ANNEX I

DEFINITIONS

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

(a) ‘compartment’ means one or more farms under a common biosecurity system containing an aquatic animal population with a distinct health status with respect to a specific disease;

(b) ‘common biosecurity system’ means that the same aquatic animal health surveillance, disease prevention, and disease control measures are applied;

(c) ‘containment area’ means an area around an infected farm or mollusc farming area where disease control measures are applied with the purpose of preventing the spread of the disease;

(d) ‘disease’ means a clinical or non-clinical infection with one or more aetiological agents in aquatic animals;

(e) ‘disease-free zones or compartments’ means zones or compartments declared disease-free in accordance with Articles 49 or 50;

(f) ‘emerging disease’ means a newly identified serious disease, the cause of which may or may not yet be established, that has the potential to be spread within and between populations, such as by way of trade in aquatic animals and/or aquatic animal products. It also means a listed disease identified in a new host species not yet included in Part II of Annex IV as a susceptible species;

(g) ‘epidemiological unit’ means a group of aquatic animals that share approximately the same risk of exposure to a disease agent within a defined location. This risk may be because they share a common aquatic environment, or because management practices make it likely that a disease agent in one group of animals would quickly spread to another group of animals;

(h) ‘fallowing’ means, for disease management purposes, an operation where a farm is emptied of aquaculture animals susceptible to the disease of concern or known to be capable of transferring the disease agent, and, where feasible, of the carrying water;

(i) ‘further processing’ means processing of aquaculture animals before human consumption by any type of measures and techniques affecting anatomical wholeness, such as bleeding, gutting/evisceration, heading, slicing and filleting, which produces waste or by-products and could cause a risk of spreading diseases;

(j) ‘increased mortality’ means unexplained mortalities significantly above the level of what is considered to be normal for the farm or mollusc farming area in question under the prevailing conditions. What is considered to be increased mortality shall be decided in cooperation between the farmer and the competent authority;

(k) ‘infection’ means the presence of a multiplying, or otherwise developing, or latent disease agent in, or on, a host;

(l) ‘infected zone or compartment’ means zones or compartments where the infection is known to occur;

(m) ‘quarantine’ means maintaining a group of aquatic animals in isolation with no direct or indirect contact with other aquatic animals, in order to undergo observation for

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

(n) 'susceptible species' means any species in which infection by a disease agent has been demonstrated by natural cases or by experimental infection that mimics the natural pathways;

(o) 'vector' means a species that is not susceptible to a disease but which is capable of spreading infection by conveying pathogens from one host to another;

(p) 'zone' means a precise geographical area with a homogeneous hydrological system comprising part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area, an entire water catchment area from its source(s) to its estuary, or more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

ANNEX II

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

PART I

Authorised aquaculture production business

1. The following minimum information on each aquaculture production business shall be kept by the competent authority in a register, as provided for in Article 6:

(a) the name and addresses of the aquaculture production business, and contact details (telephone, facsimile, e-mail);

(b) the registration number and particulars of the authorisation delivered, (i.e. dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisation(s));

(c) the geographical position of the farm defined by a suitable system of coordinates of all farm-sites (if possible, GIS coordinates);

(d) the purpose, type (i.e. type of culture system, or facilities such as land-based facilities, sea cages, earth ponds) and maximum volume of production where this is regulated;

(e) for continental farms, dispatch centres and purification centres, details on the farm's water supply and discharges;

(f) the species of aquaculture animals reared at the farm (for multi-species farms or ornamental farms, it shall as a minimum be registered whether any of the species are known to be susceptible to diseases listed in Part II of Annex IV, or known vectors of such diseases);

(g) updated information on the health status (i.e. if the farm is disease-free (located in a Member State, zone or compartment), where the farm is under

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

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

PART II

Authorised processing establishments

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

(a) the name and addresses of the authorised processing establishment, and contact details (telephone, facsimile, e-mail);

(b) the registration number and particulars of the authorisation delivered (i.e. dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisation(s));

(c) the geographical position of the processing establishment defined by a suitable system of coordinates (if possible GIS coordinates);

(d) details on the authorised processing establishment's water effluent treatment systems;

(e) the species of aquaculture animals handled in the authorised processing establishment.

ANNEX III

PART A

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

Aquaculture animals for farming and restocking

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

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

PART B

Recommended surveillance and inspections on farms and mollusc-farming areas

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

	Article 50(1)(a) or (b).					Article 52.	requirements mentioned for each health status. However, where possible, such inspections and sampling should be combined with the inspections required pursuant to Articles 7 and 10. The aim of inspections by the competent authority is to check compliance with this Directive in accordance with Article 7. The aim of inspections by qualified aquatic animal health services is to check the health status of the animals, to advise the aquaculture
Species susceptible to one or more of the diseases listed in Annex IV	Category I Declared disease-free in accordance with of Article 49(1) (c) or of Article 50(1)(c).	High	Active, targeted or passive	1 every year	1 every year		
		Medium		1 every 2 years	1 every 2 years		
		Low		1 every 4 years	1 every 2 years		
	Category II Not declared disease-free but subject to a surveillance programme approved in accordance with Article 44(1).	High	Targeted	1 every year	1 every year	Specific requirements in accordance with Article 44(1).	
		Medium		1 every 2 years	1 every 2 years		
		Low		1 every 4 years	1 every 2 years		
	Category III Not known to be infected but not subject to surveillance programme for achieving disease-free status.	High	Active	1 every year	3 every year		
		Medium		1 every year	2 every year		
		Low		1 every 2 years	1 every year		
	Category IV Known to be infected	High	Targeted	1 every year	1 every year	Specific requirements in accordance with	
		Medium		1 every 2 years	1 every 2 years		

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

Risk levels

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

(a) has a high risk of spreading diseases to or contracting diseases from other farms or wild stocks;

(b) operates under farming conditions which could increase the risk of disease outbreaks (high biomass, low water quality), taking into account the species present;

(c) sells live aquatic animals for further farming or restocking.

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

(a) has medium risk of spreading diseases to or contracting diseases from other farms or wild stocks;

(b) operates under farming conditions which would not necessarily increase the risk of disease outbreaks (medium biomass and water quality), taking into account the species present;

(c) sells live aquatic animals mainly for human consumption.

A low-risk farm 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.

ANNEX IV

Disease listing

PART I

Criteria for listing diseases

A. Exotic diseases shall meet the following criteria laid down in point 1 and either point 2 or 3.

1. The disease is exotic to the Community, i.e. the disease is not established in Community aquaculture, and the pathogen is not known to be present in Community waters.

2. It has potential for significant economic impact if introduced into the Community, either by production losses in Community aquaculture or by restricting the potential for trade in aquaculture animals and products thereof.

3. It has potential for detrimental environmental impact if introduced into the Community, to wild aquatic animal populations of species, which are an asset worth protecting by Community law or international provisions.

B. Non-exotic diseases shall meet the following criteria laid down in points 1, 4, 5, 6, 7, and 2 or 3.

1. Several Member States, or regions in several Member States, are free of the specific disease.

2. It has potential for significant economic impact if introduced into a Member State free of the disease, either by production losses, and annual costs 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.

[F1PART II

LISTED DISEASES

Exotic diseases		
	Disease	**Susceptible species**
Fish	Epizootic haematopoietic necrosis	Rainbow trout (*Oncorhynchus mykis*) and redfin perch (*Percha fluviatilis*)
Molluscs	Infection with *Bonamia exitiosa*	Australian mud oyster (*Ostrea angasi*) and Chilean flat oyster (*O. chilensis*)
	Infection with *Perkinsus marinus*	Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*)

	Infection with *Microcytos mackini*	Pacific oyster (*Crassostrea gigas*), Eastern oyster (*C. virginica*), Olympia flat oyster (*Ostrea conchaphila*) and European flat oyster (*O. edulis*)
Crustaceans	Taura syndrome	Gulf white shrimp (*Penaeus setiferus*), Pacific blue shrimp (*P. styrlirostris*), and Pacific white shrimp (*P. vannamei*)
	Yellowhead disease	Gulf brown shrimp (*Penaeus aztecus*), Gulf pink shrimp (*P. duoranum*), Kuruma prawn (*P. japonicas*), black tiger shrimp (*P. monodon*), Gulf white shrimp (*Penaeus setiferus*), Pacific blue shrimp (*P. styrlirostris*), and Pacific white shrimp (*P. vannamei*)
Non-exotic diseases		
Fish	Viral haemorrhagic septicaemia (VHS)	Herring (*Cupea* spp.), whitefish (*Coregonus* sp.), pike (*Esox Lucius*), haddock (*Gadus aeglefinus*), Pacific cod (*G. macrocephalus*), Atlantic cod (*G. morhua*), Pacific salmon (*Onchorhynchus* spp.), rainbow trout (*O. mykiss*), rockling (*Onos mustelus*), brown trout (*Salmo trutta*), turbot (*Schophtalmus maximus*), sprat (*Sprattus sprattus*), grayling (*Thymallus thymallus*) and olive flounder (*Paralichthys olivaceus*)
	Infectious haematopoetic necrosis (IHN)	Chum salmon (*Oncorchynchus keta*), coho salmon (*O. kisutch*), Masou salmon (*O. masou*), rainbow or steelhead trout (*O. mykiss*), sockeye salmon (*O. nerka*), pink salmon (*O. rhodurus*), Chinook salmon (*O. tshawytscha*), and Atlantic salmon (*Salmo salar*)

	Koi herpes virus (KHV) disease	Common carp and koi carp (*Cyprinus carpio)*
	Infectious salmon anaemia (ISA): infection with genotype HPR-deleted of the genus Isavirus (ISAV)	Rainbow trout (*Oncorhynchus mykiss*), Atlantic salmon (*Salmo salar*), and brown and sea trout (*Salmo trutta*)
Molluscs	Infection with *Marteilia refringens*	Australian mud oyster (*Ostrea angsi*), Chilean flat oyster (*O. chilensis*), European flat oyster (*O. edulis*), Argentinian oyster (*O. pelchana*), blue mussel (*Mytilus edulis*) and Mediterranean mussel (*M. galloprovincialis*)
	Infection with *Bonamia ostrea*	Australian mud oyster (*Ostrea angasi*), Chilean flat oyster (*O. chilensis*), Olympia flat oyster (*O. conchaphila*), Asiatic oyster (*O. denselammellosa*), European flat oyster (*O. edulis*) and Argentinian oyster (*O. puelchana*)
Crustaceans	White spot disease	All decapod crustaceans (*order Decapoda*)**]**

Textual Amendments

F1 Substituted by Commission Implementing Directive 2014/22/EU of 13 February 2014 amending Annex IV to Council Directive 2006/88/EC as regards infectious salmon anaemia (ISA) (Text with EEA relevance).

ANNEX V

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

PART I

Disease-free Member State

1. On historical grounds

1.1. A Member State where susceptible species are present, but where there has not been any observed occurrence of the disease for at least for a period of 10 years before the date of application for the disease-free status despite

conditions that are conducive to its clinical expression may be considered disease-free where:

(a) basic biosecurity measure conditions have been in place continuously for at least a period of 10 years before the date of application for the disease-free status;

(b) infection is not known to be established in wild populations;

(c) the implementation of trade and imports conditions to prevent the introduction of the disease into the Member State is effective.

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

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

(a) the disease is compulsorily notifiable to the competent authority, including notification of suspicion;

(b) an early detection system is in place throughout the Member State, enabling the competent authority to undertake effective disease investigation and reporting, and ensuring in particular:

(i) the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or molluscs farming areas, and in the wild;

(ii) the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay.

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

(a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians or aquatic animal health specialists in detecting and reporting unusual disease occurrence;

(b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;

(c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

2. Based on targeted surveillance

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

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

and

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

Where there are parts of the Member State in which the number of farms, or 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 source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area;

or

(c) more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

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

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

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

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

1.4. A zone where the last known clinical occurrence was within a period of 10 years before the date of application for the disease-free status or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free where it complies *mutatis mutandis* with the requirements laid down in Part I.2.

1.5. A buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease.

2. Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status regarding that disease of surrounding natural waters

2.1. A compartment may comprise one or more farms, a group or cluster of farms or a mollusc farming area that may be considered as one epidemiological unit due to its geographical localisation and distance from other groups or clusters of farms or mollusc farming areas, provided that all farms comprising the compartment fall within a common biosecurity system. The geographical demarcation of a compartment shall be clearly identified on a map.

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

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

2.3. A compartment where the last known clinical occurrence was within 10 years before the date of application for the disease-free status, or where the infection status in the compartment or in the waters surrounding the compartment prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.2.

2.4. Each farm or mollusc farming area in a compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring programme is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.

3. Compartments comprising one or more individual farms where the health status regarding a specific disease is independent of the health status regarding that disease of the surrounding natural waters.

3.1. A compartment may comprise:

(a) an individual farm which may be considered a single epidemiological unit, as it is not influenced by the animal health status in the surrounding waters;

or

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

3.2. A compartment shall be supplied with water:

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

or

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

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

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

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

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

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

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

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

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

(a) the health history of the farm over the last four years of its operation is known to the competent authority; however, if the farm

concerned has been in operation for less than four years, the actual period in which it has been in operation will be taken into account;

(b) the farm has not been subject to animal-health measures in respect of the diseases listed in Part II of Annex IV and there have been no antecedents of those diseases on the farm;

(c) prior to the introduction of the aquaculture animals, eggs or gametes, the farm is cleaned and disinfected, followed, as necessary, by a period of fallowing.

ANNEX VI

Functions and duties of laboratories

PART I

Community reference laboratories

1. In order to be designated as a Community reference laboratory in accordance with Article 55, laboratories shall fulfil the following requirements. They must:

(a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence, including trained personnel available for emergency situations occurring within the Community;

(b) possess the equipment and products needed to carry out the tasks assigned to them;

(c) have an appropriate administrative infrastructure;

(d) ensure that their staff respect the confidential nature of certain subjects, results or communications;

(e) have sufficient knowledge of international standards and practices;

(f) have available, as appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

(g) take account of research activities at national and Community level.

2. However, the Commission may designate only laboratories that operate and are assessed and accredited in accordance with the following European Standards, account being taken of the criteria for different testing methods laid down in this Directive:

(a) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

(b) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

(c) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4. For one or more of the diseases under their responsibility, the Community reference laboratories may take advantage of the skills and capacity of laboratories in other Member States or EFTA Member States, provided that the laboratories concerned comply with the requirements laid down in points 1, 2 and 3 of this Annex. Any intention to take advantage of such cooperation shall be part of the information provided as a basis for the designation in accordance with Article 55(1). However, the Community reference laboratory shall remain the contact point for the National reference laboratories in the Member States, and for the Commission.

5. The Community reference laboratories shall:

(a) coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:

(i) typing, storing and, where appropriate, supplying strains of the pathogen of the relevant disease to facilitate the diagnostic service in the Community,

(ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in each Member State, where serological tests are required,

(iii) organising periodic comparative tests (ring tests) of diagnostic procedures at Community level with the national reference laboratories designated by the Member States, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Community;

(iv) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;

(b) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(c) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Community;

(d) collaborate, as regards methods of diagnosing animal diseases falling within their areas of competence, with the competent laboratories in third countries where those diseases are prevalent;

(e) collaborate with the relevant OIE reference laboratories with regard to exotic diseases listed in Part II of Annex IV under their responsibility;

(f) collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture.

PART II

National reference laboratories

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

   (a) undertake to notify, without delay, the competent authority whenever the laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;

   (b) coordinate, in consultation with the relevant Community reference laboratory, the methods employed in Member States for diagnosing the diseases concerned under their responsibility;

   (c) assist actively in the diagnosis of outbreaks of the relevant disease by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

   (d) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Member State;

   (e) ensure confirmation of positive results of all outbreaks of exotic diseases listed in Part II of Annex IV, and of primary outbreaks of non-exotic diseases listed in that Annex;

   (f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in accordance with Article 57, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Member State;

   (g) cooperate with the Community reference laboratory referred to in Article 55 and participate in the comparative tests organised by the Community reference laboratories;

   (h) ensure a regular and open dialogue with their national competent authorities;

   (i) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:

      (i) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

      (ii) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

      (iii) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

2. The accreditation and assessment of testing laboratories referred to in point 1(i) may relate to individual tests or groups of tests.

3. The Member States may designate national reference laboratories which do not comply with the requirements referred to in point 1(i)(i) of this Part, where operation

under EN ISO/IEC 17025 is practically difficult, provided the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. Member States may authorise a national reference laboratory situated on their territory to take advantage of the skills and capacity of other laboratories designated pursuant to Article 57, for one or more of the diseases under their responsibility, provided that these laboratories comply with the relevant requirements of this Part. However, the national reference laboratory shall remain the contact point for the central competent authority of the Member State, and for the Community reference laboratory.

PART III

Designated laboratories in Member States

1. The competent authority of a Member State shall designate only laboratories for diagnostic services pursuant to Article 57 that fulfil the following requirements. They must:

   (a) undertake to notify, without delay, the competent authority whenever a laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;

   (b) undertake to participate in comparative tests (ring-tests) of diagnostic procedures arranged by the national reference laboratory;

   (c) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:

      (i) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

      (ii) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

      (iii) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

2. The accreditation and assessment of testing laboratories referred to in paragraph 1(c) may relate to individual tests or groups of tests.

3. The Member States may designate laboratories which do not comply with the requirements referred to in point 1(c)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided that the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. The competent authority shall cancel the designation where the conditions referred to in this Annex are no longer fulfilled.

ANNEX VII

CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

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

1. Provision must be made to ensure the legal powers needed to implement contingency plans and put into effect a rapid and successful eradication campaign;

2. Provision must be made to ensure access to emergency funds, budgetary means and financial resources in order to cover all aspects of the fight against exotic diseases listed in Part II of Annex IV;

3. A chain of command must be established to guarantee a rapid and effective decision-making process for dealing with exotic diseases listed in Annex IV or emerging diseases. A central decision-making unit must be in charge of the overall direction of control strategies;

4. Detailed plans must be available for Member States to be prepared for the immediate establishment of local disease control centres in the event of an outbreak of exotic diseases listed in Part II of Annex IV or emerging diseases and to implement disease control and environment protection measures at a local level;

5. Member States must ensure cooperation between the competent authorities and competent environmental authorities and bodies in order to ensure that actions on veterinary and environmental safety issues are properly coordinated;

6. Provision must be made for adequate resources to ensure a rapid and effective campaign, including personnel, equipment and laboratory capacity;

7. An up-to-date operations manual must be available, with a detailed, comprehensive and practical description of all the actions, procedures, instructions and control measures to be employed in handling exotic diseases listed in Part II of Annex IV or emerging diseases;

8. Detailed plans must be available for emergency vaccination, where appropriate;

9. Staff must be regularly involved in training in clinical signs, epidemiological enquiry and control of epizootic diseases, in real-time alert exercises, and in training in communication skills to provide ongoing disease awareness campaigns for authorities, farmers and veterinarians;

10. Contingency plans must be prepared that take into account the resources needed to control a large number of outbreaks occurring within a short period of time;

11. Without prejudice to the veterinary requirements laid down in Regulation (EC) No 1774/2002, contingency plans must be prepared to ensure that, in the event of an outbreak of diseases, any mass disposal of aquatic animal 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.

ANNEX VIII

CORRELATION TABLE

This Directive	**Repealed Directives**		
	91/67/EEC	**93/53/EEC**	**95/70/EC**
Article 1(1)(a)	Article 1, first subparagraph	—	—
Article 1(1)(b)	—	—	—
Article 1(1)(c)	—	Article 1	Article 1
Article 1(2)	—	Article 20(2)	Article 12(2)
Article 2(1)	—	—	—
Article 2(2)	—	—	—
Article 2(3)	Article 1, second subparagraph	—	—
Article 3	Article 2	Article 2	Article 2
Article 4	—	—	—
Article 5	—	—	—
Article 6	—	—	—
Article 7	—	—	—
Article 8(1)	—	Article 3(2)	Article 3(2)
Article 8(2)	—	—	—
Article 8(3)	—	—	—
Article 8(4)	—	—	—
Article 9	—	—	—
Article 10	—	—	Article 4
Article 11	—	—	—
Article 12	—	—	—
Article 13(1)	Article 4, first paragraph	—	—
Article 13(2)	Article 4, second paragraph	—	—
Article 14(1)(a)	Article 7(1), Article 8(1)	—	—
Article 14(1)(b)	—	—	—
Article 14(2)	Article 16(1)	—	—
Article 14(3)	Article 16(1),	—	—
Article 14(4)	—	—	—

Article 15(1)	Article 3(1)(a) and (2)	—	—
Article 15(2)	—	—	—
Article 15(3)	Article 3(1)(b) and (2)	—	—
Article 15(4)	—	—	—
Article 16(1)	Article 7(1)(a), first sentence Article 7(1)(b) Article 8(1)(a) Article 8(1)(b)	—	—
Article 16(2)	—	—	—
Article 17	—	—	—
Article 18(1)	Article 9	—	—
Article 18(2)	—	—	—
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Article 20	Article 14(3)	—	—
Article 21	—	—	—
Article 22	Article 19(1)	—	—
Article 23(1)	—	—	—
Article 23(2)	Article 22	—	—
Article 23(3)	Article 19(2)	—	—
Article 23(4)	Article 19(3)	—	—
Article 23(5)	—	—	—
Article 24	Article 21	—	—
Article 25(a)	Article 20	—	—
Article 25(b)	—	—	—
Article 25(c)	—	—	—
Article 25(d)	Article 21(2)	—	—
Article 25(e)	—	—	—
Article 26	—	Article 4	Article 5(1)
Article 27	—	—	Article 5(5)
Article 28(a)	—	Article 5(1) Article 10(1)(a)	Article 5(2)(a)
Article 28(b)	—	Article 5(2)(b) Article 10(1)(c)	Article 5(2)(b)

Article 29(1)	—	Article 5 (2)(h) Article 6(a), seventh indent Article 8(1) Article 9(1), first sentence Article 10(1)b	Article 4(1), third subparagraph, third indent Article 5(4), first and fourth subparagraph
Article 29(2)	—	Article 5(2)(i)	Article 5(4), second and fourth subparagraph
Article 29(3)	—	Article 6(b) Article 6(d) Article 8(2) Article 8(3) Article 9(2)	—
Article 29(4)	—	Article 5(2)(i), second indent	—
Article 30	—	Article 5(4)	Article 5(3)
Article 31	—	—	—
Article 32	—	Article 5(2), Article 6	Article 4(1), third subparagraph, second indent, Article 5(2)(b), Article 5(4), third and fourth subparagraph
Article 33(1)	Article 3(3)	Article 6(a) fourth indent	—
Article 33(2)	—	Article 6(a), fourth indent	—
Article 33(3)	—	—	—
Article 33(4)	—	—	—
Article 34(1)	—	Article 5(2)(c) Article 6(a), first and third indent	—
Article 34(2)	—	Article 6(a), fourth indent	—
Article 35	—	Article 6(a), second, fifth and sixth indent	—
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Article 39(d)	—	—	—
Article 40	—	Article 7	—
Article 41	—	—	—
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Article 44(1)	Article 10	Article 10(2)	—
Article 44(2)	Article 10	Article 10(2)	—
Article 45	Article 10(1)	—	—
Article 46	—	—	—
Article 47	—	Article 6(a), first indent Article 15	—
Article 48(1)	—	Article 14(1)	—
Article 48(2)	—	Article 14(1)	—
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Article 53(3)	—	Article 9(1), second sentence	—
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Article 56(5)	—	Article 12(1) Article 12(3)	Article 6(2)
Article 57(a)	—	Article 11(2)	—
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Article 58(2)	Article 22	—	—
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Article 62	Article 26 Article 27	Article 19	Article 10
Article 63	—	—	—
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Article 65	Article 29	Article 20	Article 12
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