COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DIRECTIVE

on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

{SEC(2005) 1047}

Proposal for a

COUNCIL DECISION

amending Decision 90/424/EEC on expenditure in the veterinary field

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- Grounds for and objectives of the proposal

  The purpose of this proposal is to update, recast and consolidate the animal health rules in relation to the trade in aquaculture products, including disease prevention and control, in order to improve the competitiveness of EU aquaculture producers.

  Aquaculture is a very important industry in the Community, particularly in rural and coastal areas. In 2004, EU aquaculture produced fish, molluscs and crustaceans worth more than €2,5 billion. However, financial losses due to disease (mortalities, reduced growth and reduced quality) are estimated to be 20 % of the production value. The proposal aims to introduce modern and targeted legislation that reduces these costs; if they could be reduced by only 20%, the result would be an added value of €100 million per year.

  The existing legislation was developed two decades ago when the EU had only 12 Member States. It was primarily designed to protect the main EU aquaculture at that time, namely salmonid (trout and salmon) and oyster farming. The legislation now needs to be updated to reflect the broader range of aquaculture practises and species that are found in the expanded EU, and to take account of the significant developments within the industry, the experience gained through 15 years of application of the existing legislation, as well as scientific advances in this field. The rules must also be updated to bring EU rules in line with international agreements and standards (like WTO/SPS and OIE).

  This proposal corresponds to the Commission legislative Working Programme project 2004/SANCO/0025

- General context

  This proposal will repeal the existing primary legislation (Council Directives 91/67/EEC, 93/53/EEC and 95/70/EC) and replace those three Directives with one new Directive. This much needed revision and consolidation will update the legislation to reflect the EU aquaculture industry in the 21st century, and simplify and modernise existing rules to provide more flexibility, and delegate more operational responsibility to Member States so that, for example, effective local or regional approaches can be taken to prevent and contain diseases.

- Existing provisions in the area covered by the proposal

  This proposal will replace

  – Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products;

– Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases;

– Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs.

The general principles laid down in the three Directives in question will be maintained.

In addition, there are 13 implementing Decisions which have been adopted pursuant to those Directives. The implementing Decisions will remain in force until they are repealed by a specific Decision, or replaced by a Decision adopted pursuant to this proposal.

- Consistency with other policies

The aquaculture industry falls under the Common Fisheries Policy (CFP). The main interaction between this proposal and the legislation related to the CFP concerns the financial support (see also Com (2004) 497 - final). It is proposed that the same principle applied for terrestrial animal diseases, namely that a financial contributions from the Community should be made available where Community law requires a slaughter/eradication policy to be carried out, should also be applied to aquatic animal diseases.

The proposal upholds the principle laid down in existing legislation that the animal health provisions shall apply without prejudice to national or international provisions on the conservation of species or the introduction of non-native species. More stringent rules may therefore be applied where this is necessary for the protection of species from an environmental or conservation point of view. The proposal would therefore not conflict with Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora. Furthermore, major change in policy to concentrate more on, - allowing Member States to allocate more resources to - disease prevention, should reduce the environmental impact of the aquaculture industry by reducing outbreaks of disease.

Public health concerns are not dealt with in this proposal, as it is regulated by the "hygiene package". None of the diseases or pathogens covered by this proposal is known to have zoonotic potential.

The welfare of farmed fish falls within the scope of the existing general provisions of Community legislation concerning the protection of animals kept for farming purposes. Scientific advice from the European Food Safety Authority, in addition to Council of Europe recommendations concerning the welfare of fish (within the scope of the European Convention for the protection of animals kept for farming purposes) will influence future policy initiatives in this area.

The present animal health provisions relating to third countries will in principle remain unchanged.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents.

Written consultations took place in 2000 and 2001 via the Advisory Committee on Fisheries and Aquaculture (ACFA). In this Committee the following organisations are represented: Federation of European Aquaculture Producers (FEAP), European Mollusc Producers Association (EMPA/AEPM), Comité des Organisations Professionnelles Agricoles de l'UE (COPA/COGECA), Organisation of the workers unions (ETF), NGO for consumer and NGO for environment. The Commission's services have regularly reported on developments in the project in the ACFA Working Group 2 (Aquaculture).

Bilateral meetings have been held with FEAP and EMPA/AEPM during 2003, 2004 and 2005.

Stakeholder consultations were held in September and December 2004. There have been several technical working group meetings with representatives from the Member States and EFTA/EEA states.

Summary of responses and how they have been taken into account.

The main comments from the Member States and stakeholders have been taken into account in the framing of the proposal.

For the stakeholders, it is essential that the Directive contains a mechanism that will enable farms to maintain and, where possible improve, their health status, and also to encourage farms to make their health status known as a means of facilitating safe trade. An appropriate categorisation of health status will be the only way to prevent a degradation of the aquatic animal health status in the Community. The concept of categorisation has been introduced in the proposal.

The aquaculture industry's need for economic compensation for disease eradication and control measures is also of importance to stakeholders, and is acknowledged by the Commission and the Member States. This acknowledgement is further discussed in a proposal for a Council Regulation - European Fisheries Fund (COM(2004) 497).

Where the requests from the stakeholders have not been taken into account, it has been due to the international commitments of the Community or due to the need for cross-compliance with other Community legislation, in particular the WTO/SPS agreement and the EU Food Law.

- Collection and use of expertise

  Scientific/expertise domains concerned.

  Aquatic animal health.

  Methodology used.

  The opinions have been considered in the draft proposal

  Main organisations/experts consulted.

  The scientific platform for the proposal was established by a working group of experts on aquatic animal health from EU and EFTA/EEA Member States. In addition experts from the industry were consulted.

  Level of scientific certainty: high.

  Advice received and used.

  Yes

  Means used to make the expert advice publicly available.

  Advice from expert working group meetings and stakeholder consultation meetings has not been made publicly available. However, the advice has been discussed with competent authorities and stakeholders in meetings.

- Impact assessment

  The main provisions for placing on the market an import remains largely unchanged. However, some existing trade barriers have been removed without jeopardising the health status of aquaculture animals. The general disease control provisions will remain unchanged, with some minor adjustments. All diseases considered exotic to the Community will be subject to eradication provisions in order to maintain the Community's free status. Under the present legislation such measures are applied for fish disease but not for mollusc diseases. The importation provisions are harmonised with the relevant provisions of Council Directive 2002/99/EC (the most recent Directive laying down animal health import provisions).

  Positive impacts

  Positive impacts will arise from an updated Community legislative framework which takes into account current scientific knowledge and the structure of today's aquaculture industry in the Community.

  There will be positive shift in focus away from preventing the spread disease and towards the occurrence of disease. Significant resources are now being used to maintain disease-free status in farms and zones that have been declared disease-free. The proposal would allow the Member State to re-allocate some of these resources to disease preventive activities.

The proposal implements the philosophy that the best solution is often found closest to the problem, and delegates more operational responsibility to the Member States.

By introducing general risk-based animal health surveillance, a better overview of the disease situation can be achieved. At the same time the risk of spreading diseases to farms or areas where the disease has not yet been found is reduced.

The proposal takes into account the potential for exchange of disease agents between farmed and wild aquatic animals.

The new legislation will be consistent with the International Aquatic Animal Health Code of the World Organisation for Animal Health (OIE), and will reduce existing trade barriers between third countries, including developing countries, and the Community.

Negative impacts

The negative impact will be limited, as the proposal will to a large extent be founded on the existing legislation. Some new elements and requirements will have an administrative and economic impact on the Member States and on the industry.

The proposal for authorisation of aquaculture production business will cause extra work for the competent authorities in the Member States. However, since all mollusc farms and the majority of fish farms are already registered, the authorisation requirement is achievable for the Member States.

The introduction of a general risk-based animal health surveillance in all farms or farming areas, is an extension of the requirements in the present mollusc legislation, under which all Member States must have a monitoring and sampling program.

3. LEGAL ELEMENTS OF THE PROPOSAL

- Summary of the proposed action

The proposal includes

– General requirements directed towards the aquaculture production business and processing establishments, such as authorisations, and provisions related to their operation;

– Animal health provisions for placing on the market of aquaculture animals and products thereof;

– Animal health provisions for introduction of aquaculture animals into the Community from third countries;

– Provisions for notification and control of certain diseases in aquatic animal;

– Provisions for declaration of disease-free status;

– Requirements directed towards the competent authorities of the Member States, and laboratories;

– Technical requirements and guidelines laid down in Annexes.

- Legal basis

  Article 37 of the Treaty

- Subsidiarity principle

  The proposal falls within the exclusive competence of the Community. The subsidiarity principle therefore does not apply.

- Proportionality principle

  The proposal complies with the proportionality principle for the following reason(s).

  For the sake of the completion of the internal market, the animal health provisions applicable to the placing on the market of aquaculture animals should be fully harmonised.

  Some of the diseases subject to harmonised trade provisions are widespread in parts of the Community. It is however not realistic to enforce the same level of control measures in Member States that are free of these diseases, as in Member States where these diseases are widespread.

  The introduction of the principle of compartmentalisation will allow for more flexibility.

  The administrative and economic burden imposed will result in a higher health status, reduction of losses due to diseases and more open trade. Increased financial burden on the Community budget will be limited to the financial contribution in relation to the control and eradication of diseases which are subject to compulsory eradication measures.

- Choice of instruments

  Proposed instruments: Directive.

  Other means would not be adequate for the following reason(s).

  Experience since 1964 with harmonised veterinary legislation in the Community, and in particular since 1991 with specific aquatic animal health legislation, have shown that a Directive gives sufficient flexibility for the Member States to apply Community veterinary legislation in the framework of national legislation and administration.

4. BUDGET IMPLICATIONS

The economic impact on Community budget is expected to be limited, and will mainly be in two areas:

(a) Economic compensation in relation to disease control.

The proposal should not affect the future development of the Community policy on animal health and the veterinary fund.

Council Decision 90/424/EEC on expenditure in the veterinary field already allows for financial support in relation to outbreaks of Infectious Haematopoietic Necrosis (IHN) and Infectious Salmon Anaemia (ISA), under Regulation (EC) No 2792/1999 solely.

It is proposed that financial contribution for aquatic animal disease control from the Community should be eligible through the European Fisheries Fund (Article 32 of COM (2004) 497).

In the proposal, compulsory slaughter/eradication will only be required under Community rules in relation to outbreaks of diseases that are considered exotic to the Community. With respect to non-exotic diseases it is proposed that the Member States may decide whether an outbreak should be subject to eradication measures or containment measures. Community funding under European Fisheries Fund may be made available for control measures of such diseases if the Member State so decides.

If an exotic disease did occur in the Community, it would have no financial impact on Community budget. The same would occur in case of compensation for eradication of non-exotic diseases, since the allocation of funds for the eradication are made within the Operational Programmes, whose budget is fixed by the Council at the beginning of the programming period.

In the interest of Member States, it would be convenient to assess the financial impact of eradication on their Operational Programmes. However, the costs related to such eradication measures are difficult to estimate, as there is limited experience in the Community of stamping out policy involving economic compensation in aquaculture. In the court case following the outbreaks of ISA in the UK and Ireland, one company owning five of the thirteen infected farms claimed total losses in the region of € 20-25 million. Sweden paid out compensation under national legislation totalling of 1,5 mill SEK (€165 000) over a period of three years in relation to four cases of VHS in 1998.

It is therefore difficult to estimate the impact of the proposal on the European Fisheries Fund, as this will depend on the size of the farm(s) affected, the value of the animals kept at the farm(s), etc. However, the figures above can give an indication.

(b) Implementation of primary legislation and adoption and management of secondary legislation

Once the Council has adopted the proposal, it will be necessary to draw up, adopt and maintain secondary legislation. It will be necessary to arrange a number of working group meetings with Member States and stakeholders, the latter normally without any additional cost for the Community budget. The number of working groups is impossible to determine, as this will depend on the complexity of the items, and the views of the Member States.

After the act's entry into force, FVO inspections of Member States' implementation will be necessary in 2008 and 2009 (13 or 14 inspections per year). Such inspections should as far as possible be combined with public health inspections for "fishery products" and "live bivalve mollusc" pursuant to Article 11 of Regulation (EC) No 854/2004. It should be possible to reduce the number of missions in subsequent years.

5. ADDITIONAL INFORMATION

- Simplification

The proposal provides for simplification of legislation, simplification of administrative procedures for public authorities (EU or national).

Three directives will be merged into one.

Most of the current provisions in Council Directive 93/53/ECC on the control of fish diseases are duplicated in Council Directive 95/70/EC on the control of mollusc diseases.

Delegating the power to declare individual compartments and zones free of disease to the Member States will lead to a simplification of administrative procedures in the Member States and in the Commission services.

- Repeal of existing legislation

  The adoption of the proposal will lead to the repeal of the three existing Directives.

- European Economic Area

  The proposed act is of EEA relevance and should therefore be extended to the EEA.

2005/0153 (CNS)

Proposal for a

COUNCIL DIRECTIVE

on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Parliament[2],

Having regard to the opinion of the European Economic and Social Committee[3],

Having regard to the opinion of the Committee of the Regions[4],

Whereas:

(1) Aquaculture animals and products are included in Annex I to the Treaty as live animals, fish, molluscs and crustaceans. The breeding, rearing and the placing on the market of aquaculture animals and products thereof constitutes an important source of income for persons working in this sector.

(2) In the context of the internal market, specific animal health rules were laid down for the placing on the market and introduction from third countries of the products concerned by Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products[5].

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ L 46, 19.2.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(3) Outbreaks of diseases in aquaculture animals could cause severe losses to the industry concerned. Minimum measures to be applied in case of outbreaks of the most important diseases in fish and molluscs were established by Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases[6], and Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs[7].

(4) Existing Community legislation was drafted mainly to take into account the farming of salmon, trout and oysters. Since that legislation was adopted, the Community aquaculture industry has developed significantly. A number of additional fish species, particularly marine species, are now used in aquaculture. New types of farming practices involving other fish species have also become increasingly common, particularly following the recent enlargement of the Community. Furthermore, farming of crustaceans, mussels, clams and abalones is becoming increasingly important.

(5) All disease control measures have an economic impact on aquaculture. Inadequate controls can lead to a spread of pathogens, which can cause major losses and compromise the animal health status of fish, molluscs and crustaceans used in Community aquaculture. On the other hand, over-regulation could place unnecessary restrictions on free trade.

(6) The Communication from the Commission to the Council and the European Parliament dated 19 September 2002 (COM/2002/0511 final) sets out a strategy for the sustainable development of European Aquaculture. That Communication proposed a series of measures designed to create long-term employment in the aquaculture sector, including promoting high animal health and welfare standards, and environmental actions to ensure a sound industry. Those measures should be taken into account.

(7) Since the adoption of Directive 91/67/EEC, the Community has ratified the World Trade Organisation (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS-Agreement). The SPS Agreement refers to the Guidelines of the World Organisation of Animal Health (OIE). The animal health requirements for placing live aquaculture animals and products thereof on the market within the Community in Directive 91/67/EEC are more stringent than those Guidelines.

(8) In order to ensure the rational development of this sector and to increase productivity, aquatic animal health rules should be laid down at Community level. These rules are necessary, among other things, in order to contribute to the completion of the internal market and to avoid the spread of infectious diseases. Legislation should be flexible to take into account the continuing developments in and diversity of the aquaculture sector, as well as the health status of aquatic animals within the Community.

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6 OJ L 175, 19.7.1993, p. 23. Directive as last amended by the 2003 Act of Accession.

7 OJ L 332, 30.12.1995, p. 33. Directive as last amended by the 2003 Act of Accession.

(9) This Directive should cover aquaculture animals, and those environments which can affect the health status of such animals. In general the provisions of this Directive should only apply to wild aquatic animals where the environmental situation may impinge on the health status of aquaculture animals, or where necessary in order to fulfil the purpose of other Community legislation, such as Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora[8] or to protect species referred to in the list draw up by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). This Directive should not prejudice the adoption of more stringent rules on the introduction of non-native species.

(10) The competent authorities designated for the purpose of this Directive should perform their functions and duties in accordance with the general principles laid down in Regulation (EC) No 854/2004 of European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[9], and Regulation (EC) No 882/2004 of European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[10].

(11) It is necessary for the development of aquaculture in the Community to increase the awareness and preparedness of the competent authorities and aquaculture production business operators in Member States with respect to the prevention, control and eradication of aquatic animal diseases.

(12) The competent authorities of Member States should have access to, and apply, state-of-the-art techniques and knowledge in the fields of risk analysis and epidemiology. This is of increasing importance because international obligations within the framework of the World Trade Organisation now focus on risk analysis in relation to the adoption of sanitary measures.

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8 OJ L 206, 22.7.1992, p. 7. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

9 OJ L 139, 30.4.2004, p. 206; corrected version (OJ L 226, 25.6.2004, p.83). Regulation as last amended by Regulation (EC) No 882/2004 (OJ L 165, 30.4.2004, p. 1); corrected version (OJ L 191, 28.5.2004, p. 1).

10 OJ L 165, 30.4.2004, p. 1.

(13) It is appropriate to introduce at Community level a system of authorisation of aquaculture production businesses. Such authorisation would enable the competent authorities to establish a complete overview of the aquaculture industry, which would assist in the prevention, control and eradication of aquatic animal diseases. Furthermore, authorisation allows the laying down of specific requirements that must be fulfilled by the aquaculture production business in order to operate. Such authorisation should, where possible, be combined with or included in an authorisation regime which the Member States may already have established for other purposes, for example under environmental legislation. In addition, such authorisation would not be an extra burden to the aquaculture industry, taking into account the Proposal of 13 January 2004 for a Directive of the European Parliament and the Council on services in the internal market[11], and in particular Article 6 thereof.

(14) Member States should refuse to issue an authorisation if the activity in question would pose an unacceptable risk of spreading diseases to other aquaculture animals or to wild stocks of aquatic animals. Before deciding to refuse an authorisation, consideration should be given to risk mitigation measures or alternative siting of the activity in question.

(15) The rearing of aquaculture animals for the purpose of human consumption falls within the scope of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[12], as primary production. Obligations imposed on individual aquaculture production businesses under this Directive, such as record keeping, and internal systems enabling the aquaculture production business to demonstrate to the competent authority that relevant requirements of this Directive are being fulfilled, should where possible be combined with the obligations laid down in Regulation (EC) No 852/2004.

(16) More attention should be paid to preventing disease occurrence than to controlling the disease once it has occurred. It is therefore appropriate to lay down minimum measures of disease prevention and risk mitigation which should be applied to the whole production chain in aquaculture, from fertilisation and hatching of eggs to the processing of aquaculture animals for human consumption, including transportation.

(17) In order to improve general animal health and assist in the prevention and control of animal disease through improved traceability, the movement of aquaculture animals should be recorded using a harmonised electronic animal movement system, such as that currently laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market[13]. Where appropriate, such movements should also be subject to animal health certification.

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11 COM/2004/2/Final.

12 OJ L 139, 30.4.2004, p. 1; corrected version (OJ L 226, 25.6.2004, p. 3).

13 OJ L 224, 18.8.1990. p. 29 Directive as last amended by Directive 2002/33/EC of the European Parliament and of the Council (OJ L 315, 19.11.2002, p. 14).

(18) In order to have an overview of the disease situation, to facilitate a rapid reaction in the case of a suspicion of disease and to protect farms or mollusc farming areas having a high animal health standard, a risk-based animal health surveillance should be applied in all such farms and mollusc farming areas.

(19) It is necessary to ensure that the main aquatic animal diseases at Community level do not spread. Harmonised animal health provisions for placing on the market should therefore be laid down with specific provisions applicable to species susceptible to those diseases. Therefore a list of such diseases and susceptible species should be laid down.

(20) The prevalence of such aquatic animal diseases is not the same throughout the Community. Reference should therefore be made to the concept of Member States which are declared disease-free, and when dealing with parts of the territory concerned, zones or compartments. General criteria and procedures for the granting, maintenance, suspension, restoration and withdrawal of such status should be laid down.

(21) In order to maintain and improve the general aquatic animal health status in the Community, Member States, zones or compartments declared free of one or more of the listed diseases should be protected against the introduction of such disease. However, in order to avoid the creation of unnecessary trade restrictions, the exchange of aquaculture animals between Member States, zones or compartments where one or more such diseases are present should be allowed, provided that risk mitigation measures are taken during transport.

(22) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread the disease, *inter alia* as a result of the discharge of effluents containing pathogens from processing plants. It is therefore necessary for the Member States to have access to processing establishments that have been duly authorised to undertake such slaughter and processing without jeopardising the health status of farmed and wild aquatic animals, including in respect of the discharge of effluents.

(23) The designation of Community and national reference laboratories should contribute to the high quality and uniformity of diagnostic results. That objective can be achieved by activities such as the application of validated diagnostic tests and the organisation of comparative testing and training of staff from laboratories.

(24) Laboratories involved in the examination of official samples should work in accordance with internationally approved procedures or criteria based on performance standards and should use diagnostic methods that have, as far as possible, been validated. For a number of activities related to such examination, the European Standardisation Organisation (CEN), and International Organisation for Standardisation (ISO) have developed European Standards (EN Standards) and ISO Standards respectively, appropriate for the purpose of this Directive. Such standards relate in particular to the operation and assessment of laboratories and to the operation and accreditation of control bodies.

(25) In order to ensure early detection of any possible outbreak of aquatic animal disease, it is necessary to oblige those in contact with aquatic animals of susceptible species to notify any suspect case to the competent authority. Routine inspections should be carried out in the Member States to ensure that aquaculture production business operators are familiar with, and apply, the general rules on disease control and biosecurity laid down in this Directive.

(26) It is necessary to prevent the spread of non-exotic but serious diseases in aquaculture animals as soon as an outbreak occurs by carefully monitoring movements of live aquaculture animals and products thereof, and the use of equipment liable to be contaminated. The choice of the measures to be used by the competent authorities should depend on the epidemiological situation in the Member State concerned.

(27) In order to advance the animal health status of the Community, it is appropriate that epidemiologically-based programmes to control and eradicate certain diseases are submitted by Member States for recognition at Community level.

(28) For diseases not subject to Community control measures, but which are of local importance, the aquaculture industry should, with the assistance of the competent authorities of the Member States, take more responsibility for controlling such diseases through self regulation and the development of "codes of practice". However, it may be necessary, pending the establishment of such codes, for the Member States to implement certain control measures. Such national control measures must be justified, necessary and proportionate to the goals to be achieved, and should not affect the trade between the Member States.

(29) There is a continuous development in knowledge with respect to hitherto unknown diseases in aquatic animals. It may therefore be necessary for a Member State to apply control measures in the case of such emerging disease. Such measures should be swift and adapted to each individual case, but should not be maintained longer than necessary to achieve their goal. As such emerging diseases may also affect other Member States, all Member States and the Commission should be informed of the presence of an emerging disease and any control measures taken.

(30) It is necessary and appropriate for the achievement of the basic objective of maintaining and, in the event of an outbreak, quickly returning to a disease-free status in Member States, to lay down rules on the measures to increase disease preparedness. Outbreaks should be controlled as speedily as possible, if necessary by emergency vaccination, in order to limit the adverse effects on the production of, and trade in, live aquaculture animals and products thereof.

(31) Directive 2001/82/EC of 6 November 2001 of the European Parliament and of the Council on the Community code relating to veterinary medicinal products [14] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[15], require that, with only minor exceptions, all veterinary medicinal products that are placed on the market within the Community are to hold a marketing authorisation. In general, all vaccines used in the Community should have a marketing authorisation. However, the Member States may permit the use of a product without a marketing authorisation in the event of a serious epidemic subject to certain conditions, in accordance with Regulation (EC) No 726/2004. Vaccines against exotic and emerging diseases in aquaculture animals may qualify for such derogation

(32) This Directive should lay down provisions to ensure the necessary level of preparedness to effectively tackle the emergency situations related to one or more outbreaks of serious exotic or emerging diseases affecting aquaculture, in particular by drawing up contingency plans to combat them. Such contingency plans should be reviewed and updated regularly.

(33) Where the control of a serious aquatic animal disease is subject to harmonised Community eradication measures, Member States should be allowed to make use of financial contribution from the Community under Council Regulation (EC) No xxxx/200Y on the European Fisheries Fund[16]. Any application for Community support should be subject to scrutiny as regards compliance with control provisions laid down in this Directive.

(34) Live aquaculture animals and products thereof imported from third countries must not present an animal health hazard for aquatic animals in the Community. To that end, this Directive should set out measures for the prevention of the introduction of epizootic diseases.

(35) It is necessary in order to safeguard the aquatic animal health situation in the Community to further ensure that consignments of live aquaculture animals transiting through the Community comply with the relevant animal health requirements applicable to the species concerned.

(36) Import conditions should be consistent with the SPS Agreement. This Directive should therefore take into account the International Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aquatic Animals of the OIE.

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14 OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004 p. 58).

15 OJ L 136, 30.4.2004, p. 1.

16 COM(2004) 497 final – Proposal for a Council Regulation European Fisheries Fund.

(37) The placing on the market of ornamental aquatic animals involves a wide variety of species, often tropical species, solely for ornamental purposes. Those ornamental aquatic animals are normally kept in private aquariums or ponds, garden centres, or in exhibition aquariums, not in direct contact with Community waters. Consequently, ornamental aquatic animals held under such conditions do not pose the same risk to other sectors of Community aquaculture or to wild stocks. It is therefore appropriate not to lay down special provisions applicable to the placing on the market, transit and import of ornamental aquatic animals, kept under such conditions.

(38) However, where ornamental aquatic animals are kept outside closed systems or aquariums, in direct contact with the natural waters of the Community, they could pose a significant risk to Community aquaculture or wild stocks. That is particularly the case for the populations of carp (*Cyprinidae*), as popular ornamental fish such as koi-carp are susceptible to some diseases affecting other carp species farmed in the Community or found in the wild. In such cases, the general provisions of this Directive should apply.

(39) The setting up of electronic means of exchange of information is vital for simplification, for the benefit of the aquaculture industry and of the competent authorities. In order to meet that obligation, common criteria need to be introduced.

(40) Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

(41) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objectives of this Directive to provide for the approximation of the concepts, principles and procedures forming a common basis for aquatic animal health legislation in the Community. This Directive does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.

(42) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[17].

(43) It is appropriate to update Community animal health legislation concerning aquaculture animals and products thereof. Accordingly, Directives 91/67/EEC, 93/53/EEC and 95/70/EC should be repealed and replaced by this Directive,

HAS ADOPTED THIS DIRECTIVE:

[17] OJ L 184, 17.7.1999, p. 23.

Chapter I
Subject matter, scope and definitions

Article 1
Subject matter

1. This Directive lays down:

   (a) the animal health requirements to be applied for the placing on the market, the importation and the transit of aquaculture animals and products thereof;

   (b) minimum preventive measures aimed at increasing the awareness and preparedness of the competent authorities, the aquaculture production business operators and others related to this industry, for diseases in aquaculture animals;

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

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

Article 2
Scope

1. This Directive shall not apply to:

   (a) ornamental aquatic animals reared in non-commercial aquaria;

   (b) wild aquatic animals harvested or caught for direct entry into the food chain;

   (c) aquatic animals caught for the purpose of production of fishmeal, fish oil and similar products.

2. Chapter II, Sections 1 to 4 of Chapter III, and Chapters IV and VII shall not apply to ornamental aquatic animals that are kept in pet-shops, garden centres or commercial aquaria:

   (a) without any direct contact with natural waters in the Community; or

   (b) which are equipped with effluent treatment systems.

3. This Directive shall apply without prejudice to provisions on the conservation of species or the introduction of non-native species.

Article 3
Definitions

1. For the purposes of this Directive, the following definitions shall apply:

(1) *"aquaculture"* means the rearing or cultivation of aquatic organisms using techniques designed to increase the production of those organisms beyond the natural capacity of the environment and where the organisms remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting;

(2) *"aquaculture animal"* means all life stages, including eggs and sperm/gametes, of any aquatic animal reared in a farm or mollusc farming area, including any such animal from the wild intended for a farm or mollusc farming area;

(3) *"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 of aquaculture animals;

(4) *"aquaculture production business operator"* means the natural or legal persons responsible for ensuring that the requirements of this Directive are met within the aquaculture production business under their control;

(5) *"aquatic animal"* means:

(a) fish belonging to the classes *Agnatha*, *Chondrichytes* and *Osteichtyes*;

(b) molluscs belonging to the group *Mollusca*;

(c) crustaceans belonging to the class *Crustacea*;

(6) *"authorised processing establishment"* means any food business:

(a) approved or authorised in accordance with Article 4 of Regulation (EC) No 853/2004 for processing aquaculture animals for food purposes; and

(b) authorised in accordance with Articles 4 and 5 of this Directive;

(7) *"authorised processing establishment operator"* means the natural or legal persons responsible for ensuring that the requirements of this Directive are met within the authorised processing establishment under their control;

(8) *"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, but excluding those where wild aquatic animals harvested or caught for the purpose of human consumption are temporarily kept awaiting slaughter without being fed;

(9) "*farming*" means the rearing of aquaculture animals in a farm or in a mollusc farming area;

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

(11) *"ornamental aquatic animals"* means aquatic animals which are reared, or placed on the market for ornamental purposes only;

(12) *"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;

(13) *"production area"* means any sea, estuarine or lagoon area, containing natural beds of molluscs or sites used for the cultivation of molluscs, and from which molluscs are taken;

(14) *"put and take fisheries"* means ponds, lakes or unenclosed waters that are sustained by the introduction of aquatic animals primarily for recreational activities rather than for conservation or improvement of the natural population;

(15) *"relaying area"* means any 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;

(16) *"wild aquatic animals"* means aquatic animals which are not aquaculture animals.

2. For the purposes of this Directive, the technical definitions laid down in Annex I shall also apply.

Chapter II
Aquaculture production businesses and authorised processing establishments

Article 4
Authorisation of aquaculture production businesses and processing establishments

1. Member States shall ensure that every aquaculture production business is duly authorised by the competent authority in accordance with Article 5.

   Where appropriate, such authorisation may cover several aquaculture production businesses for molluscs in a mollusc farming area.

   However, dispatch centres, purification centres or similar businesses located inside a mollusc farming area shall have an individual authorisation.

2. Member States shall ensure that a sufficient number of processing establishments on their territory are authorised for the slaughtering and processing of aquaculture animals being harvested and slaughtered for disease control purposes, in accordance with Chapter V.

   Those authorised processing establishments shall have an authorisation issued by the competent authority in accordance with Article 5.

3. Member States shall ensure that aquaculture production businesses and authorised processing establishments have a unique authorisation number.

4. Member States may require that installations other than aquaculture production businesses, where aquatic animals are kept without the intention of being placed on the market, and put and take fisheries must be registered by the competent authority.

   In that case, the provisions of this Directive shall apply *mutatis mutandis* taking into account the nature, characteristics and situations of the installation or put and take fishery concerned and the risk of spreading aquatic animal diseases to other populations of aquatic animals as a result of its operation.

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

Article 5
Authorisation conditions

1. Member States shall ensure that authorisations, as provided for in Article 4(1) and (3), are only granted by the competent authority if the aquaculture production business operator or authorised processing establishment operator:

   (a) fulfils the relevant requirements of Articles 8, 9 and 10;

   (b) has a system in place which enables the operator to demonstrate to the competent authority that those relevant requirements are being fulfilled;

   (c) remains under the supervision of the competent authority, which shall perform the duties laid down in Article 54(1).

2. An authorisation shall not be granted if the activity in question would lead to an unacceptable risk of spreading diseases to farms, mollusc farming areas or to wild stocks of aquatic animals in the vicinity of the farm or mollusc farming area.

   However, before a decision to refuse authorisation is taken, considerations shall be given to risk mitigation measures including possible alternative siting of the activity in question.

3. Member States shall ensure that the aquaculture production business operator or authorised processing establishment operator submit all relevant information in order to allow the competent authority to assess that the conditions for authorisation are fulfilled, including supplying the competent authority with information required in accordance with Annex II.

Article 6
Register

The Member States shall establish and keep up-to-date a register of aquaculture production businesses and authorised processing establishments containing at least the information set out in Annex II.

For the purpose of the traceability requirements provided for in Article 14, the contents of that register shall be made available to the other Member States and the Commission.

Article 7
Supervision

The competent authority shall supervise aquaculture production businesses and authorised processing establishments.

Such supervision shall at least consist of regular visits and audits. The frequency of such visits and audits shall be determined taking account of the risk the aquaculture production business and authorised processing establishment poses in relation to the spreading of disease to aquatic animals in the vicinity of the aquaculture production business or authorised processing establishment.

Article 8
Recording obligations

1. Member States shall ensure that aquaculture production businesses keep a record of:

   (a) all movements of aquaculture animals and products thereof, into and out of the farm or mollusc farming area;

   (b) the mortality in each epidemiological unit as relevant for the type of production;

   (c) the results of the risk-based animal health surveillance scheme provided for in Article 10.

2. Member States shall ensure that authorised processing establishments keep a record of all movement of aquaculture animals and products thereof, into and out of such establishments.

3. Member States shall ensure that when aquaculture animals are transported, a record is kept by the transporters of:

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

   (b) farms, mollusc farming areas and processing establishments visited by the means of transport;

   (c) any water exchange during transport, in particular the sources of new water and release of water.

Article 9
Good hygiene practice

Member States shall ensure that aquaculture production businesses and authorised processing establishments implement good hygiene practice, as relevant for the activity concerned, to prevent the introduction and spreading of diseases.

Article 10
Animal health surveillance scheme

1. Member States shall ensure that a risk-based animal health surveillance scheme is applied in all farms and mollusc farming areas, as appropriate for the type of production.

2. The risk-based animal health surveillance scheme shall aim at the detection of:

   (a) any increased mortality in all farms and mollusc farming areas as appropriate for the type of production;

   (b) the diseases listed in Part II of Annex III, in farms and mollusc farming areas were species susceptible to those diseases are present.

3. Minimum requirements for the animal health surveillance scheme, for the diseases listed in Part II of Annex III, based on the principles laid down in Annex IV, may be adopted in accordance with the procedure referred to in Article 62(2)

Chapter III
Animal health requirements for placing on the market of aquaculture animals and products thereof

SECTION 1
GENERAL PROVISIONS

Article 11
Scope

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

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

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

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

Article 12
General requirements for the placing of aquaculture animals on the market

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

2. Aquaculture animals shall only be introduced into another farm or mollusc farming area with a recognised health status equivalent or lower than the farm or mollusc farming area of origin.

Article 13
Disease prevention requirements in relation to transport

1. Member States shall ensure that:

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

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

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

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

   (a) the aquaculture animals being transported;

   (b) any aquatic animals at the place of water exchange;

   (c) aquatic animals at the place of destination.

Article 14
Traceability and certification

1. Member States shall ensure that placing on the market of aquaculture animals for farming and restocking purposes, including movement of molluscs between mollusc farming areas, are reported using the computerised system provided for in Article 20(1) of Council Directive 90/425/EEC.

2. Paragraph 1 of this Article shall also apply to aquaculture animals placed on the market for human consumption in accordance with point (a) of Article 18(1), point (a) of Article 18(2) and Article 19(2).

3. Paragraph 1 shall not apply when aquaculture animals are moved inside a mollusc farming area or between different farms belonging to one aquaculture production business, provided that the mollusc farming areas or the farms are within the same Member State and, where applicable, within the same disease-free zone or compartment.

   Such movements shall be recorded by the aquaculture production business operator.

4. Member States shall ensure that introduction of aquaculture animals for farming and restocking purposes into other Member States, zones or compartments declared disease-free in accordance with Articles 49 and 50 are subject to animal health certification.

5. This Article shall also apply to diseases and the species susceptible thereto not listed in Part II of Annex III.

SECTION 2
AQUACULTURE ANIMALS INTENDED FOR FARMING AND RESTOCKING

Article 15
General requirements for the placing of aquaculture animals on the market for farming and restocking

1. Member States shall ensure that aquaculture animals placed on the market for farming do not come from a farm or mollusc farming area where there has been any increased mortality or a clinical outbreak of any disease within 31 days prior to the date of placing on the market, unless such animals originate from a part of the farm or mollusc farming area epidemiologically independent of the part where the increased mortality or clinical signs of disease have occurred.

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

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

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

   (a) comply with the requirements in paragraph 1;

   (b) come from a farm or mollusc farming area with a health status at least equivalent to the health status of the waters in which they are to be released.

   However, Member States may decide that the aquaculture animals shall come from a zone or compartment, declared disease-free in accordance with Articles 49 or 50.

Article 16

Introduction of aquaculture animals of susceptible species into disease-free areas

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

2. Paragraph 1 shall not apply where it can be scientifically justified that susceptible species at certain life stages do not transmit the specific disease in question.

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

Article 17

Introduction of aquaculture animals of non-susceptible species into disease-free areas

1. Where scientific data or practical experience substantiates that species other than those referred to in Part II of Annex III as susceptible species can be responsible for the passive transmission of a specific disease, such carrier species shall, where introduced into a Member State, zone or compartment declared free of that specific disease in accordance with Articles 49 or 50:

   (a) originate from another Member State, zone or compartment also declared free of that specific disease; or

   (b) be held in quarantine facilities in water free of the pathogen in question for a period of time sufficient to reduce to an acceptable level the risk of passive transmission of the specific disease.

2. Paragraph 1 shall not apply where scientific data or practical experience substantiates that carrier species at certain life stages do not transmit the specific disease in question.

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

SECTION 3
AQUACULTURE ANIMALS AND PRODUCTS THEREOF INTENDED FOR HUMAN CONSUMPTION

Article 18

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

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

   (a) they originate from another Member State, zone or compartment declared free of the disease in question;

   (b) they are processed in an authorised processing establishment under conditions which prevents the spreading of diseases;

   (c) as regards fish: they are slaughtered and eviscerated before dispatch;

   (d) as regards molluscs and crustaceans: they are dispatched as unprocessed or processed products.

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

   (a) they originate from another Member State, zone, or compartment declared free of the disease in question; or

   (b) they are temporarily kept in dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system capable of inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.

Article 19

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

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

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

SECTION 4
WILD AQUATIC ANIMALS

Article 20
Release of wild aquatic animals in Member States, zones or compartments declared disease-free

1. Wild aquatic animals of species susceptible to one or more of the diseases listed in Part II of Annex III caught in a Member State or zone or compartment not declared disease-free in accordance with Articles 49 or 50, shall be placed in quarantine under the supervision of the competent authority in suitable facilities, for a period of time sufficient to reduce to an acceptable level the risk of transmission of the disease, before they can be released into a farm situated in a Member State, zone, or compartment declared free from the disease in question in accordance with Articles 49 or 50.

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

SECTION 5
ORNAMENTAL AQUATIC ANIMALS

Article 21
Placing on the market of ornamental aquatic animals

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

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

Chapter IV
Introduction of aquaculture animals and products thereof into the Community from third countries

Article 22
General requirements for introduction of aquaculture animals and products thereof from third countries

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

Article 23
Lists of third countries and parts of third countries from which introduction of aquaculture animals and products thereof is permitted

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

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

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

   (a) the legislation of the third country;

   (b) the organisation of the competent authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and the means at their disposal, including staff capacity, to apply their legislation effectively;

   (c) the actual aquatic animal health requirements applying 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 can 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 of 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);

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

4. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance Article 22 to be available to the public.

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

Article 24
Documents

1. A document containing an animal health certificate shall accompany consignments of aquaculture animals and products thereof upon their entry into the Community.

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

(a) the requirements laid down for such commodities under this Directive; and

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

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

Article 25
Detailed rules

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

(a) special import conditions for each third country, parts thereof or group of third countries;

(b) the criteria for classifying third countries and parts thereof with regard to aquatic animal diseases;

(c) the use of electronic documents;

(d) model animal health certificates and other documents;

(e) procedures and certification for transit.

Chapter V
Notification and minimum measures for control of diseases of aquatic animals

SECTION 1
DISEASE NOTIFICATION

Article 26
National notification

1. Member States shall ensure that:

   (a) when there are any reasons to suspect the presence of a disease listed in Part II of Annex III, or a confirmation of such disease in aquatic animals, the suspicion is immediately notified to the competent authority;

   (b) when increased mortality occurs in aquaculture animals, the mortality is immediately notified to the competent authority or private veterinarian for further investigations.

2. Member States shall ensure that the obligations to notify the matters referred to in paragraph 1 are imposed on:

   (a) the owner and any person attending aquatic animals;

   (b) any person accompanying aquaculture animals during transport;

   (c) veterinary practitioners and other professionals involved in aquatic animal health services;

   (d) official veterinarians, senior staff of veterinary or other official or private laboratories;

   (e) any other person with an occupational relationship to aquatic animals of susceptible species or to products of such animals.

Article 27
Notification of the other Member States, the Commission and EFTA Member States

Member States shall notify the other Member States, the Commission and the European Free Trade Association (EFTA) Members within 24 hours in case of confirmation of:

(a) an exotic disease listed in Part II of Annex III;

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

SECTION 2
SUSPICION OF A LISTED DISEASE

Article 28
Initial control measures

Member States shall ensure that in case of suspicion of an exotic disease listed in Part II of Annex III or, in the case of suspicion of a non-exotic disease listed in Part II of Annex III in Member States, zones or compartments declared free of such disease:

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

(b) pending the result of the examination provided for in point (a):

(i) the farm, or mollusc farming area, in which the disease is suspected, is placed under official surveillance and relevant control measures are implemented to prevent the disease spreading to other aquatic animals; and

(ii) no aquaculture animals are allowed to leave or enter the affected farm or mollusc farming area in which the disease is suspected, unless authorised by the competent authority.

Article 29
Epizootic investigations

1. Member States shall ensure that an epizootic investigation is carried out by the competent authority if the examination provided for in point (a) of Article 28 shows the presence of

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

(b) a non-exotic disease listed in Part II of Annex III in Member States, zones or compartments declared free of such disease.

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

(a) determining the possible means of contamination; and

(b) investigating whether aquaculture animals have left the farm or mollusc farming area during the relevant period preceding the notification of the suspicion in accordance with Article 26(1).

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

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

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

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

Article 30
Lifting restrictions

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

SECTION 3
MINIMUM CONTROL MEASURES IN THE CASE OF CONFIRMATION OF EXOTIC DISEASES IN AQUACULTURE ANIMALS

Article 31
Introductory provision

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

Article 32
General measures

Member States shall ensure that:

(a) the farm or mollusc farming area is officially declared infected;

(b) a containment area appropriate to the disease in question, is established, including a control 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.

Article 33
Harvesting and further processing

1. Aquaculture animals which have reached commercial size and exhibit no clinical sign of disease may be harvested under the supervision of the competent authority for human consumption, or further processing.

2. Harvesting, introduction into dispatch centres or purification centres, further processing and any other related operations involved in the preparation of the aquaculture animals for entry into the food chain shall be carried out under conditions which prevent the spread of the pathogen responsible for causing the disease.

3. Dispatch centres, purification centres or similar businesses shall be equipped with an effluent treatment system capable of inactivating the pathogen referred to in paragraph 2, or the effluent must be subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.

4. Further processing shall be performed in authorised processing establishments.

Article 34
Removal and disposal

1. Member States shall ensure that dead fish and crustaceans, as well as live fish and crustaceans exhibiting clinical signs of disease are removed and disposed of under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council[18], as soon as possible in accordance with the contingency plan provided for in Article 47 of this Directive.

2. Aquaculture animals which have not reached commercial size and do not exhibit clinical signs of disease shall, in an appropriate timeframe taking into account the type of production and the risk such animals pose for further spread of the disease, be removed and disposed of under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002, and the contingency plan provided for in Article 47 of this Directive.

[18] OJ L 273, 10.10.2002, p. 1.

Article 35
Fallowing

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

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

Article 36
Protection of aquatic animals

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

Article 37
Lifting measures

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

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

(b) sampling and surveillance as appropriate for the disease in question and the types of aquaculture production businesses affected has been carried out in the containment area with negative results.

SECTION 4
MINIMUM CONTROL MEASURES IN THE CASE OF CONFIRMATION OF NON –EXOTIC DISEASES IN AQUACULTURE ANIMALS

Article 38
General provisions

1. In the case of confirmation of a non-exotic disease listed in Part II of Annex III in a Member State, zone or compartment declared free of that disease, the Member State concerned shall apply the measures provided for in Section 3 in order to regain such disease-free status.

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

Article 39
Containment measures

In the case of confirmation of a non-exotic disease listed in Part II of Annex III in a Member State, zone or compartment free of that disease, the Member State concerned shall take measures to contain the disease.

Those measures shall at least consist of:

(a) declaring the farm or mollusc farming area to be infected;

(b) establishing a containment area appropriate to the disease in question, including a control 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 Article12(2); or

  (ii) harvested and slaughtered for human consumption in accordance with Article 33(1);

(d) the removal and disposal of dead fish and crustaceans, under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002, in an appropriate timeframe taking into account the type of production and the risk such dead animals pose for further spread of the disease.

SECTION 5
MINIMUM CONTROL MEASURES IN THE CASE OF CONFIRMATION OF DISEASES LISTED IN PART II OF ANNEX III IN WILD AQUATIC ANIMALS

Article 40
Control of diseases listed in Part II of Annex III in wild aquatic animals

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

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

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

SECTION 6
CONTROL MEASURES IN CASE OF EMERGING DISEASES

Article 41
Emerging diseases

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

2. In the case of an emerging disease situation, the Member State concerned shall inform the Member States, the Commission and the European Free Trade Association (EFTA) Members without delay where the findings are of epidemiological significance to another Member State.

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

SECTION 7
ALTERNATIVE MEASURES AND NATIONAL PROVISIONS

Article 42
Procedure for adoption of ad hoc epidemiological measures for diseases listed in Part II of Annex III

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

(a) the measures provided for in this Chapter are found not to be suited to the epidemiological situation; or

(b) the disease appears to be spreading despite the measures taken in accordance with this Chapter.

Article 43

National provisions for limiting the impact of diseases not listed in Part II of Annex III

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

2. Member States shall ensure that the national control measures referred to in paragraph 1 do not exceed the limits of what is appropriate and necessary in order to control the disease as referred to in paragraph 1.

3. Member States shall ensure that any national measures referred to in paragraph 1 that may affect trade between Member States are not applied before they are approved in accordance with the procedure referred to in Article 62(2).

   Such approval may only be granted where:

   (a) the establishment of intra-Community trade restrictions is unavoidable in order to control the disease;

   (b) those intra-Community trade restrictions are consistent with the Standards issued by the World Organisation for Animal Health (OIE).

Chapter VI
Control programmes and vaccination

SECTION 1
CONTROL AND ERADICATION PROGRAMMES

Article 44
Drawing up and approval of control and eradication programmes

1. Where a Member State not declared free of one or more of the non-exotic diseases listed in Part II of Annex III, draws up a control and eradication programme ('the programme') for achieving disease-free status for one or more of those diseases, it shall submit that programme for approval in accordance with the procedure referred to in Article 62(3).

   Such programmes may also be amended or terminated in accordance with that procedure.

   However, where a programme provided for in paragraph 1 is to cover individual compartments or zones, which comprise less than 75% of the territory of the Member State, and the zone or compartment consists of a water catchment area not shared with another Member State or third country, the procedure referred to in Article 50(1) shall apply for any approval, or amendment or termination of such programme.

2. An overview of the programmes approved in accordance with paragraph 1 of this Article shall be made available at Community level in accordance with the procedures provided for in Article 51.

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

Article 45
Content of programmes

Programmes shall not be approved unless they contain at least the following:

(a) a description of the epidemiological situation of the disease before the date of commencement of the programme;

(b) an analysis of the estimated costs and the anticipated benefits of the programme;

(c) the likely duration of the programme and the objective to be attained by the completion date of the programme;

(d) a description and demarcation of the geographical and administrative area in which the programme is to be applied.

Article 46
Period of application of programmes

1. Programmes shall continue to be applied until:

   (a) the requirements laid down in Annex V have been fulfilled, and the Member State, zone or compartment is declared free of the disease; or

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

2. If the programme is withdrawn as provided for in paragraph 1 (b), the Member State concerned shall apply the containment measures in Article 39 from the date of withdrawal of the programme.

SECTION 2
CONTINGENCY PLAN FOR EMERGING AND EXOTIC DISEASES

Article 47
Contingency plan for emerging and exotic diseases

1. Each Member State shall draw up a contingency plan specifying the national measures required to maintain a high level of disease awareness and preparedness and to ensure environmental protection.

2. The contingency plan shall:

   (a) provide the competent authority with the authority and means to access all facilities, equipment, personnel and other appropriate materials necessary for the rapid and efficient eradication of an outbreak;

   (b) ensure coordination and compatibility with neighbouring Member States and encourage cooperation with neighbouring third countries;

   (c) give a precise indication of the vaccine requirements and vaccination conditions considered necessary in the event of emergency vaccination, where relevant.

3. Member States shall comply with the criteria and requirements laid down in Annex VII when drawing up contingency plans.

4. Member States shall submit the contingency plans for approval in accordance with the procedure referred to in Article 62(2).

Every five years, each Member State shall update its contingency plan and submit the updated plan for approval in accordance with that procedure.

5. The contingency plan shall be implemented in the event of an outbreak of emerging diseases and of exotic diseases listed in Part II of Annex III.

SECTION 3
VACCINATION

Article 48
Vaccination

1. Member States shall ensure that vaccination against the exotic diseases listed in Part II of Annex III is prohibited unless such vaccination is approved in accordance with Articles 41, 42, 44, or 47.

2. Member States shall ensure that vaccination against the non-exotic diseases listed in Part II of Annex III is prohibited in any parts of their territory declared free of the diseases in question, or covered by approved control and eradication programmes.

Member States may allow such vaccination in parts of their territory not declared free from the diseases in question, or where vaccination is a part of approved control and eradication programmes.

3. Member States shall ensure that the vaccines used are authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004.

4. Paragraphs 1 and 2 shall not apply to scientific studies for the purpose of developing and testing vaccines under controlled conditions.

During such studies, Member States shall ensure that the appropriate measures are taken to protect other aquatic animals from any adverse effect of the vaccination carried out within the framework of the studies.

Chapter VII
Disease-free status

Article 49
Disease-free Member State

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

   (a) none of the susceptible species are present in its territory;

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

   (c) the Member State meets the conditions laid down in Part I of Annex V.

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

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

Article 50
Disease-free zone or compartment

1. The central competent authority of a Member State may, after having informed the Commission and the other Member States thereof, and after having, on request, submitted the supporting evidence therefore, declare the disease-free status of a zone or compartment within its territory of one or more of the non-exotic diseases listed in Part II of Annex III where:

   (a) none of the susceptible species are present in the zone or compartment, and in its water source;

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

   (c) the zone or compartment complies with the conditions laid down in Part II of Annex V.

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

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

Article 51
Lists of disease-free Member States, zones or compartments

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

2. The Commission shall draw up and update a list of Member States, zones or compartments declared disease-free in accordance with Article 49 or 50(2), and shall make this list public.

Article 52
Maintenance of disease-free status

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

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

Article 53
Suspension and restoration of disease free status

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

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

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

Chapter VIII
Competent authorities and laboratories

Article 54
General obligations

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

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

2. Each Member State shall ensure that effective and continuous co-operation based on the free exchange of information relevant to the implementation of this Directive is established between the competent authorities it designates for the purposes of this Directive and any of its other authorities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin.

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

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

Article 55
Community reference laboratories

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

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

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

Article 56
National reference laboratories

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

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

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

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

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

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

Article 57
Diagnostic services and methods

Member States shall ensure that:

(a) laboratory examinations for the purposes of this Directive are carried out in laboratories designated for such purpose by the competent authority;

(b) laboratory examinations in the case of suspicion and to confirm the presence of the diseases listed in Part II of Annex III are carried out by diagnostic methods to be established in accordance with the procedure referred to in Article 62(2);

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

Chapter IX
Inspections, electronic management and penalties

Article 58
Community inspections and audits

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

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

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

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

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

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

Article 59
Electronic management

1. Member States shall, by 1 January 2007 at the latest, ensure that all procedures and formalities relating to making the information provided for in Article 6, Article 51(1), and Article 56(2) available by electronic means, are in place.

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

Article 60
Penalties

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

Chapter X
Amendments, detailed rules and committee procedure

Article 61
Amendments and detailed rules

1. Article 15(1) may be amended in accordance with the procedure referred to in Article 62(2), after consultation of the appropriate scientific committee.

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

3. Any detailed rules necessary for the implementation of this Directive may be adopted in accordance with the procedure referred to in Article 62(2).

Article 62
Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health ('the Committee').

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

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

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

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

4. The Committee shall adopt its Rules of Procedure.

Chapter XI
Transitional and final provisions

Article 63
Repeal

1. Directives 91/67/EEC, 93/53/EEC and 95/70/EC shall be repealed as from 1 January 2007

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

Article 64
Transitional provisions

Transitional provisions may be adopted in accordance with the procedure referred to in Article 62(2) for a period of four years from the date of entry into force of this Directive.

Article 65
Transposition

1. Member States shall adopt and publish, by [30 June 2006] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from [1 January 2007].

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

Article 66
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*

Article 67
Addresses

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

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 recognised 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 may also mean the recognition of a known disease in a new host 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 must be decided in cooperation between the farmer and the competent authority.

(k) '*Infection'* means propagation of the disease agent in the 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 a certain disease agent can multiply or otherwise develop.

(o) '*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 co-ordinates of all farm-sites (if possible GIS coordinates);

   (d) the purpose, type (i.e. type of culture system, or facilities, like 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 must as a minimum be registered whether any of the species are known to be susceptible to diseases listed in Annex III, or known carriers of such diseases)

   (g) updated information on the diseases status (i.e. if the farm is disease-free (located in a Member State, zone or compartment), where the farm is under programme with a view of achieving such status, or where the farm is declared infected by a disease referred to in Annex III).

2. Where an authorisation is granted to a mollusc farming area in accordance with Article 4(2), the data required under point 1(a) of this Part shall be recorded for all aquaculture production businesses which operate inside the mollusc farming area. The data required under 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 co-ordinates (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
Disease listing

PART I
CRITERIA FOR LISTING DISEASES

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

1. The disease is exotic to the Community, as 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 or international provisions.

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

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

2. It has potential for significant economic impact if introduced into a Member State that is 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 disease-free Member State, to wild aquatic animal populations of species that by Community or international provisions is an asset worth protecting.

4. The disease is difficult to control and contain at farm level without stringent control measures and trade restrictions.

5. The disease can be controlled at Member State level, experience having shown that disease-free compartments can be established and maintained, and that this maintenance is cost beneficial.

6. During placing on the market, there is a likely risk that the disease will establish itself in a previously uninfected area.

7. Reliable and simple tests for infected animals are available. The tests must be specific and sensitive and the testing method harmonised at Community level.

PART II
LISTED DISEASES

EXOTIC DISEASES		
	DISEASE	**SUSCEPTIBLE SPECIES**
FISH	Epizootic haematopoietic necrosis	Redfin perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*), Macquarie perch (*Macquaria australasica*), silver perch (*Bidyanus bidyanus*), mountain galaxias (*Galaxias olidus*), sheatfish (*Silurus glanis*), catfish (*Ictalurus melas*) and mosquito fish (*Gambusa affinis*) and other species belonging to the family Poeciliidae
	Epizootic ulcerative syndrome	Genera Channa, Mastacembelus, Puntius, Trichogaster, Catla, Mugil, Labeo.
MOLLUSCS	Infection with *Bonamia exitiosa*	*Ostrea chilensis* and *O. angasi*
	Infection with *Xenohaliotis californiensis*	Members of the genus *Haliotis* including black abalone *(H. cracherodii)*, red abalone *(H. rufescens)*, pink abalone *(H. corrugata)*, green abalone *(H. fulgens)* and white abalone *(H. sorenseni)*.
	Infection with *Perkinsus marinus*	*Crassostrea virginica* and *C. gigas*
	Infection with *Microcytos mackini*	*Crassostrea gigas, C. virginica, Ostrea edulis* and *O. conchaphila.*
CRUSTACEANS	Taura syndrome	Pacific white shrimp (*Penaeus vannamei*), Pacific blue shrimp (*P. stylirostris*) and Gulf white shrimp (*P. setiferus*).
	Yellowhead disease	Black tiger shrimp (*Penaeus monodon*), Pacific white shrimp (*P. vannamei*), Pacific blue shrimp (*P. stylirostris*), Gulf white shrimp (*P. setiferus*), Gulf brown shrimp (*P. aztecus*), Gulf pink shrimp (*P. duorarum*), and Kuruma prawn (*P. japonicus*

NON-EXOTIC DISEASES		
	DISEASE	**SUSCEPTIBLE SPECIES**
FISH	Spring viraemia of carp	Common carp and koi carp (*Cyprinus carpio*), grass carp (*Ctenopharyngodon idellus*), silver carp (*Hypophthalmichthys molitrix*), bighead carp (*Aristichthys nobilis*), crucian carp (*Carassius carassius*), goldfish (*Carassius auratus*), tench (*Tinca tinca*) and sheatfish (*Silurus glanis*)
	Viral haemorrhagic septicaemia	Fish belonging to the family *Salmonideae*, grayling (*Thymallus thymallus*), white fish (*Coregonus* spp.), pike (*Esox lucius*), turbot (*Scophthalmus maximus*), herring and sprat (*Clupea* spp.), Pacific salmon (*Oncorhynchus* spp.), Atlantic cod (*Gadus morhua),* Pacific cod (*G. macrocephalus*), haddock (*G. aeglefinus*) and rockling (*Onos mustelus*).
	Infectious haematopoietic necrosis	Fish belonging to the family *Salmonidae,* pike (*Esox lucius*)
	Koi herpes virus	Common carp and koi carp (*Cyprinus carpio*).
	Infectious salmon anaemia	Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), brown trout (*Salmo trutta*),
MOLLUSCS	Infection with *Marteilia refringens*	*Ostrea edulis, O. angasi* and *Ostrea chilensis*
	Infection with *Bonamia ostreae*	*Ostrea edulis, O. angasi, O. denselammellosa, O. puelchana, Ostreola conchaphila (= O. lurida) and O. chilensis (= Tiostrea lutaria),*
CRUSTACEANS	White spot disease	Most commercially cultivated penaeid (Family Penaeidae) shrimps and prawns.

ANNEX IV

Surveillance and inspections in farms and mollusc farming areas

Species present	Disease status	Risk level	Surveillance	Recommended inspection frequency by competent authority	Recommended inspection frequency by private services	Comments
Species susceptible to one or more of the diseases listed in Annex III	Declared disease-free in accordance with Articles 49 or 50	High	Active, targeted or passive	To be adopted by secondary legislation.	To be adopted by secondary legislation.	Will be adopted by implementing legislation, taking into account the OIE Guidelines, the relevant disease and type of aquaculture production.
		Medium				
		Low				
	Under programme for declaration of freedom in accordance with Article 44	High	Targeted	To be adopted by secondary legislation.	To be adopted by secondary legislation.	
		Medium				
		Low				
	Not declared disease-free	High	Active	1 every year	3 every year	Detailed rules should be adopted by implementing legislation and contain – further inspection frequencies – what investigation and sampling should take place, taking into account the relevant disease and type of aquaculture production.
		Medium		1 every year	2 every year	
		Low		1 every 2 years	1 every year	
	Declared infected in accordance with Article 38	High	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	
No species susceptible to the listed diseases	Declared disease-free in accordance with point (a) of Article 49(1) or point (a) of Article 50(1)	High	Passive	1 every 4 years	1 every year	Aim of surveillance is to detect increased mortality Main aim of inspections by private services is to check health standards Main aim of inspections by competent authority is to check compliance with Directive
		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 or contracting diseases to/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 or contracting diseases to/from other farms or wild stocks;

(b) operates under farming conditions which not necessarily would 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 or contracting diseases to/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 includes mandatory immediate notification of the occurrence or suspicion of specified diseases or of any increased mortalities. Investigation in accordance with Section 2 of Chapter V is required.

Active surveillance shall include:

(a) Routine inspection by 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 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 V
Requirements for declaring disease-free Member State, zone or compartment

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 25 years before the date of entry of force of this Directive despite conditions that are conducive to its clinical expression may be considered disease-free where:

(a) basic disease control conditions have been in place continuously for at least a period of 10 years before the date of entry into force of this Directive; and

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

(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 as provided for in this point, must submit an application in accordance with Article 49 no later than 2 years after entry into force of this Directive.

1.2. The basic disease control conditions 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; and

(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 suspicious of a disease, emerging disease, or unexplained mortality in farms or molluscs farming area s, and in the wild; and

(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) must at least include 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; and

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

(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 the period of 25 years before the date of entry into force of this Directive or where the infection status prior to targeted surveillance was unknown, because of the absence of conditions conducive to clinical expression, may be considered free from the 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 before the date of entry into force of this Directive 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 are limited, and consequently targeted surveillance in these parts do not to provide sufficient epidemiological data, but in which there are wild populations of any of the susceptible species, those wild populations must 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 can only be declared a disease-free zone if the conditions outlined in point 1.3, point 1.4 and point 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 25 years before the date of entry into force of this Directive, 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.

A Member State wishing to benefit from a disease-free status as provided for in this point must notify its intention in accordance with Article 50(1) no later than 2 years after the entry into force of this Directive

1.4. A zone where the last known clinical occurrence was within a period of 25 years before the date of entry into force of this Directive or where the infection status prior to targeted surveillance was unknown, because of the absence of conditions conducive to clinical expression, may be considered free from the disease where it complies *mutatis mutandis* with the requirements in Part I.2.

1.5. A buffer zone in which a monitoring programme is carried out must be established, as appropriate. The demarcation of the buffer zones must 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 disease status is dependent on the disease status 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 can be considered as one epidemiological unit due to geographical localisation and distance to other groups or clusters of farms, or molluscs farming areas, provided that all farms comprising the compartment are under 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 for a period of 25 years before the date of entry of force of this Directive 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 must notify their intention in accordance with Article 50(1) no later than 2 years after the entry into force of this Directive.

2.3. A compartment where the last known clinical occurrence was within a period of 25 years before the date of entry into force of this Directive or where the infection status prior to targeted surveillance was unknown, because of the absence of conditions conducive to clinical expression, may be considered free from the disease where it complies *mutatis mutandis* with the requirements in Part I.2, and the disease is not known to occur in the waters surrounding the compartment.

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 disease status is independent of the disease status of the surrounding natural waters

3.1. A compartment may comprise:

(a) an individual farm which can be considered as 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, must be considered as a single epidemiological unit, and where all farms are under a common biosecurity system.

3.2. A compartment must be supplied with water:

(a) Through a water treatment plant capable of inactivating the relevant pathogen; however, such water treatment is not considered acceptable for use in a disease-free compartment where the disease is known to occur in the water feeding the treatment plant.

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

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

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

3.5. The compartment must comply, *mutatis mutandis*, with the requirements laid down in Part I.2 of this Annex.

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.

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

4.1. A new farm, which meets the requirements referred to in points 3.1.(a) and 3.2 – to 3.6 of this Part, but which commences its activities with aquaculture animals from a declared disease-free compartment may be declared 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 declared disease-free compartment, and meets the requirements referred to in points 3.1.(a) and points 3.2 to 3.6 of this Part, may be declared 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; and

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

(c) prior to the introduction of the aquaculture animal, 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, the laboratories must 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 only designate 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 the laboratories concerned comply with the requirements in points 1, 2 and 3 of this Annex. Any intention to take advantage of such cooperation must 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 III for which they are responsible;

(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 respective Member State. These national reference laboratories must:

   (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 III;

   (b) coordinate, in consultation with the relevant Community reference laboratory, the methods employed in Member States for diagnosing the diseases concerned for which they are responsible;

   (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 III, 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 paragraph 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 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 only designate 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 III;

   (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 in point 1 (c) (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. 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 III.

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 III 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 III 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 III 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 and take into account the resources needed to control a large number of outbreaks occurring within a short period of time.

11. Without prejudice to veterinary requirements in Regulation (EC) No 1774/2002, contingency plans must be prepared to ensure that, in the event of an outbreak of diseases, any mass disposal of aquatic animal carcasses and aquatic animal waste is done without endangering animal and human health, using processes or methods which prevent damage to the environment and in particular:

    (i) with minimum risk to soil, air, surface and groundwater, and to plants and animals;

    (ii) with minimum nuisance through 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 Council Directives		
	91/67/EEC	**93/53/EEC**	**95/70/EC**
Article 1 (1) a	Article 1, paragraph 1	———	———
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, paragraph 2	———	———
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 9	———	———	———
Article 10	———	———	Article 4 (1)
Article 11	———	———	———
Article 12	———	———	———
Article 13 (1)	Article 4, paragraph 1	———	———
Article 13 (2)	Article 4, paragraph 2	———	———
Article 14	Article 16 (1), paragraph 2	———	———

Article 14 (2)	———	———	———
Article 14 (3)	———	———	———
Article 14 (4)	Article 7 (1) Article 8 (1)	———	———
Article 15 (1)	Article 3 (1) a	———	———
Article 15 (2)	Article 3 (1) b	———	———
Article 15 (3)	———	———	———
Article 16 (1)	Article 7 (1) a, 1st sentence Article 7 (1) b Article 8 (1) a Article 8 (1) b	———	———
Article 16 (2)	———	———	———
Article 17	Article 14 (1) Article 14 (2) Article 14 (4)	———	———
Article 18	Article 9 (1) and (2)	———	———
Article 19	———	———	———
Article 20	Article 14 (3)	———	———
Article 21	———	———	———
Article 22	Article 19 (1)	———	———
Article 23(1)	———	———	———
Article 23(2)	———	———	———
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 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), 7th indent Article 8(1) Article 9 (1), 1st sentence Article 10 (1) b	Article 4 (1), paragraph 3, 3rd indent Article 5 (4), paragraph 1
Article 29(2)	———	Article 5(2)i	Article 5(4), paragraph 2
Article 29(3)	———	Article 6(b) Article 6(d) Article 8(2) Article 8(3) Article 9 (2)	———
Article 29 (4)	———	Article 5 (i) 2nd indent	———
Article 30	———	Article 5(4)	Article 5(3)
Article 31	———	———	———

Article 32(a)	———	———	Article 4(1), paragraph 3 1st and 2nd indent
Article 32(b)	———	———	———
Article 32(c)	———	Article 5 (2) b	Article 5 (2) b Article 5 (4), paragraph 3
Article 33 (1)	Article 3 (3)	Article 6 (a) 4th indent	———
Article 33 (2)	———	———	———
Article 33 (3)	———	———	———
Article 33 (4)	———	———	———
Article 34 (1)	———	Article 5(2)c Article 6(a) 1st and 3rd indent	———
Article 34 (2)	———	Article 6(a) 4th indent	———
Article 35	———	Article 6(a) 2nd, 5th and 6th indent	———
Article 36	———	———	———
Article 37 (a)	———	———	———
Article 37 (b)	———	Article 5 (4)	Article 5 (3)
Article 38 (1)	———	Article 9 (1), 2nd sentence	———
Article 38 (2)	———	———	———
Article 39 (a)	———	Article 10 (1) c	Article 4 (1) paragraph 3, 1st indent
Article 39 (b)	———	———	———
Article 39 (c)	———	Article 10 (1) c	———
Article 39 (d)	———	———	———
Article 40	———	Article 7	———

Article 41	———	———	———
Article 42	———	———	———
Article 43	———	———	———
Article 44	Article 10	Article 10 (2)	———
Article 45	Article 10 (1)	———	———
Article 46	———	———	———
Article 47	———	Article 15	———
Article 48 (1)	———	Article 14 (1)	———
Article 48 (2)	———	Article 14 (1)	———
Article 48 (3)	———	———	———
Article 48 (4)	———	———	———
Article 49(1)	Article 5 Article 6	———	———
Article 49(2)	Article 5 Article 6	———	———
Article 49(3)	Article 5 Article 6 Article 15	———	———
Article 50(1)	Article 5 Article 6	———	———
Article 50(2)	Article 5 Article 6	———	———
Article 50(3)	Article 5 Article 6 Article 15	———	———
Article 51(1)	———	———	———

Article 51(2)	Article 5 (2)	———	———
Article 52	———	———	———
Article 53 (1)	———	———	———
Article 53 (2)	———	———	———
Article 53 (3)	Article 9 (1), 2nd sentence	———	———
Article 54 (1)	———	———	———
Article 54 (2)	———	Article 6 (d) Article 8 (3)	———
Article 54 (3)	———	———	———
Article 55 (1)	———	Article 13 (1)	Article 7 (1)
Article 55 (2)	———	Article 13 (2)	Article 7 (2)
Article 55 (3)	———	———	———
Article 56 (1)	———	Article 12 (1) Article 12 (4)	Article 6 (2) Article 6 (3)
Article 56 (2)	———	———	———
Article 56 (3)	———	Article 12 (6)	Article 6(5)
Article 56 (4)	———	———	———
Article 56 (5)	———	Article 12 (1) Article 12 (3)	Article 6 (2)
Article 57 a	———	Article 11 (2)	———
Article 57 b	———	Article 11 (1)	Article 6 (1)
Article 57 c	———	———	———
Article 58	Article 17	Article 16	Article 8
Article 59	———	———	———
Article 60	———	———	———

Article 61	Article 9 (3) Article 25	Article 10 (4) Article 12 (7) Article 18	Article 4 (2) Article 9
Article 62	Article 26 Article 27	Article 19	Article 10
Article 63	———	———	———
Article 64	———	———	———
Article 65	Article 29	Article 20	Article 12
Article 66	———	———	Article 13
Article 67	Article 30	Article 21	Article 14

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health and Consumers Protection

Activity: Food safety, animal health, animal welfare and plant health

TITLE OF ACTION: PROPOSAL FOR A COUNCIL DIRECTIVE ON ANIMAL HEALTH REQUIREMENTS FOR AQUACULTURE ANIMALS AND PRODUCTS THEREOF, AND ON THE PREVENTION AND CONTROL OF CERTAIN DISEASES IN AQUATIC ANIMALS

1. BUDGET LINE(S) + HEADING(S)

17 01: Administrative expenditure of health and consumer protection policy area

17 04 02: Other measures in the veterinary, animal welfare and public-health field

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 2.094 € million for commitment

2.2. Period of application:

Action is open ended

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million (*to three decimal places)*

	Year [2007]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments	0.349	0.349	0.349	0.349	0.349	0.349	2.094
Payments	0.349	0.349	0.349	0.349	0.349	0.349	2.094

(b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

Commitments		0.000	0.000	0.000	0.000	0.000	0.000
Payments		0.000	0.000	0.000	0.000	0.000	0.000

Subtotal a+b							
Commitments	0.349	0.349	0.349	0.349	0.349	0.349	2.094
Payments	0.349	0.349	0.349	0.349	0.349	0.349	2.094

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

Commitments/ payments	0.243	0.243	0.243	0.243	0.193	0.193	1.358

TOTAL a+b+c							
Commitments	0.592	0.592	0.592	0.592	0.542	0.542	3.452
Payments	0.592	0.592	0.592	0.592	0.542	0.542	3.452

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:

Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

3. BUDGET CHARACTERISTICS

Type of expenditure		**New**	**EFTA contribution**	**Contributions form applicant countries**	**Heading in financial perspective**
Comp	Non-diff	NO	NO	NO	No 5 – 1a

4. LEGAL BASIS

Article 37 of the Treaty and Council Decision 90/424/EEC

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention

5.1.1. Objectives pursued

It is envisaged to update current Community legislation on diseases in aquaculture animals laid down in Council Directives 91/67/EEC, 93/53/EEC and 95/70/EC, with the objective to achieve better prevention and control of disease outbreaks in aquaculture animals and, the costs and losses and the negative impact to the whole of society due to aquatic animal diseases.

Since fish, molluscs and crustaceans are listed in Annex II of the Treaty, one of the Community's tasks in the veterinary field is to improve the health status of such animals, thereby facilitating trade in aquaculture animals and products thereof to ensure the development of this sector.

Furthermore, thanks to the adoption of other disease control measures envisaged under the current proposal, other savings should result from the expected reduced occurrence of diseases in aquaculture animals. It is, however, extremely difficult to quantify these savings.

As mentioned already, these actions as such have no financial implications for the EU-budget.

However, in combination with Council Decision 90/424/EC, as it is already the case with existing aquatic animal health legislation, has financial impact on Community budget:

Objective 1: establishment of Community Reference Laboratories for aquatic animal diseases

5.1.2. Measures taken in connection with ex ante *evaluation*

In 2000 the Advisory Committee for Fisheries and Aquaculture (ACFA) proposed to initiate a project to update existing Community legislation on aquaculture animal health. The initiative was endorsed in the Communication from the Commission on a strategy for the sustainable development of European aquaculture ((Com (2002) 511).

The designation of Community and national reference laboratories should contribute to the high quality and uniformity of diagnostic results. That objective can be achieved by activities such as the application of validated diagnostic tests and the organisation of comparative testing and training of staff from laboratories.

5.1.3. Measures taken following ex post *evaluation*

Not applicable

5.2. Action envisaged and budget intervention arrangements

Not applicable

5.3. Methods of implementation

Not applicable

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. Financial intervention

Commitments (in € million to three decimal places)

Breakdown	[2007]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Operational objective Nr 1	0.349	0.349	0.349	0.349	0.349	0.349	2.094
TOTAL	0.349	0.349	0.349	0.349	0.349	0.349	2.094

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)

		[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. years]	Total
1.	Technical and administrative assistance							
	(a) Technical assistance offices							
	(b) Other technical and administrative assistance: – intra mu-ros: – extra mu-ros: *of which for construction and maintenance of computerised management systems*							
	Subtotal 1							
2.	Support expenditure							
	(a) Studies							
	(b) Meetings of experts							
	(c) Information and publications							
	Subtotal 2							
	TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1…n)	Average unit cost	Total cost (total for years 1…n)
	1	2	3	4=(2X3)
Action 1 - *Measure 1* - *Measure 2* Action 2 - *Measure 1* - *Measure 2* - *Measure 3* *etc.*				
TOTAL COST				

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	1	-	1	
	B	-	-	-	
	C	-	-	-	
Other human resources			-	-	
Total		1	-	1	

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials Temporary staff	108,000	1 full time official per year
Other human resources (specify budget line)		
Total	108,000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line	Amount €	Method of calculation
Overall allocation (Title A7) 1701021101 – Missions 1701021102 – Meetings A07031 – Compulsory committees* A07032 – Non-compulsory committees * A07040 – Conferences A0705 – Studies and consultations Other expenditure (specify)	35,000 - 100,000 - - - -	Based on 5 missions per year at an average of 7000 Euro per mission - 4 expert working group meetings of the Standing committee on Food Chain and Animal Health only on the subject of aquatic animal diseases during the first 4 years, and then 2 meetings each year[19] - - -
Information systems (A-5001/A-4300)	-	-
Other expenditure - Part A (specify)	-	-
Total	135,000	

The amounts are total expenditure for twelve months.

*Specify the type of committee and the group to which it belongs.

[19] See Part II, point 3.2 of Impact Assessment.

I a.	Annual total year n to n+3 (7.2 + 7.3)	243,000 €
I b.	Annual total year n+4 and n+5 (7.2 + 7.3)	193,000 €
II.	Duration of action	6 years
III.	Total cost of action (I x II)	1,358,000 €

The human and administrative resources requirements will be met within the appropriation allocated to DG SANCO, within the framework of the annual allocation procedure.

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The Commission will have at its disposal several ways to evaluate the impact of the proposal:

– the occurrence of future diseases in aquaculture animals giving an overall indication on the effectiveness of the new measures,

– results of the risk based animal health surveillance programmes,

– control measures on aquatic animal disease outbreaks.

Already at this stage the Commission has the basic tools to monitor, such as the Standing Committee for the Food Chain and animal health and the network of Community and national reference laboratories.

8.2. Arrangements and schedule for the planned evaluation

As mentioned above, the Commission has at its disposal tools, such as the Standing Committee for the Food Chain and Animal Health and the network of Community and national reference laboratories; these instruments will allow for the proper evaluation of the measures proposed.

9. ANTI-FRAUD MEASURES

Not relevant

EXPLANATORY MEMORANDUM

1. Context of the proposal

- Grounds for and objectives of the proposal

  – The proposal from the Commission for a new Council Directive on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, updates current disease control measures laid down in Council Directives 93/53/EEC and 95/70/EC, with the objective to achieve better control of outbreaks and to reduce the costs and losses and the negative impact to aquaculture industry due to diseases.

  – The proposal for a Council Regulation European Fisheries Fund (COM (2004) 497), allows Member States to allocate financial resources from the Operational Programmes set up in accordance with Title III of that Regulation, to control diseases in aquaculture animals, provided the diseases are referred to in Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field

  – By this proposal, the Commission envisages therefore the necessary amendments of the current procedures governing the Community's financial contribution towards veterinary measures in aquaculture animals, laid down in Council Decision 90/424/EEC, in order to take into account the proposals for a new aquatic animal health Directive and the European Fisheries Fund.

- General context

  – The proposed changes in Community legislation on animal health requirements for aquaculture animals and products thereof should be made in parallel with amendments to Council Decision 90/424/EEC on Community expenditure in the veterinary field to bring it in line with the proposed new Directive and the proposal for the European Fisheries Fund (2007-2013), to ensure adequate financial support to the Member States in relation to the most serious diseases in aquaculture animals.

  – At present, Article 24 of Council Decision 90/424/EEC provides for a Community financial contribution eligible under Regulation (EC) No 2792/1999 to be granted to the Member States for some of the expenditure which they may incur when eradicating infectious salmon anaemia and infectious haematopoietic necrosis.

- Consistency with other policies

  – The proposal would not affect the future development of the Community policy on animal health and the veterinary fund.

  – This proposal is in line with the proposal from the Commission to the Council for Council Regulation European Fisheries Fund (COM (2004) 497).

2. Consultation of interested parties and impact assessment

- Consultation of interested parties

  – On the Proposal for a new Council Directive on animal health requirements for aquaculture animals and products thereof, consultation with Member States in Commission Working Group, stakeholder consultations and consultations with the aquaculture industry in the Advisory Committee for Fisheries and Aquaculture has taken place.

- Impact assessment

  – Impact assessments of the newly envisaged Council Directive on animal health requirements for aquaculture animals and products thereof and of the amendments proposed by means of this proposal to Council Decision 90/424/EEC has been produced.

3. Legal elements of the proposal

- Summary of the proposed actions

  – The current proposal envisages the following changes to Decision 90/424/EEC:

    – to allow Member States to use the budget set up under Operational Programmes according to Title III of the European Fisheries Fund for the control and eradication of certain diseases in aquaculture animals.

    – to ensure that the procedures for such financial support, is in line with the current procedures applicable to financial contribution for control and eradication of terrestrial animal diseases.

- Legal basis

  – Treaty establishing the European Community, and in particular Article 37 thereof.

- Subsidiarity principle

  – The measures laid down in this proposal falls under the competence of the Community.

- Proportionality principle

  – The proposal sets out the procedures and sources of Community financial support to Member States for the control and eradication of certain diseases in aquaculture animals.

- Choice of instruments

  – The proposed instrument is a Decision. This proposal concerns amendments to existing provisions on expenditure in the veterinary field that are laid down in a Council Decision. The legal instrument chosen to amend those provisions is therefore another Council Decision.

4. Budget implications

– Council Decision 90/424/EEC already allows for financial support in relation to outbreaks of Infectious Haematopoietic Necrosis (IHN) and Infectious Salmon Anaemia (ISA). Disease control actions for these diseases are currently eligible for a Community financial contribution under Regulation (EC) No 2792/1999 solely.

– It is proposed that future financial contributions for aquatic animal disease control from the Community should be eligible through the European Fisheries Fund (Article 32 of COM (2004) 497).

– In the proposal, compulsory slaughter/eradication will only be required under Community rules in relation to outbreaks of diseases that are considered exotic to the Community. With respect to non-exotic diseases it is proposed that the Member States may decide whether an outbreak should be subject to eradication measures or containment measures. Community funding under the European Fisheries Fund may be made available for control measures of such diseases if the Member State so decides.

– If an exotic disease did occur in the Community, it would have no additional financial impact on Community budget. The same would occur in case of compensation for eradication of non-exotic diseases, since the allocation of funds for the eradication are made within the Operational Programmes, whose budget is fixed by the Council at the beginning of the programming period.

– In the interest of Member States, it would be convenient to assess the financial impact of eradication measures on their Operational Programmes. However, the costs related to such eradication measures are difficult to estimate, as there is limited experience in the Community of stamping out policy involving economic compensation in aquaculture. In the court case following the outbreaks of ISA in the UK and Ireland, one company owning five of the thirteen infected farms claimed total losses in the region of € 20-25 million. Sweden paid out compensation under national legislation totalling of 1.5 million SEK (€165 000) over a period of three years in relation to four cases of VHS in 1998.

– It is therefore difficult to estimate the impact of the proposal on the European Fisheries Fund, as this will depend on the size of the farm(s) affected, the value of the animals kept at the farm(s), etc. However, the figures above can give an indication.

2005/0154 (CNS)

Proposal for a

COUNCIL DECISION

amending Decision 90/424/EEC on expenditure in the veterinary field

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[20],

Having regard to the opinion of the European Parliament[21],

Having regard to the opinion of the European Economic and Social Committee[22],

Having regard to the opinion of the Committee of the Regions[23],

Whereas:

(1) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field[24] provides for the possibility of a financial contribution from the Community to the Member States for the eradication of certain animal diseases. Currently, that Decision also provides for the possibility to grant such contribution for the eradication of the diseases infectious salmon anaemia (ISA) and infectious haematopoietic necrosis (IHN), both affecting salmonides.

(2) Disease control actions for ISA and IHN are eligible for Community financial contributions under Regulation (EC) No 2792/1999 of 17 December 1999 laying down the detailed rules and arrangements regarding Community structural assistance in the fisheries sector[25] solely.

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20 OJ C ,, p..
21 OJ C ,, p..
22 OJ C ,, p..
23 OJ C ,, p..
24 OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
25 OJ L 337, 30.12.1999, p. 10.

(3) In the light of the adoption of Council Directive 200Y/xxx on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals[26], it is appropriate to amend Decision 90/424/EEC so that Community financial contribution should also be granted for eradication measures carried out by the Member States to combat other diseases in aquaculture animals, subject to Community control provisions.

(4) The Member States have been granted financial contributions to support their national fisheries and aquaculture sector under Regulation (EC) No xxxx/2005 of zz/zz 2005 on the European Fisheries Fund[27]. Article 30a of that Regulation authorises Member States to allocate funds for the eradication of diseases in aquaculture under the terms of Decision 90/424/EC.

(5) The funds for the eradication of diseases in aquaculture animals should be allocated within the Operational Programmes set up under Regulation (EC) No xxxx/2005, whose budget is fixed at the beginning of the programming period.

(6) Financial contributions from the Community budget for disease control purposes in aquaculture animals should be subject to scrutiny regarding compliance with the control provisions laid down in Directive 200Y/xxx, in accordance with the same procedures that apply for such scrutiny and control for certain terrestrial animal diseases.

(7) It is therefore appropriate to apply the procedures for financial contributions laid down in Decision 90/424/EEC, also to the use of financial contribution for the control of diseases in aquaculture animals under Regulation (EC) No xxxx/2005.

(8) It is appropriate that the amendments proposed herein should enter into force at the same time as Directive 200Y/xxx and Regulation (EC) No XXXX/2005.

(9) Decision 90/424/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

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[26] COM (2005) 362 final.
[27] COM (2004) 497.

Article 1

Decision 90/424/EEC is amended as follows:

1. In Article 3(1), the following indents shall be added:

" -Epizootic haematopoietic necrosis in fish (EHN),
-Epizootic ulcerative syndrome in fish (EUS),
-Infection with *Bonamia exitiosa*,
-Infection with *Xenohaliotis californiensis*,
-Infection with *Perkinsus marinus*,
-Infection with *Microcytos mackini*,
-Taura syndrome in crustaceans,
-Yellowhead disease in crustaceans."

2. The following Article 3b shall be inserted:

"Article 3b

Member States may allocate funds within the Operational Programmes drawn up in accordance with Article 18 of Regulation (EC) No xxxx/2005 to the eradication of the exotic diseases in aquaculture animals referred to in Article 3(1) of this Decision, under the procedures laid down in Article 3(3), (4) and (5) of this Decision, provided that the minimum disease control and eradication measures laid down in Section 3 of Chapter V of Directive 200Y/xxx are complied with".

3. Article 5(2) shall be replaced by the following:

"2. In accordance with the procedure laid down in Article 41, the list in Article 3 (1) may be supplemented in line with developments in the situation, to include diseases which must be notified in accordance with Directive 82/894/EEC and diseases which can be transmitted to aquaculture animals, or amended or shortened to take account of progress made with the measures decided at Community level to control certain diseases."

4. In Article 24, the following paragraph shall be added:

"12. Member States may allocate funds within the Operational Programmes drawn up in accordance with Article 18 of Regulation (EC) No xxxx/2005 for the eradication of the diseases in aquaculture animals referred to in the Annex

The funds shall be allocated in accordance with the procedures laid down in this Article.

The eradication must be carried out in accordance with Article 38(1) of Directive 200Y/xxx, or under an eradication programme drawn up, approved and carried out in accordance with Article 44 of that Directive.

5. The following indents shall be added to the Annex:

" -Spring viraemia of carp (SVC)
-Viral haemorrhagic septicaemia (VHS)
-Koi herpes virus infection
-Infection with *Bonamia ostreae*
-Infection with *Marteilia refringens*
-White spot disease in crustaceans"

Article 2

This Decision shall apply from 1 January 2007.

Article 3

This Decision is addressed to the Member States.

Done at Brussels

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health and Consumers Protection

Activity: Food safety, animal health, animal welfare and plant health

TITLE OF ACTION: PROPOSAL FOR A COUNCIL DECISION AMENDING COUNCIL DECISION 90/424/EEC ON EXPENDITURE IN THE VETERINARY FIELD

1. BUDGET LINE(S) + HEADING(S)

– European Fisheries Fund

– 17 01: Administrative expenditure of health and consumer protection policy area

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 0 € million for commitment

2.2. Period of application:

Action is open ended

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million (*to three decimal places)*

	Year [2006]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Payments	0.000	0.000	0.000	0.000	0.000	0.000	0.000

(b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

Commitments	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Payments	0.000	0.000	0.000	0.000	0.000	0.000	0.000

Subtotal a+b							
Commitments	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Payments	0.000	0.000	0.000	0.000	0.000	0.000	0.000

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

Commitments/ payments	0.000	0.000	0.000	0.000	0.000	0.000	0.000

TOTAL a+b+c							
Commitments	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Payments	0.000	0.000	0.000	0.000	0.000	0.000	0.000

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:[28]

Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

3. BUDGET CHARACTERISTICS

Type of expenditure		**New**	**EFTA contribution**	**Contributions form applicant countries**	**Heading in financial perspective**
Comp	Non-diff	YES	NO	NO	No 1a

4. LEGAL BASIS

Council Decision 90/424/EEC

[28] For further information, see separate explanatory note.

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention

5.1.1. Objectives pursued

Objective 1: EXTENSION of emergency measures (Article 3 of Decision 90/424/EEC) to all exotic aquaculture animal diseases subject to harmonised Community measures

Objective 2: EXTENSION of control and eradication measures related to non-exotic diseases (Article 24 of Decision 90/424/EEC) to all non-exotic aquaculture animal diseases subject to harmonised Community measures

5.1.2. Measures taken in connection with ex ante evaluation

Since fish, molluscs and crustaceans are listed in Annex II of the Treaty, one of the Community's tasks in the veterinary field is to improve the health status of such animals, thereby facilitating trade in aquaculture animals and products thereof to ensure the development of this sector.

The necessity of establishing financial contribution for the eradication and control of diseases in aquaculture animals is presented in the proposal for a Council Regulation European Fisheries Fund 2007-2013.

5.1.3. Measures taken following ex post evaluation

Not applicable

5.2. Action envisaged and budget intervention arrangements

Not applicable

5.3. Methods of implementation

Not applicable

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. Financial intervention

Commitments (in € million to three decimal places)

Breakdown	[2006]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Operational objective Nr 1	The diseases listed in Part II of Annex III to the proposal for Council Directive 200Y/xxx are all exotic to the Community. Taking into account the import provisions laid down in that proposal, the likelihood of the occurrence of such disease is small.						0.000
Operational objective Nr 2	It is impossible to predict when and where there will be an outbreak of the disease and the relative costs. The overall financial contribution from the Community is fixed by the Council Regulation European Fisheries Fund. The impact assessment annexed to the proposal has considered various scenarios.						0.000
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)

	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. years]	Total
1. Technical and administrative assistance							
(a) Technical assistance offices							
(b) Other technical and administra-tive assistance:							
– intra mu-ros:							
– extra mu-ros:							
of which for construction and maintenance of computerised management systems							
Subtotal 1							
2. Support expenditure							
(a) Studies							
(b) Meetings of experts							
(c) Informa-tion and publica-tions							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[29]

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1…n)	Average unit cost	Total cost (total for years 1…n)
	1	2	3	4=(2X3)
Action 1				
- *Measure 1*				
- *Measure 2*				
Action 2				
- *Measure 1*				
- *Measure 2*				
- *Measure 3*				
etc.				
TOTAL COST				

[29] For further information, see separate explanatory note.

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	2	-	2	*The management of the action will be undertaken by existing staff described under COM(2005) 171*
	B	-	-	-	
	C	-	-	-	
Other human resources			-	-	
Total		2	-	2	

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials Temporary staff	216,000	1 full time official per year
Other human resources (specify budget line)		
Total	216,000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line	Amount €	Method of calculation
Overall allocation (Title A7) 1701021101 – Missions 1701021102 – Meetings A07031 – Compulsory committees [1] A07032 – Non-compulsory committees [1] A07040 – Conferences A0705 – Studies and consultations Other expenditure (specify)		
Information systems (A-5001/A-4300)		
Other expenditure - Part A (specify)		
Total		

The amounts are total expenditure for twelve months.

[1] Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	216,000 €
II.	Duration of action	6 years
III.	Total cost of action (I x II)	1,296,000 €

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The Commission will have at its disposal several ways to evaluate the impact of the proposal:

– the occurrence of future diseases in aquaculture animals giving an overall indication on the effectiveness of the new measures,

– results of the risk based animal health surveillance programmes,

– control measures on aquatic animal disease outbreaks.

Already at this stage the Commission has the basic tools to monitor, such as the Standing Committee for the Food Chain and animal health, in addition to the evaluation instruments described under the European Fisheries Fund.

8.2. Arrangements and schedule for the planned evaluation

As mentioned above, the Commission has at its disposal tools, such as the Standing Committee for the Food Chain and Animal Health and the network of Community and national reference laboratories; these instruments will allow for the proper evaluation of the measures proposed.

9. ANTI-FRAUD MEASURES

Not relevant