52. When declared free from one or more non-exotic diseases listed in Part II of Schedule IV in accordance with rule 49, the competent authority 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 these Rules are implemented:

Provided that, for disease-free zones or compartments within the territory of Malta 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 sub-rules 49 (3) or 50 (4) as appropriate, but at a level commensurate with the degree of risk.

Suspension and restoration of disease-free status.

53. (1) Where the territory of Malta has reason to believe that any of the conditions for maintaining its status as a disease-free zone or compartment have been breached, it 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 Schedule III and it shall apply the provisions of Sections 2 and 4 of Chapter V.

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

(3) Where the epizootic investigation confirms a

significant likelihood that infection has occurred, the disease-free status of the zone or compartment within the territory of Malta shall be withdrawn, in accordance with the procedure under which that status was declared. The requirements laid down in Schedule V shall be complied with before the disease-free status is restored.

CHAPTER VIII

Competent Authorities and Laboratories

General obligations.

54. (1) The territory of Malta shall designate its competent authorities for the purposes of these rules and shall notify the Commission thereof and the competent authorities shall operate and perform their duties in accordance with Regulation (EC) No. 882/2004.

(2) Effective and continuous cooperation based on the free exchange of information relevant to the implementation of these rules shall be established between the competent authority and any of its other authorities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin. Such information shall also, to the extent necessary, be exchanged between the competent authorities of the different Member States.

(3) The competent authorities shall have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology, having a free exchange of any information relevant to the implementation of these rules between the competent authorities and laboratories.

Community reference laboratories.

55. (1) Community reference laboratories for the aquatic animal diseases relevant to these rules shall be designated in accordance with the procedure referred to in sub-rule 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 Schedule VI.

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

National reference laboratories.

56. (1) A national reference laboratory shall be designated by the competent authority for each of the Community reference laboratories referred to in rule 55 and the competent authority 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) The competent authority shall inform the Commission with the name and address of each designated national reference laboratory, 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 rule 55.

(4) The national reference laboratory shall collaborate with any laboratory designated in accordance with rule 57 in order to ensure an efficient diagnostic service in accordance with the requirements of these rules.

(5) Any national reference laboratory within the territory of Malta shall be adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with these rules and shall comply with the functions and duties laid down in Part II of Schedule VI.

Diagnostic services and methods.

57. The competent authority shall ensure that:

(a) laboratory examinations for the purposes of these rules 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 Schedule IV are carried out by diagnostic methods to be established in accordance with the procedure referred to in sub-rule 62 (2); and

(c) laboratories designated for diagnostic services in accordance with this rule shall comply with the functions and duties laid down in Part III of Schedule VI.

CHAPTER IX

Inspections, Electronic Management and Penalties

Community inspections and audits.

58. (1) On-the-spot inspections including audits, may be carried out by experts from the Commission in cooperation with the competent authority, insofar as they are necessary for the uniform application of these rules and the competent authority shall provide the experts carrying out such inspections and audits with all the assistance necessary for carrying out their duties, and 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 competent authority shall immediately take all measures necessary to safeguard animal health:

Provided that, 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 sub-rule 62 (3) and the competent authority shall be informed thereof.

Electronic management.

59. (1) All procedures and formalities relating to making the information provided for in rule 6, sub-rules 50 (2), 51 (1) and 56 (2) available by electronic means shall be in place.

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

Penalties.

60. The competent authority shall lay down the rules on penalties applicable to infringements pursuant to these rules and shall take all measures necessary to ensure that they are implemented. The competent authority shall notify those provisions to the Commission and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER X

Amendments, Detailed Rules and Committee Procedure

Amendments and detailed rules.

61. (1) Sub-rule 50 (2) may be amended in accordance with the procedure referred to in sub-rule 62 (2).

(2) The Schedules to these rules may be amended in accordance with the procedure referred to in sub-rule 62 (2).

(3) The measures necessary for the implementation of these rules shall be adopted in accordance with the procedure referred to in sub-rule 62 (2).

Committee procedure.

62. (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 sub-rule, articles 5 and 7 of Decision 1999/468/EC shall apply and the period laid down in sub-article 5 (6) of Decision 1999/468/EC shall be set at three months.

(3) Where reference is made to this sub-rule, articles 5 and 7 of Decision 1999/468/EC shall apply and the period laid down in sub-article 5 (6) of Decision 1999/468/EC shall be set at 15 days.

(4) The Committee shall adopt its Rules of Procedure.

SCHEDULE I

Definitions

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

"common biosecurity system" means that the same aquatic animal health surveillance, disease prevention, and disease control measures are applied;

"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;

"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;

"disease" means a clinical or non-clinical infection with one or more aetiological agents in aquatic animals;

"disease-free zones or compartments" means zones or compartments declared disease-free in accordance with rules 49 or 50;

"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 Schedule IV as a susceptible species;

"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;

"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;

"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;

"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;

"infected zone or compartment" means zones or compartments where the infection is known to occur;

"infection" means the presence of a multiplying, or otherwise developing, or latent disease agent in, or on, a host;

"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;

"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;

"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;

"zone" means a precise geographical area with a homogeneous hydrological system comprising part of a water catchment area from the source or sources 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 or sources 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.

SCHEDULE 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 rule 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 (that is, dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisations);

(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 (that is, 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 Schedule IV, or known vectors of such diseases);

(g) updated information on the health status (that is, 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 Schedule IV).

2. Where an authorisation is granted to a mollusc farming area in accordance with the second sub-paragraph of sub-rule 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 rule 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 (that is, dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisations);

(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.

SCHEDULE III

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 of 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.

SCHEDULE 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, that is, 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 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

SCHEDULE 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 rule 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 sub-rule 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 molluscs 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 sources 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 sub-rule 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 Schedule.

Member States wishing to benefit from this provision shall notify their intention in accordance with sub-rule 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 sub-rule 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 Schedule 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.

SCHEDULE 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 rule 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 these Rules:

(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 Schedule. Any intention to take advantage of such cooperation shall be part of the information provided as a basis for the designation in accordance with sub-rule 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 Schedule 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 rule 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 Schedule 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 Schedule IV, and of primary outbreaks of non-exotic diseases listed in that Schedule;

(f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in accordance with rule 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 rule 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 these Rules:

(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 rule 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 rule 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 Schedule 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 these rules:

(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 Schedule are no longer fulfilled.

SCHEDULE 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 Schedule 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 Schedule 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 Schedule 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 Schedule 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 carcases 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.