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Annex to the

Proposal from the Commission on 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 and for a Council Decision amending Decision 90/424/EEC on expenditure in the veterinary field

IMPACT ASSESSMENT

{COM (2005) 362 final}

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PART I
IMPACT ASSESSMENT

Proposal for an updated EU aquatic animal health legislation

1. INTRODUCTION – PROBLEM IDENTIFICATION

The present rules for placing on the market of aquaculture animals and minimum Community measures for control of certain fish- and mollusc diseases are laid down in:

- 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.

This legislation was drafted mainly to take into account the European aquaculture industry farming salmonids (salmon and trout) and oysters. Since the time of adoption, the aquaculture industry has developed significantly. In fish farming, a number of new species are used, in particular marine fish species, and the recent enlargement of the EU has brought in new types of farming practices including more new fish species. In the mollusc industry, the importance of farming mussels, clams and abalones is continuously increasing. In addition, crustacean farming is developing in EU.

The total aquaculture production of fish, molluscs and crustaceans in the countries, which today constitutes the EU-25, has increased over the last decade.

Table 1. Total aquaculture production and value in 1990 and 2003[1].

	Quantity (MT)	**Value (1000 €)**
1990	1.013.406	1.774.012
2003	1.373.150	2.576.434
Increase	35%	45%

[1] Figures from FAO FIGIS database. Do not include molluscs from harvested natural beds.

In a survey done by the Community reference laboratories for fish- and mollusc diseases in 2003, it was estimated that there are approximately of 15.000 fish farms and 6.500 mollusc farms or farming areas in the Community. For further detailed information about EU aquaculture production, see Annex I.

Live fish, molluscs and crustaceans and products thereof are widely traded in the Community, and as well imported from third countries. In 2004, altogether 185.431 metric tonnes (MT) of live fish was traded between EU Member States, while 5.702 MT was imported from Third countries. There is also a significant trade in ornamental fish. Until recently, this trade has not been regarded as posing a significant disease risk to either aquaculture or wild aquatic animals in importing countries and so has mostly been unrestricted by import health certification requirements. There is, however, also a substantial trade in 'coldwater' ornamental fish, particularly goldfish and koi carp, which are coloured varieties of common cyprinid fish species and susceptible to the same diseases. These species have been implicated in the spread of certain diseases of farmed and wild fish (e.g. spring viraemia of carp and koi herpes virus disease). In 2004, the trade in ornamental fish between EU Member States was 24.352 MT, while 26.491 MT was imported from Third countries[1]. With respect to molluscs, the majority of trade in live molluscs are for the purpose of human consumption

In the framework of Advisory Committee for Fisheries and Aquaculture (ACFA), which is under the responsibility of DG Fisheries, it was in 2000 proposed to initiate a project with a view of updating the existing legislation on aquaculture. In a Communication from the Commission (see Com (2002) 511 final - on a strategy for the sustainable development of European Aquaculture), it was concluded that the legislative framework must be updated to take into account the above mentioned issues.

A revision is also needed to take into account the practical and scientific experiences gained during the last ten years, in particular in relation to the fact that the existing legislation

- is not fully applicable to today's farming practice
- is more focused on *how* to reach a goal than on the *goal itself*
- creates double work (approval of disease free farms and zones)
- is inflexible
- the placing on the market provisions applicable within the Community are inconsistent with the Standards of the World Organisation for Animal Health (OIE).

[1] All trade an import figures are from the Comext database of Eurostat.

As regards the last bullet, the rules for placing on the market in the Community (Council Directive 91/67/EEC) are inconsistent with the OIE Standards. They focus more on establishing barriers to trade than on risk mitigation, which is not in line with the overall policy of the WTO/SPS. As a consequence, the import rules applicable to third countries (Commission Decisions 2003/804/EC and 2003/858/EC) are more flexible than the placing on the market rules applicable to Member States

Since the adoption of the primary legislation, the Parliament and the Council have passed new Community legislation, which have an impact on the aquaculture industry. These are Regulation EC No178/2002 (Feed and food law), Regulation EC No 852/2004 and 853/2004 (Hygiene of foodstuffs), Regulation EC No 854/2004 (Official controls of animal products for human consumption) and Regulation EC No 882/2004 (Official control to ensure verification of compliance with feed and food law, animal health and animal welfare rules). Aquaculture (at least the part of aquaculture where the purpose is to raise aquatic animals for the purpose of human consumption) is considered a "food business". Relevant for the proposal is that these new Regulations lay down how "food business operators" shall ensure compliance with the legislation, how the competent authority shall operate, and the requirements for laboratories for animal health.

All disease control measures have an economic impact on fish-, mollusc and crustacean farmers. However, inadequate controls can lead to a spread of pathogens, which can cause great losses and compromise the aquaculture animal health situation in the Community. On the other hand, an "over-regulation" may case unnecessary restriction on free trade. The inappropriate use of outdated rules can cause as much or greater loss without any appreciable gain either to the health of aquaculture animals or to economic viability of producers.

2. OBJECTIVE OF THE PROPOSAL

The main policy objectives are to (in non-priority order):

- Acknowledge the interaction of diseases between farmed and wild aquatic animals by taking the potential exchange of disease agents between farmed and wild aquatic animals;
- Create a simpler and clearer legislation;
- Delegate more responsibility to Member States (flexibility and subsidiarity) and develop a more flexible legislation that could meet the needs for local adoptions and solutions;
- Facilitate free trade;
- Focus more on disease prevention (shift the focus in the legislation from preventing disease spread, to preventing disease occurrence);
- Have a placing on the market legislation which is consistent with the OIE Standards.

- Improve the general aquaculture animal health in Europe;
- Prevent introduction of exotic diseases into the Community and to facilitate export of aquaculture animals and products to third countries by having a legislation which is consistent with the International Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aquatic Animals of the OIE;
- Protect the disease-free farms and areas from introduction of important diseases.

In order to achieve this, it is proposed to repeal Council Directives 91/67/EEC, 93/53/EEC and 95/70/EC, and replace them by a new Directive updating existing provisions taking into account the points raised above.

3. POLICY OPTIONS

3.1. Zero option

Since this project was initiated by the need for updating the existing legislation, the zero-option would be to maintain the existing legislation. As the whole project has been driven by a need to update the legislation (see points 1 and 2), the zero-option is not discussed.

3.2. Type of legislation for regulating animal health conditions for trade

3.2.1. Regulation

Regulations have direct application in the Member States and are binding in their entirety. Their provisions should therefore be drafted in such a way that the addressees have no doubts as to the rights and obligations resulting from them. References to intermediary national authorities should therefore be avoided, except where the act provides for complementary action by the Member States. Directives, on the other hand are addressed to the Member States, and must be transposed into national law. A Directive should be drafted in a less detailed manner in order to leave Member States sufficient discretion in their implementation. If the enacting terms are too detailed and do not leave such discretion, the appropriate instrument will be a regulation, rather than a directive.

By choosing a Regulation, and thereby avoiding the Member States to transpose the act into national law, time needed to have the legislation fully applicable would be significantly reduced compared to a Directive.

However, the Commission acknowledge the fact that it may be difficult to draw up, implement and apply a Regulation which would meet the demands of an industry which is as diverse in nature as the European aquaculture industry. The main reasons for this are:

- different species are raised in different parts of the Community, and different species needs different management practice.

- different climatic conditions influences the manifestation of disease even in the same species (infection with some pathogens does not cause problems in high temperature waters in the south of the Community, but in the low temperatures in the north of the Community there will be extensive mortalities due to the infection).

- different farming practices in the Community, like cage farming of salmonids versus pond farming of carps, farming areas or harvested natural beds for molluscs versus "cage or pond farms" for fish versus scrimp farms measured in hectares

3.2.2. Intra-Community Trade Directive

With an Intra Community Trade Directive, the Community legislation will lay down the animal health conditions for border crossing trade of aquaculture animals. A special problem in aquatic animal diseases, compared to terrestrial animal diseases, is that the spread of diseases is directly linked to the flow of the watercourse, or coastal current, in addition to the migration of wild aquatic animals, which does not respect national boundaries. It is therefore important that the Member States applies at least the same animal health conditions for trade inside a Member State as between Member States. This fact is also acknowledged in the present legislation (Council Directive 91/67/EEC), as this is a Placing on the Market Directive.

With a view of completing the Internal Market, the view of the Commission is that the same minimum rules should apply within the Member States as between the Member States.

3.2.3. Placing on the market Directive

As a consequence of the discussion under point 3.2.1 and 3.2.2, the best legislative option is to propose a Directive for placing on the market. This will be in line with, and not represent any change in the policy compared to the present legislation.

Taking into account the wide variety of production types and species raised in EU aquaculture, however all necessary technical details, in particular concerning risk management and disease control, are not possible to include in the primary legislation. Consequently, the proposal should be a Directive. It is therefore proposed to establish the principles, strategies and aims in the Directive, while detailed implementing rules should be adopted as secondary legislation under commitology procedures.

4. MORE SPECIFIC ABOUT THE PROPOSAL

The new directive will maintain the current *principles* for placing on the market laid down in Council Directive 91/67/EEC, and disease control provisions in Council Directives 93/53/EEC and 95/70/EC. However, the proposal contains several elements of simplification and greater flexibility in relation to the declaration of "disease free" status. The proposal also includes a legal base to adopt secondary legislation for risk mitigation.

Chapter I contains subject matter, scope and the definitions which is important for the scope for the proposed Directive. The main purpose of the proposal is to regulate the aquatic animal diseases which can have significant impact on Community aquaculture. However, as it is important to acknowledge the interaction between aquaculture animals and wild aquatic animals. Traditional fisheries (wild catch), is not regulated since it is impossible to have a reasonable control of the animal health status at the place of harvest, and that even if this area has not previously been subject to animal health regulation, no outbreaks of aquatic animal diseases have been traced back to processing wild catch for the purpose of human consumption. The placing on the market and import of ornamental aquatic animals is proposed not to be included in the scope of the Directive as long as these animals are kept in non-commercial aquaria (i.e. aquaria for visual enhancement in private homes, in schools, in office receptions, in restaurants etc). This is due to the fact that such aquatic animals represents a negligible risk to Community aquaculture or wild stocks of aquatic animals, and that policing such provisions in private homes, schools, restaurants etc would not be const beneficial. Finally, this Directive will not regulate aquatic animals caught for the purpose of production of fish meal, fish oil or similar products, as this is regulated under the Animal By-Product Regulation (Regulation (EC No 1774/2002)

The definitions in Article 3 are definitions which draw up the scope of the proposed Directive. The definitions are where possible based on definitions in other EU legislation to ensure cross-compliance, for example General Food Law , the "Hygiene Package" and the Regulation on the Fisheries Fund.

Chapter II contains the general requirements addressed to the aquaculture production businesses and processing establishments.

In Article 4, it is proposed that all farms should have an authorisation issued by the competent authority, taking animal disease considerations into account, in order to operate. This is an extension of the existing legal requirement where all mollusc farms must be registered, and all fish farms raising fish susceptible to List I and II diseases must be registered. Taking into account the OIE list of susceptible species, the existing registration requirements applies consequently to all farms keeping or rearing molluscs or fish belonging to the family *Salmonideae,* (including Atlantic salmon (*Salmo salar),* Pacific salmon (*Oncorhynchus* spp.)*,* Brown trout (*Salmo trutta*), and Rainbow trout (*Oncorhynchus mykiss*)), White fish (*Coregonus* spp.), Grayling (*Thymallus thymallus*), Pike (*Esox lucius*), Turbot (*Scophthalmus maximus*), Herring and Sprat (*Clupea* spp.), Cod fish (including Atlantic cod (*Gadus morhua),* Pacific cod (*G. macrocephalus*)*,* Haddock (*G. aeglefinus*) and Rockling (*Onos mustelus*)). Consequently, the current registration requirements cover between 80 to 85% of the EU aquaculture production measured in volume.

However, the Member States may authorise all molluscs farms operating inside a "production area" or "relaying area" (as defined under Regulation EC No 853/2004) *en bloc*.

As registration is considered a more passive process, the competent authority has limited possibilities for refusing registration and laying down conditions for being registered. It is therefore propose to introduce authorisation. With authorisation the competent authority may lay down requirements in relation to the farm, and in case of repeated and/or severe violation of the rules an authorisation may be withdrawn.

Article 5 contains the conditions for authorisation, the requirement for the official register of the authorised businesses and establishments, and the provisions for supervision by the competent authority. It is important to emphasise that the competent authority may deny an authorisation if the activity in question would cause an unacceptable risk of spreading diseases. What is "unacceptable risk" must be decided on a case-by-case basis, taking into account possible risk mitigation, likelihood of spreading of diseases and consequences of a possible disease spread.

It is also important that the information in the register (Article 6) is made available to other Member States and the aquaculture industry, as this may be a core source of information for possible trade and as well the health status of possible trading partners.

All authorised aquaculture production businesses and establishments shall remain under the supervision of the competent authority. The frequency of inspections/visits shall be established on a risk based level. Where possible, the supervision (inspections/visits) in establishments and in mollusc farming areas should be combined with the supervision under Regulation (EC) No 854/2004. The supervisions (inspections/visits) of other aquaculture production businesses, should as well be established on a risk based level, and should be combined with the inspections foreseen in Article 10 and Annex IV.

The record obligations in Article 8, is an extension of the existing record obligation in Article 3.2 in both Council Directives 93/53/EEC (fish) and 95/70/EC (molluscs). Record keeping in establishments is already laid down in Regulation (EC) No 853/2004, and should be combined with the record keeping pursuant to this proposal.

Article 9 is a legal base for the competent authorities to ensure that the authorised aquaculture business and establishment operator applies good hygiene practice, as risk mitigations procedures in farms or farming areas, and in establishments authorised to process aquaculture animals subject to disease control measures. These measures will in sum reduce the likelihood of a disease outbreak, and if the disease outbreak occurs, reduce its impact on other aquaculture animals and wild stocks of aquatic animals. This provision is new.

In Article 10, it is proposed to introduce a general requirement for a risk based animal health surveillance to be applied in all farms or farming areas. This is an extension of the requirements in the present mollusc legislation, where all Member States must have a monitoring and sampling program to detect abnormal mortality in farmed mollusc stocks and harvested natural beds. It is proposed to make the surveillance risk based. It is therefore impossible to lay down in the primary legislation specific requirements on inspections frequency and sample size taking into account the diversity of the industry in the Member States. It is therefore proposed to establish detailed provisions by secondary legislation. However, some general indications are outlined:

1. A low risk farm (low risk of spreading of disease to other farms or wild stocks, low biomass, sell live fish only for slaughter), may apply passive surveillance, be visited by the competent authority once every 2 to 4 years, and visited by aquatic animal health services (normally private veterinarians) once a year or less.

2. A medium risk farm (medium to high risk of spreading of disease to other farms or wild stocks, medium to high biomass, sell live fish only for slaughter), may apply active or passive surveillance, be visited by the competent authority once a year, and visited by aquatic animal health services minimum 2 times a year

3. A high risk farm (high risk of spreading of disease to other farms or wild stocks, medium to high biomass, sell live fish for further farming or restocking), should apply active surveillance, be visited by the competent authority at least once a year, and visited by aquatic animal health services minimum 3 times a year

4. However, the where a Member State, or part thereof is known to be infected with a certain disease, and that Member State has decided to contain the disease in the infected area (not to eradicate/regain freedom), the appropriate level of surveillance with respect to the disease in question should be passive surveillance only. The same would apply where no species susceptible to the disease in question is present.

It is therefore proposed that there would be a certain amount of discretion for the competent authorities of the member States to determine the inspection frequency, surveillance type and sampling regime for each individual farm.

Chapter 3 contain the general animal health provisions for placing on the market of aquaculture animals. The principles from Directive 91/67/EEC are maintained in Articles 11, 12, 15 and 16.

The diseases that are subject to Community measures are divided into two groups, compared to three groups in the existing legislation. Important diseases which are exotic to the Community (exotic diseases) and important diseases which are present in the Community, but where there are regions free of the diseases (non-exotic diseases).

The placing on the market provisions are relevant for the non-exotic diseases (diseases which are present in the Community, but where there are regions free of the diseases).

Pathogens/diseases subject to Community provisions in existing and proposed legislation

	Fish diseases		Mollusc diseases		Crustacean diseases		SUM
	Exotic	Non-exotic[1]	Exotic[2]	Non-exotic[1]	Exotic	Non-exotic[1]	
Existing legislation	1	8[1]	9	2[1]	0	1[1]	21
Proposal	2	5	4	3	2	1	16

[1] The non-exotic diseases in the existing legislation comprise the diseases referred to in List II and List III of Annex A to Directive 91/67/EEC.

[2] The exotic mollusc diseases comprise the diseases referred to in Annex D to Directive 95/70/EC.

The listing of diseases subject to Community provisions should also take into account the listing by the OIE. This is an important element with respect to controlling international trade in aquatic animals under the WTO/SPS agreement. The proposed disease list takes the current OIE list into account.

Transport of live aquaculture animals are one of the major risk factors in relation to the spreading of diseases. It is therefore important to have a legal base to adopt the necessary measures that should apply in relation to transport. As the Community aquaculture industry is diverse and develops rapidly, such detailed provisions should be adopted by secondary legislation. The legal base in Article 13 is new.

An important element in preventing and controlling animal diseases is to keep track of the movement of live animals. In Article 14 it is proposed to take advantage of the TRACES system implemented under Council Directive 90/425/EEC. However, if the movement takes place between different sites belonging under one ownership, or inside a farming area of molluscs, record keeping as required as a normal management routine should be sufficient. Furthermore, where live aquaculture animals are introduced into a compartment declared free of a certain disease, the consignment shall in addition be accompanied by an animal health certificate to document the animal health status of the place of origin.

Article 17, in the proposal deals with the provisions applicable to species not defined as susceptible to one or more of the listed diseases. It is proposed to that they could be traded freely, independent of the disease status at the place of origin and destination. This is in contradiction to the corresponding Article in the existing legislation (Article 14 of Directive 91/67/EEC), where such species must come from a compartment (zone or farm) declared free of a certain disease or be proven not capable of transmitting the disease passively. This change in policy brings the placing on the market provisions in line with the OIE Standards, and will open up trade significantly. However, if there is evidence supporting a claim that non-susceptible species can act as carriers, they should be treated as susceptible species according to the provisions of Article 13 of the proposal, or other risk mitigation procedures applied.

Article 18 which lays down the animal health provisions related to the placing on the market of aquaculture animals or products thereof for further processing before human consumptions. The processing of aquaculture animals have shown by epidemiological studies to a high risk factor in the spreading of disease. Therefore it is necessary to ensure that this activity does not jeopardise the aquatic animal health status where the processing takes place. The provisions of the Article are more flexible and include more risk mitigation procedures than the corresponding provisions in the existing legislation.

Article 19 deals with those aquaculture animals which are placed on the market for human consumption without further processing. This form of placing on the market is common with respect to molluscs and crustaceans (for example lobsters), and eels. The risk associated with this activity would normally be low. However, in many situations, the animals are re-immersed or relayed in water for the benefit of freshness. Such activity must not be blocked, but should neither jeopardise the aquatic animal health status where this activity takes place.

For some species, in particular turbot and halibut, it is usual to catch wild broodstock fish which are stripped for eggs and sperm. The provisions of Article 20 should ensure the maintenance of the health status of disease free Member States, zones and compartments where such wild animals by means of human activity, are introduced declared disease free areas. It is not the intention that this Article should regulate the collection of eggs and sperm from salmonids migrating up rivers.

The placing on the market and import of ornamental aquatic animals is in principle covered by the existing legislation. However, no specific provisions have been laid down pursuant to that legislation, since the legislation is not designed to cover such commodities. It is therefore proposed a separate article (Article 21) which has the aim of focusing on the problem, and gives a legal base to draw up specific secondary legislation which could both meet the need for protecting farmed and wild stocks of aquatic animals form relevant diseases, as well as taking into account the special needs of this industry. It is not the intention of the proposal to regulate the ornamental aquatic animals *per se*. This should be left to the ornamental industry as self regulation. Ornamental aquatic animals is in the proposal regulated insofar as their health status could pose a threat to Community fish, mollusc and crustacean farming and wild stocks in the Community. Consequently, it is proposed that fish, molluscs and crustaceans placed on the market, or imported for ornamental purpose should only be covered by such special provisions when they are not kept in aquariums or in other facilities without direct contact to natural Community waters. No specific animal health conditions should apply where ornamental aquatic animals are kept in kept in pet-shops, commercial aquaria, garden centres ponds, or under similar conditions, not in direct contact with Community waters.

Chapter IV contains the provisions for introduction into the Community from third countries. These provisions remains *de facto* unchanged compared to the existing provisions. However, for the sake of harmonisation between different Community legislation laying down animal health import requirements, the legal text is drafted taking into account the most current Council Directive laying down animal health import provisions (Directive 2002/99/EC). The impact of the import provisions are described in detail in point 7.5.

Chapter V contains the notification and control provisions.

It is important for the competent authorities to be notified at an early stage where there is a suspicion of listed diseases. Consequently all suspicions of listed diseases should immediately be notified to the competent authorities. As a part of the policy to pay more attention to preventative measures, it is proposed that any increased mortality in aquaculture animals should be notified to, and investigated by competent aquatic animal health services. It is however impossible to define at Community level, what should be considered as increased mortality. What mortality that should be considered as "increased mortality" must be defined for each farm in cooperation between the farmer, the competent authority and where appropriate any private aquatic animal health service. Any farming of aquatic animals have a certain "background mortality" which is considered normal for the farm in question under the prevailing conditions, and is dependent on which species is raised, the farming system, the water quality, etc.

The obligation of notifying such increased mortality is new, and will have the function of an "early warning system", enabling the quick reaction and investigation. It is proposed not be make it compulsory to have increased mortality notifiable to the competent authority, in order to limit the number of notifications that should go the authorities in the first place. However, where the primary investigations conclude that there are reasons to suspect the presence of a listed disease, the competent authority must be notified.

The principles for the provisions for initial control measures in case of a suspicion (Section 2), minimum measures in case of confirmation of an exotic disease (Section 3) or non-exotic disease (Section 4) are mainly unchanged compared to the existing control provisions in Directives 93/53/EEC and 95/70/EEC. However, the provisions in Article 35 (fallowing) and 36 which includes the protection of wild aquatic animals, are new.

In addition, minor technical amendments have been made to take into consideration the need for flexibility. Whether a non-exotic disease shall be eradicated from an area or contained should be decided by each Member State taking into account the likelihood of achieving/maintaining disease freedom, socioeconomic impacts, environmental impacts etc. Member States previously not considered free from a non-exotic disease may have a disease control and eradication programme approved according to Section 1 of Chapter VI.

An important new element of the control provisions are the two "fast track procedures" for adopting disease control measures. Article 42 gives a legal base to adopt ad hoc provisions by commitology procedures in order to meet situations where the control provisions of the Directive is not adaptive to the epidemiological situation. Similarly Article 41 gives a legal base of adopting control measures in case of emerging diseases, which are disease situations not foreseen (new diseases, often with an unknown aetiology) when the Directive was adopted.

There are a significant number of diseases not subject to Community provisions which have local importance. In such cases, the aquaculture industry should with the assistance of competent authorities of the Member States, take more responsibility through self regulation and the development of "codes of practice". However, it may be necessary pending the establishments of such codes for the Member States to implement certain control measures. Such control measures must be justified, necessary and proportional to the goal to achieve, and should not affect the trade between the Member States. Article 43 gives a clear legal base for such national measures.

The provisions for a contingency plan (Section 2 of *Chapter VI*) has been amended compared to the existing legislation. In the existing legislation, there is only a requirement for a contingency plan for diseases referred to as List I diseases for fish, and no requirements for mollusc or crustacean diseases. It is important that a contingency plan is drawn up to cover in principle the occurrence of all exotic diseases subject to Community provisions, and situations involving emerging diseases.

Article 48 contains the provisions for vaccination. These provisions follow the principles in the existing legislation. The main rule is that only vaccines authorised pursuant to Directive 2001/82/EC and Regulation (EC) No 726/2004, shall be used. However, it is important to note that the market for vaccines for aquatic animals is relatively small, in particular with respect to diseases with low occurrence subject to international trade rules, such as infectious salmon anaemia (ISA). No vaccine against ISA is licensed on the European market, but in Canada and USA. If an ISA-outbreak should occur in a Member State, vaccine may be an option to stop the spread of the disease. In such case, it would be impossible to go through a full licensing procedure before it could be used, and the Member States could provisionally allow the use of a vaccine for which an authorisation for placing on the market has not been delivered, in accordance with the Directive 2001/82/EC and Regulation (EC) No 726/2004.

Chapter VII contains the provisions for declaring status as disease free Member State or compartment, and the maintaining, and suspension such freedom. The *principles* are the same as in the current legislation. However, the provisions have been re-written to be more flexible in order to take into account the diversity of EU aquaculture and to take into account the OIE Standards. This latter point is of importance in order for the Community legislation to be consistent with the Community obligations under the WTO/SPS agreement. The principle of compartmentalisation has replaced the present zoning principle. This increases the flexibility without increasing the risk of transmitting diseases through trade to an unacceptable level. With respect to compartmentalisation, it is proposed that the competence of declaring a compartment free of a disease is at Member State level, and not at Commission level as in the existing legislation. However, for the sake of transparency, a Member State must notify other Member States and the Commission about their intention of such declaration, whereby any interesting parties should have the possibility to submit comments, or raise objections the Member State concerned. The competence of declaring an entire Member State free should remain at Community level.

Chapter VIII contains the provisions relating competent authority, to laboratory testing and investigation, and the requirements for laboratories.

The general obligations in Article 53 takes into account the appropriate principles laid down in Regulation EC No178/2002 (Feed and food law), and Regulation EC No 882/2004 (Official control to ensure verification of compliance with feed and food law, animal health and animal welfare rules).

An important difference compared to other animal health Community legislation is that the aquatic animal health legislation has always covered several diseases (21 diseases in existing legislation, and 16 diseases in this proposal). It is therefore impossible to establish one Community reference laboratory for each disease (as in the terrestrial animal health legislation). Due to the fact that one laboratory have to cover more than one disease. The present situation is that CRL for fish diseases covers 3 diseases/pathogens, and CRL for mollusc diseases covers 11 diseases/pathogens. It is therefore proposed that the designated CRL (Article 55) may "subcontract" some of their tasks, provided the "subcontractor" has a standard equivalent to the CRL. However, the designated CRL will always remain the contact point towards the Commission and the National reference laboratories (NRL). The same principle will apply with respect to the NRL's (Article 56).

Another major change compared to the existing legislation, is that laboratory examination for the purpose of this Directive must be carried out in laboratories designated by the competent authority (Article 57). In addition, the proposal follows up the intentions of Regulation (EC) No 882/2004.

Chapter IX contains the provisions for Community inspections, e-management and penalties.

Chapter X and XI contains the implementing measures and transitory provisions respectively. It is proposed that the technical provisions in the Annexes and Article 15(1) could be amended by Committee procedure. Furthermore, it will be necessary to adopt secondary legislation, taking into account the diversity of Community aquaculture according to the same procedure.

The definitions in *Annex I*, the listing criteria and disease lists in *Annex III* and the requirements for declaring disease freedom in *Annex V* are as far as possible harmonised with those of the OIE, in order to establish a common platform for the legislation in relation to third country trading partners.

In *Annex IV* the framework of the risk based animal health surveillance foreseen required according to Article 10 has been drawn up. It will be necessary with implementing legislation to meet the flexibility and diversity necessary in relation to this Annex.

The functions and duties of laboratories in *Annex VI*, takes into account and are harmonised with the provisions of Regulation (EC) No 882/2004, which is applicable from 1. January 2006.

The requirement for the contingency plan in *Annex VII* is consistent with the requirements for the contingency planning for exotic terrestrial animal diseases, where the most current provisions are laid down in Council Directive 2003/858/EC on the control of Foot and mouth disease.

5. DETAILED DISCUSSION ON IMPORTANT ELEMENTS

5.1. Flexibility

Due to the diversity in Community aquaculture it is not appropriate to fully harmonise of the whole field of aquatic animal health. However, for the sake of the completion of the internal market, the animal health provisions applicable to placing on the market of aquaculture animals should be fully harmonised. On the other hand, some diseases in aquatic animals are not equally important to the whole Community. Consequently, it is necessary to enable Member States that experience severe problems with diseases not subject to Community wide control provisions to enforce national control measures, provided such measures do not come in conflict the harmonised rules for placing on the market.

The existing provisions regarding "disease free zones" or "disease free farms situated in non-disease free zones" (see Annexes B and C of Directive 91/67/EEC) are only applicable to certain types of fish farms rearing salmonids. As stated previously, it is necessary to adapt the primary legislation to be applicable also to farming of other species than salmonids and oysters, like marine fish species, carps, mussels and crustaceans.

Compartmentalisation will allow for more flexibility. This principle will enable the Member States to decide the delimitations of a compartment provided the requirements in the Community provisions are fulfilled. The provisions in Annex V are drawn up following discussions between the Commission and veterinary experts from the Member States in the context of the preparatory work for the General Session of the OIE of May 2004. The proposal was endorsed by the Council, and sent by the Commission and the Council within the overall Community position documents for discussion held at the General Session. The principle of compartmentalisation is proposed to be included in the OIE Code for 2005.

The existing legislation has no provisions for general surveillance for keeping track of the health status of fish or crustacean, while such provisions exist for molluscs. It is therefore appropriate to introduce a minimum risk based animal health surveillance, which should be applied in all farms, farming areas or natural beds. The purpose is to gain information about the animal health status in all farms, in order to be able to take any necessary action at the earliest possible stage before a single disease outbreak turns into an epizooty, with trade restrictions and financial losses to the industry as a result. Such risk based animal health surveillance will also provide protection to those farms that can not, for various reasons, comply with OIE rules for declaring disease freedom. The intention is therefore to lay down guidelines for the minimum level of surveillance necessary for different types of farms, where the focus should be on which risk this farm poses for spreading diseases to other farms or wild stocks of aquatic animals. It will be the responsibility of the Member State to, within the limits of the guideline, to define in which risk group a farm should placed and apply the guidelines. This surveillance will also be the basis of disease reporting in the Community.

5.2. Delegation of responsibility to Member States

It is proposed to delegate to the Member State level more of the risk management, as the diversity and complexity of the EU aquaculture industry makes it very difficult if not impossible to have all technical details harmonised at Community level. This will give the Member State a certain amount of flexibility in the way they implement these rules in their own country. Furthermore, the closer you come to the problem and real life, the more likely it is that you can find a solution that is tailor made in each individual case. By the present proposal, such strategy is encouraged.

The Commission propose furthermore to delegate more to the competence of the Member State than before, for example:

- ► approval of disease free compartments at Member State level, compared to present legislation where all zones and individual farms are approved by Commission Decisions
- ► Member State may decide if they wish to combat/be free of List II diseases or if they just wish to contain the disease
- ► Member State can decide if they wish to control diseases not subject to Community legislation

5.2.1. Delegation of declaration of disease free status

With respect to the requirements for declaring disease free status (sampling, surveillance, and testing), the general principles of the existing legislation and the philosophy of the OIE Standards are proposed to be maintained.

However, it is proposed to delegate to the Member State level the competence to declare a "zone" or "compartment" disease free. Today, individual farms are approved by Commission Decisions. The requirements for declaring such freedom will be laid down in the Directive (the requirements in Annex V are in line with OIE Standards). Consequently what is delegated to Member State level is to confirm that a certain compartments comply with Community rules.

The procedure today, is that the local/regional veterinary administration completes and signs a checklist to verify that the provisions of the Directive, and sampling, surveillance and testing are fulfilled. Then, the contents of this checklist is confirmed and signed by the central veterinary administration in the Member State, before forwarding the application for approval to the Commission. The Commissions services distribute the application to all Member States (in the Standing Committee of the Food Chain and Animal Health) for comments. Then, normally 1-2 months after, the Commission services present a draft Commission Decision for including the farm/zone in the list of approved farms and zones. This whole process takes between 6 and 12 months to complete.

Most Member States and the stakeholders support the proposal for simplification of the procedure.

However, some concern is raised about the fact that individual farms and zones (compartments) can be approved at Member State level. It is argued that experience has shown that some Member States has forwarded applications for Community approval under the existing regime that do not comply fully with the requirements in the existing Directive. To some extent this view is right, but the problem is relatively small (about 2-3 % of applications are rejected). The problems arises mainly due to the fact that

- ► present legislation is unclear
- ► present legislation is not applicable to all farms/production forms (hence farms/production forms not taken into account when legislation was drafted, always "fails" to comply with the requirements)
- ► there has over the years been a "stretching" of the interpretation of the existing legislation.

The proposal to delegate to the Member State to declare compartments free of a certain disease, provided it complies with the requirements (the requirements in the legislation will be identical to the OIE Standards) is maintained, but a procedure for notification of the intention to declare freedom is built in. This will enable those Member States expressing concerns, to have full access to the data supporting a Member State notification.

In addition, Regulation (EC) No 882/2004 provides for administrative enforcement measures for Member States to address particular problems of non-compliance as well as enforcement measures at EU level. Where the Commission has proof that a Member State's control system is inadequate, the Regulation will allow the Commission to take interim measures to ensure the protection animal health, and the environment. These measures would be taken in co-operation with the Member States within the Standing Committee of the Food Chain and Animal Health, or in serious cases on the Commission's own initiative. These measures include suspending the right to aquatic animals or certain products thereof on the EU's Internal Market.

5.2.2. Decision on containment or combating/controlling non-exotic diseases

Some of the diseases subject to harmonised trade provisions are widespread in parts of the Community. It is therefore not realistic to enforce the same level of control measures in Member States free of these diseases, and in Member States where these diseases are widespread. However, it should be the decision of the Member States, on a cost-benefit basis, if the disease should be subject to containment or control measures.

5.2.3. Control of diseases not subject to harmonised Community provisions

Due to the diversity of the aquaculture industry throughout the Community, certain diseases in aquatic animals may be of great importance for one or two Member States only. Such diseases should normally not be subject to harmonised Community provisions for trade and disease control. However, the Member States should be able to enforce proper disease control measures, provided they are justified, necessary and proportional to the goal to be achieved. Such disease control measures should not be of trade restrictive character. If trade restrictions is the only possible mean to enforce the measures, the measures should be approved by the Commission.

5.3. Trade between Member States, zones or compartments declared disease free.

There is a dissension to what extent live aquaculture animals originating in, what in the existing legislation is called "approved farm situated in a non-approves zone", can be introduced into an approved zone, without jeopardising the animal health status in that zone. The existing legislation foresees some additional requirements related such introduction (see Art 7.1.a of Council Directive 91/67/EEC). However, such requirements have never been established and national provisions have applied. Most Member States considers the health status of an "approved farm situated in a non-approves zone" and an "approved zone" as equivalent, but a few Member States maintains national provisions which makes it illegal to introduce animals from an "approved farm situated in a non-approves zone" into an "approved zone".

In the proposal, the "OIE-concept" of disease free zones and compartments is introduced. It is the opinion of the Commissions services that movement between zones and compartments that have been declared disease free should be allowed, irrespectively of the size of the compartment and who has declared the compartment free, provided the requirements for such declaration of freedom are laid down in Community law. For the Commission, this is a matter of the trustworthiness of the competent authorities in the different Member States, whether such declaration can be made by the member States themselves or must be done by the Commission.

There main two arguments forwarded by some Member States against this proposal, are that there might be a higher risk related to introduction from a small compartment compared to zone or a large compartment, and that the declaration of "disease free compartments" is done at Member State level.

The Commission proposes to maintain this principle, despite the arguments above opposition for the following reasons

- ► the requirements will be laid down in the Directive
- ► a Member State must trust another Member State when it say a certain zone or compartment complies with the Directive (the whole veterinary certification system is based on trust)
- ► a zone or a large compartment is not "more free" than a small compartment (previously called an approved farm situated in a non-approved zone)
- ► the introduction of live aquaculture animals into declared disease free compartments will be subject to animal health certification (see furtherer clarification below)

However, in order to meet some of the concerns, it is proposed a procedure for notification of the intention of such declaration that would allow full transparency. In addition, where it is a matter of declaring a major part of the territory of a Member State, or an entire Member State free, this should be done at Community level.

5.4. Animal health certification

According to present legislation, there are no general requirements for movement documents or animal health certificates unless animals are introduced into declared disease free zones or, where certain species are moved between non-approved zones of declared infected farms.

Article 14 of the proposal will ensure that there will be a traceability of animals easily accessible to competent authorities and to ensure that disease status is not jeopardised.

There has been a concern in the Member State that issuing of animal health certification should be required for movement inside a Member State. The Commissions services, believes that the critical issue should not be if the animals crosses a Member State border, but rather are introduced into a declared disease free compartment.

It is therefore proposed that placing on the market of live aquaculture animals is subjected to animal health certification as follows:

- ► Movement between different sites belonging to one aquaculture business (under one ownership) or one farming area (for molluscs) shall be subject to record keeping by the aquaculture business only, provided that the different sites are within the same disease free compartment

- ► Movement between two aquaculture businesses inside a Member State should be subject to registration in TRACE only, provided the movement is not "introduction into a disease free zone or compartment".

- ► The introduction into a disease free compartment shall be subject to animal health certification (TRACE + AH certificate) irrespectively of the place of origin is the same Member State (between disease free compartments in the same Member State) or another Member State (border crossing movement).

Such tracing and movement recording system will be of vital importance whenever an epizootiological investigation must be conducted, due to a suspicion or confirmation of an outbreak. As a consequence of the use of electronic notification system (TRACES), this will not create unacceptable administrative burdens.

Between 1 April 2004 and 15 November 2004, approximately 2500 consignments of live fish have been recorded in TRACES.

5.5. Disease prevention rather than disease control

The main policy shift introduced by the proposal is to focus more on, and allocate more resources to, disease prevention (to prevent disease occurrence). More attention should be paid to preventing disease occurrence, rather than controlling the disease once it has occurred. It is therefore appropriate to lay down minimum disease preventative and risk mitigation measures that should be applied during the whole production chain in aquaculture, from fertilisation and hatching of eggs to the processing of aquaculture animals for human consumption, and including transportation. Examples requirements for minimum management routines in farms, establishments (Article 9), risk based health surveillance (Article 10), disease preventative measures in relation to transport (Article 13), traceability (Article 14), contingency planning (Article 47) and vaccination (Article 44).

All disease preventative measures will have an economic impact. However, if disease occurs, this will affect the principle of free trade, and will also result in mortalities (losses), reduced growth, and reduced quality of the products. The losses due to diseases could be significant. Little data is available with respect to losses in Community aquaculture. However, in the USA, an estimate of 10% of the fish production is lost each year due to diseases in aquaculture. Furthermore, the Norwegian Ministry of Agriculture estimated that in 1990 alone (when Norway produced 130.000 tonnes of salmon compared to 530.000 tonnes in 2004), the economic losses due to furunculosis and ISA was 1 bn NOK (120 mill €). Adjusted for inflation into 2004 value, this corresponds to 160 mill €. The economic consequences of the 13 outbreaks of ISA in UK and Ireland in 2000/2001 has never been calculated in total, but in the court case after the outbreaks (C-64/00 Hydro Seafood GSP Ltd versus The Scottish Ministries), it was claimed total losses in the region of 22 million €. In contrast to those figures, the Norwegian Government has calculated that the Norwegian fish farming industry's losses due to ISA in 2000, a year Norway experienced 17 outbreaks and disease control was done in accordance with Council Directive 93/53/EEC, were approximately 10 million €. Sweden paid under national legislation compensation in relation to 4 cases of VHS in 1998 a total of 1,5 mill SEK (165 000 €) over a period of 3 years.

6. IMPACTS - POSITIVE AND NEGATIVE

6.1. Positive impacts

Positive impact will arise from an updated Community legislative framework which takes into account the present scientific knowledge as well as the structure of today's aquaculture industry in the Community.

There will be positive impact on the shift in focus from preventing disease spread to preventing disease occurrence. Significant resources are used today to maintain disease free status in farms and zones that have been declared disease free. The existing requirement for maintaining disease free status is to maintain targeted active surveillance, even if the pathogen never has been found in the area concerned. As an example, Member States like Ireland and UK (both declared free of VHS and IHN) annually have to sample and test all farms with susceptible species regularly, regardless of the fact that the diseases have not been found for decades. The new proposal would allow the Member State to re-allocate some of the resources used for this purpose to disease preventive activities.

It is a general wish to delegate more responsibility to the Member States, and the proposed legislation is far more flexible legislation that than the existing legislation, and can meet the needs for local adoptions or solutions. The proposal implements the idea that the best solution is often found closes to the problem.

It is necessary to improve the general aquaculture animal health in Europe. The vast majority of Community aquaculture farms, have not, or can not, join the costly control programs necessary to achieve status as declared disease free. By way of introducing a general risk based animal health surveillance, a better overview of the disease situation is achieved, and at the same time the risk of spreading diseases to farm or areas where the disease has not yet been found is reduced.

One of the challenges for Community aquaculture is its interaction with the wildlife. Some diseases are of great importance for wild aquatic animals and must be controlled both in the wild and in farmed aquatic animals. The proposal will to a greater extend consider the potential exchange of disease agents between farmed and wild aquatic animals.

The balance between the animal health conditions for placing on the market of aquaculture animals and the disease control provisions will facilitate free trade to a greater extent than what is the situation today. Furthermore, it will continue to protect the disease-free farms and areas that exist today, and as described above provide protection for those farms than can not comply fully with today's strict rules for declaring disease freedom.

In relation to third country trade the proposal will prevent introduction of exotic diseases into the Community and to facilitate export of aquaculture animals and products to third countries by having a legislation which is consistent with the International Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aquatic Animals of the OIE.

6.2. Negative impacts

In general, the negative impact will be limited, as the proposal will to a large extent build on the existing legislation. This impact assessment will not deal with the impacts of those provisions which remain unchanged. However, some new elements and requirements are proposed, which will have administrative and economic impact in the Member States and industry.

6.2.1. Authorisation

This proposal will cause extra work for the competent authorities in the Member States, but since all mollusc farms and a significant portion of fish farms are already registered, the authorisation requirement should be achievable by the Member States authorities. In addition, a transitional period may be proposed (limited to 4 years according to Article 64 of the proposal), where the Member States may require the authorisation of the farms considered to have the highest of risk of spreading of aquatic animals diseases first, while to farms having a lower risk of spreading of aquatic animals diseases may be authorised at a later stage. The extra work related to the authorisation will also be limited in time, since the major part of the work is related to authorising farms already in business. There is little information available on the number of farms not covered by the existing registration requirement. However, having regard to the total aquaculture production in the Community (2002) of approximately 1,4 mill tonnes, between 80 to 85% of the production is in species and farms already covered by the registration requirements. The other 15-20% represents mainly farming of seabass/seabream, eel, and carps. These species are mainly farmed in the 10 new Member States and in the Mediterranean area. The amount of time needed to authorise one farm is difficult to establish. If an average of one working day pr authorisation (farm or farming area) is estimated, only a few Member States will need more than one man/year to undertake the task within 4 years (France (3-4), Germany (8-10), Italy (2) and UK (2)).

The authorisation of establishments will not lead to significant extra work. These establishments are already authorised under Directive 91/493, and the number of establishments needed to be authorised under this Directive may not be significant. If an estimate of 10% of the establishments already authorised under Directive 91/493/EC is authorised for slaughtering aquaculture animals subject to disease control measures, the number will be approximately 400 on Community level, ranging from a few (1-5 pr Member State) to a limited number (40-60 pr Member State)

The industry fears this proposal will cause significant extra work to the industry. In many Member States, the industry already needs authorisation from several other authorities (e.g. environmental, coastal/fisheries etc) to operate. It is claimed another authorisation would not be beneficial, and just cause extra work. It is however the opinion of the Commission that the extra work needed by the industry will not be an argument, provided the Council and European Parliament agree with the proposal of the Commission (Com (2004)2) for a Directive on services in the internal market, in particular Article 6 thereof, where it is stated businesses the Member States should have a "single point of contact" with the authorities of the Member States and therefore, if this proposal is adopted, the amount of work needed by the industry will be reduced.

6.2.2. Risk based animal health surveillance

The introduction of a general requirement for a risk based animal health surveillance to be applied in all farms or farming areas, is an extension of the requirements in the present mollusc legislation, where all Member States must have a monitoring and sampling program to detect abnormal mortality in farmed mollusc stocks and harvested natural beds. It is proposed to make the surveillance risk based. It is therefore impossible to lay down in the primary legislation specific requirements on inspections frequency and sample size taking into account the diversity of the industry in the Member States. The details (sample frequency, sample size etc) will be laid down by secondary legislation in accordance with Article 10.3 of the proposal, taking into account the guidelines and recommendations in Annex IV. Consequently, it is impossible in this impact assessment to give a precise estimate of the financial and administrative burden to the Member States or the industry. A separate impact assessment will be made in relation to the adoption of such secondary legislation.

However, it is important to notice that the intention of the Commissions services is to propose that passive surveillance only may be sufficient in Member States and zones known (or declared) to be infected with a certain disease, or where no susceptible species are present. Consequently, if one Member State declares its entire territory infected with all non-exotic diseases, only passive surveillance for these diseases will be necessary.

6.2.3. Other negative impacts to the industry: visits –administration

The farming of aquaculture animals for the purpose of human consumption is under Regulation (EC) No 178/2002 (General Food Law) considered as primary production. Consequently such activity falls under the provisions of the different Regulations adopted under the "Hygiene package".

It should be in the interest of both the industry, and the competent authorities of the Member States to see the obligations imposed under this Directive and under the "hygiene package" together, and thereby preventing double work and increased costs.

Some costs to the industry are already established under Regulation (EC) No 882/2004.

However, to what extent the competent authorities should charge the industry for other work they do for the purpose of this Directive, should be decided by each Member State, taking into account possible conflicts of state aid.

Where secondary legislation will be adopted for the implementation of this Directive (for example establishing the frequency of routine visits according to Article 10 of the proposal), impact assessments will have to be made in order to analyse the administrative and economical impact of the proposals.

7. RELATIONS TO OTHER LEGISLATIVE SECTORS

7.1. Fisheries

Directorate General for Fisheries is responsible for the aquaculture industry, and the aquaculture industry falls under the Common Fisheries Policy (CFP). DG Fish has been involved and kept updated throughout the project.

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

Council Decision 90/424/EEC on expenditure in the veterinary field already allows for financial support in relation to outbreaks of Infectious Haematopoietic Necrosis and Infectious Salmon Anaemia. Disease control actions for aquatic animal diseases are eligible for a Community financial contribution under Regulation (EC) No 2792/1999 solely.

In the proposal, compulsory slaughter/stamping out will only be required under Community rules in relation to outbreaks of diseases that are considered exotic to the Community. The likelihood of introduction and occurrence of an exotic disease is considered low taking into account the provisions of the proposal.

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 ever an exotic disease should 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 to the eradication are made within the Operational Programmes, whose budget is fixed by the Council at the beginning of the programming period.

The necessary amendments i.e. the addition of the proposed exotic diseases to Decision 90/424/EEC, should be done by means of a separate proposal that is sent to the Council together with this proposal, although it would undergo a much shorter legal procedure.

7.2. Environment

The proposal maintains the principle from the existing legislation that the animal health provisions shall apply without prejudice to national or international provisions for the conservation of species or introduction of non-native species. More stringent rules may be applied where this is necessary to for the protection of species from an environmental/conservational point of view.

With the introduction of compartmentalisation and increased flexibility with respect to declaration of disease free zones and compartments, disease free zones or compartments are not to the same degree dependent upon artificial barriers in watercourses as delimitations of the zones or compartments.

The main policy shift to focus more on, and allocate more resources to, disease prevention (to prevent disease occurrence), will reduce the environmental impact of the aquaculture industry. It should therefore be in the interest of achieving the overall aims of the Community environmental policy, to have better overview of aquaculture businesses requirements related to aquaculture business operators (authorisation in Article 4), reduce the likelihood of a disease outbreak (good management procedures in Article 9, risk based animal health surveillance – Article 10), and reduce the consequences of a disease outbreak (Chapter V).

Consequently there are no conflict of interest between the animal health legislation and Community legislation of conservation of species and habitats and Community action in the field of water policy.

7.3. Public health

Non on the diseases and pathogens regulated by the proposal is known to have a zoonotic potential.

The provisions protecting the consumer from possible risk related to microbial contaminants (bacteria, vira, parasites or toxins) originating in aquatic animals are included in the "hygiene package", where the main new regulations will become applicable from 1 January 2006. Consequently public health concerns are not dealt with in this proposal.

7.4. Animal Welfare

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 and the outcome of future 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 help to inform future policy initiatives in this area. The OIE has also identified aquaculture as a priority issue to be addressed within the scope of its new animal welfare initiative and a specific OIE *ad hoc* group has been established to prepare guidelines on the welfare of farmed fish.

The Commission is committed to monitoring and taking into account the outcome of these various international discussions, stakeholder views and ongoing scientific advances in the context of formulating integrated and balanced measures to improve the welfare of farmed fish. However, in view of the afore-mentioned ongoing processes it could be premature for the Commission to undertake specific initiatives on this issue at this moment in time.

7.5. Third countries and developing countries

There is a significant import of fish, molluscs and crustaceans into the European Union. This proposal does not affect import of fisheries products originating from wild catch of fish or crustaceans intended for human consumption (see Article 1 Scope), as it only regulates import of aquaculture animals and certain products thereof.

It is important to emphasise that the placing on the market provisions, and consequently the import provisions, only affects species known to be susceptible and known carrier species of the listed diseases.

The existing provisions relating to third countries will in principle remain unchanged, with respect to animal health provisions for fish and molluscs (see points 7.5.1 - 7.5.3). With respect to crustaceans, the proposal will result in harmonised animal health provisions with respect to import from third countries. Today, no such provisions exist.

The import of shrimps and prawns from third countries raised from 8000 tonnes in 2001 to 19000 tonnes in 2003. The countries exporting more than 100 tonnes shrimps and prawns per year are; Morocco, Bangladesh, Greenland, Tunisia, Algeria, Malaysia, Surinam, Ivory Coast, India, Croatia, Greenland, Thailand, Pakistan, and China. Most shrimps and prawns are imported as processed products for human consumption. These products will not be affected by the new proposal. The only commodities that will be affected are live shrimps and prawns imported for farming purposes. Having regard to the information gathered from the exporting third countries during Community inspections, the export of live shrimps and prawns for farming in the Community is negligible.

Lobsters and crayfish are not susceptible to any of the diseases listed in Annex III of the proposal, nor known to be carriers of these diseases. Import of lobsters and crayfish will therefore not be affected by this proposal.

Consequently this proposal will not have significant negative effect on third countries, including developing countries.

7.5.1. Aquaculture animals and products thereof for human consumption

Where aquaculture animals and products thereof are imported for the purpose of human consumption *without further* processing in the Community (for example bleeding or gutting/evisceration, of fish which produces waste or by-products which could cause a risk of spreading diseases), no specific animal health rules should apply (see Article 18), provided the consignment complies with the provisions for packaging and labelling laid down in Regulation EC No 853/2004.

Where aquaculture animals and products thereof are imported for the *purpose of further processing* in the Community (for example bleeding or gutting/evisceration, of fish which produces waste or by-products which could cause a risk of spreading diseases) before human consumption, the general current provisions implemented by Commission Decisions 2003/804/EC and 2003/858/EC will be maintained. These provisions are in line with the OIE Standards and have been notified to World Trade Organisation (WTO).

Import of aquaculture animals and products thereof for the purpose of human consumption should be authorised from third countries approved for export pursuant Chapter III of Regulation EC No 854/2004. Consequently, third countries exporting aquaculture animals for the purpose of human consumption solely should not be “listed” pursuant to this Directive in addition to Regulation EC No 854/2004.

7.5.2. Live aquaculture animals for further farming or restocking purposes

The import of live fish, molluscs and crustaceans for farming or restocking purposes (does not include ornamental aquatic animals) in the Community is limited.

With respect to import of live aquaculture animals for further farming purposes, it is proposed to maintain the principle that the animals should originate from a third country that is "Listed", i.e. the animal health situation, the powers of the competent authority, the legislation etc have been assessed and found to provide equivalent animal health guarantees applicable to the placing on the market of Community animals.

The current animal health provisions applicable to fish and molluscs implemented by Decisions 2003/804/EC and 2003/858/EC will remain in force. However, the proposal will, due to the fact that it is proposed to reduce the number of listed fish and mollusc disease, reduce existing trade barriers between third countries and the EU. In addition, the principal change in the provisions related to non-susceptible species (see Article 17), will further reduce existing trade barriers. The said Decisions will be amended accordingly.

As no current import rules with respect to crustaceans for farming are in place, this would theoretically affect third countries. However, as stated previously, the import of live shrimps and prawns for further farming is considered negligible, and consequently the impact on third countries will be negligible.

7.5.3. Ornamental aquatic animals

There is a significant import of ornamental aquatic animals into the Community, mainly fish. Some species of ornamental aquatic animals are susceptible to one or more of the diseases referred to in Annex III of the proposal. However, when ornamental aquatic animals are kept in are held in pet-shops, in commercial aquaria, or in garden centre ponds, without direct contact to natural waters in the Community or equipped with effluent treatment systems, they pose a negligible risk to Community aquaculture and wild stock. Consequently, the proposal does not foresee any special animal health provisions for import of ornamental aquatic animals where are kept under such conditions.

On the other hand as some ornamental aquatic animals (in particular carps and koi-carps) can be held under conditions where any disease they carry can be transmitted to Community aquaculture animals or wild stocks with sever impact. In such cases, it is necessary to safeguard Community aquaculture and wild stocks, and the proposal provides for special import conditions to be laid down. Import conditions for such ornamental animals are already included in Decision 2003/858/EC, and the proposal will therefore not result in any new import constrains.

8. CONSULTATIONS

This project was initiated in 2000. Since then numerous consultations have been held.

8.1. Private experts

Private experts with special competence in aquatic animal diseases which have been consulted:

Name	Country	Expertise	Remarks
N.J. Olesen	DK	head of Community reference laboratory for fish diseases	
F. Berthe	F	head of Community reference laboratory for mollusc diseases	Member of the OIE Aquatic Animal Health Commission
J. Castric	F	Fish diseases	
H.J. Schlotfeldt	D	Fish diseases	
F. Geoghegan	IRL	Fish and mollusc diseases	
G. Bovo	It	Fish diseases	
O. Haen	NL	Fish diseases	
T. Håstein	NOR	Fish, mollusc and crustacean diseases	Former President of the OIE Aquatic Animal Health Commission
A. Figuareas	ES	Mollusc diseases	
U.P. Wichard	S	Fish diseases	
R. Stagg	UK	Fish diseases	
B. Hill	UK	Fish, mollusc and crustacean diseases	Member of the OIE Aquatic Animal Health Commission
J.R. Bonami	F	Crustacean diseases	

8.2. Stakeholders

Stakeholder representatives have been invited as experts to the initial meetings held with private experts in 2000 and 2001. These were N. Yonge and W. Crowe (Federation of European Fish Producers) and D. McLeod (European Mollusc Producers Association).

3 written consultations with the industry took place in 2000 and 2001 via the Advisory Committee on Fisheries and Aquaculture (ACFA), a Committee under the responsibility of DG Fish. In this committee the following organisations are present:

– Federation of European Fish 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

– NGO for environment

Developments in the project have been presented regularly in ACFA WG2 (Aquaculture) during the whole project.

3 bilateral meetings with Federation of European Fish Producers have been held during 2004, due to the fact that the major changes compared to the existing legislation, will affect the fish farmers and not the mollusc farmers.

1 bilateral meeting with EMPA/AEPM has been held. The meeting was schedule for 2004, but was postponed to January 2005 on the request of EMPA/AEPM.

2 Stakeholder consultations were in addition held in September and December 2004. To these consultations, representatives for all organisations represented in ACFA WG 2 (see above), as well as representatives from the ornamental industry, were invited.

8.3. Member States

At the beginning of this project all Member States and EEA/EFTA states were invited to submit their view on the existing legislations and any proposals they would have for a future legislation. When the project reached a stage where a skeleton for a future Directive could be presented, the Member States (15+10) and EEA/EFTA States (2) were invited to Working group meetings where the skeleton were discussed and any comments welcomed. Three working group meetings were held in 2004.

8.4. Summary of consultations held

	2000	2001	2002	2003	2004	2005	Total
Meetings with private experts	27-28 Sept 15 Oct	23-24 Jan 21-22 Feb 13-14 Mar 21-22 May 7-8 June		25-28 Aug	6 May		**9**
Meetings with all industry in WG Aquaculture of ACFC (under DG Fish)		21 June 30 Oct	5 Mar 1 June 7 Nov	13 Mar 25 June 24 Nov	22 Apr 2 July 30 Nov	11 Feb	**12**
Stakeholder consultation	Written consultations				21 Sept 2 Dec		**2**
Bilateral meetings with FEAP			22 Jan		24 Jan 21 Apr		**3**
Bilateral meetings with EMPA						6 Jan	**1**
WG meetings with MS	Written consultation				9 Jan 7 May 1 Dec		**3**
SUM	**2**	**7**	**4**	**4**	**11**	**2**	**30**

PART II
FINANCIAL IMPACT ASSESSMENT

Proposal for an updated EU aquatic animal health legislation

1. INTRODUCTION

This part of the document concerns an assessment of the potential economic impact on the Community budget related to the implementation of the proposal from the Commission 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, if adopted in accordance with the attached proposal which will replace Council Directives 91/67/EEC, 93/53/EEC and 95/70/EC.

2. THE EXISTING LEGILSATION – ECONIMIC IMPACT ON COMMUNITY BUDGET

The economic impact to Community budget of the existing legislation (i.e. Council Directives 91/67//EEC, 93/53/EEC and 95/70/EC is limited to four areas.

2.1. Human resources

It takes 1 A staff (100%) to handle the aquatic animal health file in general (trade, import, disease control, OIE-coordination etc). In 2005 figures, this is estimated to be € 108000 per year.

2.2. Other administrative expenditure

To manage, update the existing legislation taking into account the scientific development in the field covered and the disease situation in the Community, and to hold, on average, 2 working group meetings with Member States each year, in order to prepare the Commission legislative proposals. In 2005 figures, this is estimated to be € 50000 per year.

2.3. Community reference laboratories

Currently there are two Community reference laboratories receiving financial support under the Community budget, one for fish diseases and the other for mollusc diseases. These two laboratories cover 11 diseases. The financial contribution for 2005 is scheduled to be € 240000.

2.4. Financial contributions for disease control actions

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). Disease control actions for these diseases are currently eligible for a Community financial contribution under Council Regulation (EC) No 2792/1999 of 17 December 1999 laying down the detailed rules and arrangements regarding Community structural assistance in the fisheries sector, solely.

However, no financial contributions have been expended under this legislation, since these fish diseases where made eligible for funding.

3. THE PROPOSAL – ECONIMIC IMPACT ON COMMUNITY BUDGET

Although the proposal to a large extent contains elements and requirements already found in one or more of the 3 existing Directives, some new elements and requirements are proposed that will have administrative and economic impacts in the Member States and industry. These are authorisation of farms (Article 4 of the proposal) and risk based animal health surveillance (Article 10 of the proposal), and will not be dealt with in this impact assessment.

The economic impact of the proposal on the Community budget is expected to be limited and should not entail significant additional costs for the Community budget, compared to the costs resulting from the present legislation.

3.1. Human resources

There will be no changes in the human resources needed.

3.2. Other administrative expenditure

In the period between the adoption of the proposal and its entering into force, it will be necessary to arrange a number of working group meetings with Member States and stakeholders, the latter normally without any additional expenses on Community budget. The number of working groups which may be required is difficult to determine, as this will depend on the complexity of the items, and the discussions between the Member States. However, it is *estimated* that during the four transitional years following the entry into force of the proposal, at least 4 working group should be held each year and then the normal frequency of 2 meetings each year would be sufficient. This will cost € 100,000 for the first four years and then € 50,000 for the following years.

After the proposal enters into force FVO inspections of Member States' implementation will be necessary in 2008 and 2009 (13/14 each year). Therefore it can be assumed that for the years n[2] and n+1, the impact will be € 87,500 annually. After that, it is foreseen that an inspection frequency of one inspection every 5 years (on average) to each Member State, resulting in 5 inspections per year would be required, giving an impact of € 35,000 for the years n+3 and the following years.

It is proposed that only third countries exporting live aquaculture animals for further farming or restocking in the Community must be listed for aquatic animal health reasons. However the third countries must be "assessed", whereby a risk based approach could be taken on deciding whether an inspection is necessary or if a document assessment is sufficient prior to listing. This allows making use of exiting lists in Decisions 2003/804/EC and 2003/858/EC. Inspection by the FVO will therefore not be compulsory prior to listing. Where such inspections are necessary, animal health inspections should as far as possible be combined with "fishery products" and "live bivalve mollusc" public health inspections pursuant to Article 11 of Regulation (EC) No 854/2004.

3.3. Community reference laboratories

The proposal fixes the number of Community reference laboratories necessary. However, in the future, the Community reference laboratory/laboratories will as a consequence of the proposal be responsible for 16 diseases, compared to the current 11. The financial contribution may therefore increase from the current expenditure of € 240,000. If calculated per disease the future expenditure would be € 349,000 per year.

3.4. Financial contributions for disease control actions

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

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

In the proposal, compulsory slaughter/stamping out will only be required under Community rules in relation to outbreaks of diseases that are considered exotic to the Community. The likelihood of introduction and occurrence of an exotic disease is considered low taking into account the provisions of the proposal.

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[2] N = year of entry into force of the proposed Directive.

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 a Member State so requests.

If an exotic disease should 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, as the allocation of funds for the eradication of these diseases are made within the Operational Programmes set up by Member States in accordance with Title III of the European Fisheries Fund. The budget of these operational programmes is fixed by the Council at the beginning of the programming period.

In the interest of Member States, it would be useful to assess the financial impact of such eradication under their Operational Programmes. However, the costs related to the eradication measures are difficult to estimate, as there is limited experience in the Community of the stamping out policy involving economic compensation in aquaculture. In the court case after the outbreaks of ISA in UK and Ireland, one company owning 5 of the 13 infected farms claimed total losses in the region of 20-25 million €. Sweden paid under national legislation compensation in relation to 4 cases of VHS in 1998 a total of 1.5 million SEK (165,000 €) over a period of 3 years. In contrast to the Community figures on ISA, the Norwegian Government has calculated that the Norwegian fish farming industry's losses due to ISA in 2000, a year Norway experienced 17 outbreaks and disease control was done in accordance with Council Directive 93/53/EEC, were approximately 10 million €.

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

4. OTHER ISSUES

4.1. Delegation of granting disease free status to Member State level

It has been a long outstanding request from a majority of Member States to simplify the procedures for achieving the status as declared disease free zones or farms. In the proposal it is proposed to delegate to the Member State level the granting of the status of declared disease free zones and compartment.

The procedure today, is that the local/regional veterinary administration completes and signs a checklist to verify that the provisions of the Directive, in particular sampling, surveillance and testing are fulfilled. Then, the contents of this checklist is confirmed and signed by the central veterinary administration in the Member State, before forwarding the application for approval to the Commission. The Commissions services distribute the application to all Member States (in the Standing Committee of the Food Chain and Animal Health) for comments. Then, normally 1-2 months after, the Commission services present a draft Commission Decision for including the farm/zone in the list of approved farms and zones. This whole process takes between 6 and 12 months to complete.

This proposal will reduce the workload of the Commission services. Between the consolidation of the Decisions for disease free farms and zones in April 2002 and October 2004, 12 Commission Decisions have been adopted for the purpose of approving individual farms and zones and programs, representing 103 applications. This causes delays for farmers/producers in the Member States and causes an unnecessary burden on the Commission.

If one estimates 2-5 man-days per Decision at desk office level in DG SANCO (depending on the complicity of the application and number of applications included in each Decisions [an average of 9 per year]), it represents 5-10% of a full position.

In addition there is the necessary work in relation to interservice consultation procedures, adoption and translation, mainly concerning other DG's.

4.2. Making use of electronic communication and publications

There is a general approach in the proposal for more use of electronic communication and exchange of information, compared with the current situation.

There are no legal requirements in the proposal for regular or annual status reports to the Commission.

Use of electronic reporting is already required, by means of TRACES for recording and reporting the movements of animals, and ADNS for reporting disease outbreaks.

Furthermore, as presented in point 4.1, the delegation to the Member States of approving individual farms/compartments and zones free of disease, will reduce the need for paper publications in the Official Journal.

It is planned to set up a common entry point on the Commissions Animal Health Web-site, where links to Member States Web-sites will be established. In these national Web-sites, the Member States will make available the same information which is presented in the Official Journal today, mainly listing of declared disease free farms and zones. The current listings (Commission Decisions 1994/722/EEC, 2002/300/EC, 2002/308/EC and 2003/634/EC) comprise 30 pages in the Official Journal. Decision 2002/308/EC (comprising 20 pages) is normally updated and republished 2-3 times a year. These regular publications will be superfluous according to the proposal.

ANNEX

Aquaculture in EU

Part I
Importance of species in EU (25) – Data from Euro Stat

Top 30 species sorted by quantity (average quantity per year 1999-2002)

Rank	Species	Group	Quantity per year (metric tonnes)
1	Blue mussel - Mytilus edulis	Mollusc	421.474
2	Rainbow trout - Salmo gairdneri	Fish	233.728
3	Atlantic salmon - Salmo salar	Fish	156.182
4	Mediterranean mussel - Mytilus galloprovinciali	Mollusc	129.959
5	Pacific cupped oyster - Crassostrea gigas	Mollusc	128.600
6	Common carp - Cyprinus carpio	Fish	66.711
7	Gilthead seabream - Sparus aurata	Fish	57.968
8	Japanese(=Manila)clam - Venerupis japonica	Mollusc	52.120
9	Seabass - Dicentrarchus labrax	Fish	39.489
10	European eel - Anguilla anguilla	Fish	9.841
11	Freshwater fishes nei - Osteichthyes	Fish	8.309
12	European flat oyster - Ostrea edulis	Mollusc	6.230
13	Turbot - Psetta maxima	Fish	4.695
14	Grooved carpet shell - Tapes decussatus	Mollusc	4.118
15	Tuna-like fishes nei - Scombroidei	Fish	4.098
16	Common cockle - Cardium edule	Mollusc	3.767
17	Sea trout - Salmo trutta	Fish	3.355
18	Cupped oysters nei - Crassostrea spp	Mollusc	3.144
19	North African catfish - Clarias lazera	Fish	2.846
20	Flathead grey mullet - Mugil cephalus	Fish	2.757
21	Roach - Rutilus rutilus	Fish	2.551
22	Silver carp - Hypophthalmichthys molit	Fish	1.840
23	Tench - Tinca tinca	Fish	1.613
24	Carpet shell - Tapes pullastra	Mollusc	1.600
25	Marine fishes nei - Osteichthyes	Fish	1.505
26	Carp - Cyprinids nei - Cyprinidae	Fish	1.498
27	Sturgeons nei - Acipenseridae	Fish	1.111
28	Bighead carp - Hypophthalmichthys nobil	Fish	880
29	Grass carp (= White amur) - Ctenopharyngodon idella	Fish	760
30	Banded carpet shell - Venerupis rhomboides	Mollusc	700

Top 30 species sorted by value (average value 1999-2002)

Rank	Species	Group	Value in 1000 €
1	Rainbow trout - Salmo gairdneri	Fish	648.363
2	Atlantic salmon - Salmo salar	Fish	495.131
3	Blue mussel - Mytilus edulis	Mollusc	281.973
4	Gilthead seabream - Sparus aurata	Fish	279.482
5	Pacific cupped oyster - Crassostrea gigas	Mollusc	233.139
6	Seabass - Dicentrarchus labrax	Fish	218.461
7	Japanese(=Manila)clam - Venerupis japonica	Mollusc	144.963
8	Common carp - Cyprinus carpio	Fish	143.745
9	Mediterranean mussel - Mytilus galloprovinciali	Mollusc	84.403
10	European eel - Anguilla anguilla	Fish	78.450
11	Tuna-like fishes nei - Scombroidei	Fish	65.336
12	Turbot - Psetta maxima	Fish	41.689
13	Grooved carpet shell - Tapes decussatus	Mollusc	35.935
14	European flat oyster - Ostrea edulis	Mollusc	24.293
15	Freshwater fishes nei - Osteichthyes	Fish	16.253
16	Sea trout - Salmo trutta	Fish	13.254
17	Carpet shell - Tapes pullastra	Mollusc	13.201
18	Flathead grey mullet - Mugil cephalus	Fish	9.495
19	Sturgeons nei - Acipenseridae	Fish	7.714
20	Marine fishes nei - Osteichthyes	Fish	7.437
21	Common cockle - Cardium edule	Mollusc	6.640
22	North African catfish - Clarias lazera	Fish	6.181
23	Roach - Rutilus rutilus	Fish	5.880
24	Cupped oysters nei - Crassostrea spp	Mollusc	4.429
25	Tench - Tinca tinca	Fish	4.206
26	Banded carpet shell - Venerupis rhomboides	Mollusc	3.284
27	Carp - Cyprinids nei - Cyprinidae	Fish	2.639
28	Brook trout - Salvelinus fontinalis	Fish	2.428
29	Chars nei - Salvelinus spp	Fish	2.395
30	Bighead carp - Hypophthalmichthys nobil	Fish	2.127

Top 30 species sorted by price 2002 figures (value in €/production in kg)

Rank	Species	Group	Value in €/kg produced
1	Noble crayfish - Astacus astacus	Crustacean	27,80
2	Signal crayfish - Pacifastacus leniusculus	Crustacean	19,20
3	Kuruma prawn - Penaeus japonicus	Crustacean	18,27
4	Danube crayfish - Astacus leptodactylus	Crustacean	17,80
5	Crayfishes - Astacus spp+ Cambarus sp	Crustacean	17,68
6	Warty venus - Venus verrucosa	Mollusc	16,60
7	Huchen - Hucho hucho	Fish	16,00
8	Tuna-like fishes nei - Scombroidei	Fish	15,94
9	Indian white prawn - Penaeus indicus	Crustacean	15,31
10	Sturgeon - Acipenser sturio	Fish	12,67
11	Common sole - Solea vulgaris	Fish	11,11
12	Atlantic halibut - Hippoglossus hippoglossu	Fish	9,67
13	Shi drum(=Corb) - Umbrina cirrosa	Fish	9,00
14	Turbot - Psetta maxima	Fish	8,88
15	Grooved carpet shell - Tapes decussatus	Mollusc	8,73
16	Soles nei - Soleidae	Fish	8,45
17	Carpet shell - Tapes pullastra	Mollusc	8,25
18	European eel - Anguilla anguilla	Fish	7,97
19	Meagre - Argyrosomus regius	Fish	7,25
20	Sturgeons nei - Acipenseridae	Fish	6,95
21	Red porgy(=Common seabr - Sparus pagrus	Fish	6,93
22	Stony sea-urchin - Paracentrotus lividus	Echinoderm ata	6,67
23	Siberian sturgeon - Acipenser baeri	Fish	6,63
24	Porgies + seabreams+ etc - Sparidae	Fish	6,31
25	Sharpsnout seabream - Diplodus puntazzo	Fish	6,16
26	Largemouth black bass - Micropterus salmoides	Fish	6,04
27	Common pandora - Pagellus erythrinus	Fish	5,86
28	Pike-perch - Stizostedion lucioperca	Fish	5,70
29	Seabass - Dicentrarchus labrax	Fish	5,53
30	Red (=Blackspot) seabream - Pagellus bogaraveo	Fish	5,50

Part II
Aquaculture production in EU (25) and EFTA/EEA (2) – Data from EuroStat

Rank species	BE	CZ	DK	DE	EE	GR	ES	FR	IE	IT	CY	LV	LT	HU	MT	NL	AT	PL	PT	SL	SK	FI	SW	UK	ICE	NOR	SUM
Atlantic salmon - Salmo salar			15			28	150	338	23231															145609	1471	465249	**636091**
Blue mussel - Mytilus edulis				8018			201025	55000	31703							45061							1382	17580		2467	**362236**
Rainbow trout - Salmo gairdneri	400	666	28061	24184	210	2271	32442	45248	1693	33770	80	7	21	19		43	1738	10709	1309	891	634	14894	3545	14319	248	83424	**300826**
Mediterranean mussel - Mytilus galloprovinciali						21792		18000		99219										83							**139094**
Pacific cupped oyster - Crassostrea gigas				85			591	107000	5444										249					796			**114165**
Common carp - Cyprinus carpio	800	16596		11373	42	135		5200		232		406	1676	7735			303	19000		208	154						**63860**
Gilthead seabream - Sparus aurata						37944	11183	1100		4954	1266				1066				1854	12							**59379**
Japanese(=Manila)clam - Venerupis japonica							422	1000	100	41139														36			**42697**
Seabass - Dicentrarchus labrax				40		23860	3338	2746		7176	442				50				808	25					40		**38525**
Freshwater fishes nei - Osteichthyes		384		6000		137		610		276			1	470			5	900			3	38					**8824**
European eel - Anguilla anguilla		1	1166	150	5	433	554			1699				36		3868			4				167				**8083**
European flat oyster - Ostrea edulis						10	4565	1600	280							75								132			**6662**
Turbot - Psetta maxima			1	2			3847	728	50	3									386					45	9		**5071**
Sea trout - Salmo trutta			2455				87	2100		170							52			8		7	3	162			**5044**
Tuna-like fishes nei - Scombroidei							4917																				**4917**
Grooved carpet shell - Tapes decussatus							54	1000											3174								**4228**
Cupped oysters nei - Crassostrea spp										302						2789											**3091**
Roach - Rutilus rutilus								2300												2							**2302**
Carp - Cyprinids nei - Cyprinidae								360									5	1500									**1865**
Common cockle - Cardium edule							3	1600											41					105			**1749**
Sturgeons nei - Acipenseridae										1281				13				300									**1594**
Silver carp - Hypophthalmichthys molit														1516			1			22	11						**1550**
Arctic char - Salvelinus alpinus			42														1							7	1479		**1529**
Atlantic cod - Gadus morhua																									192	1253	**1445**
Tench - Tinca tinca		186					100	1100				1		6			6				1						**1400**
Clams nei - Bivalvia								1300																			**1300**
Finfishes nei - Osteichthyes																										1087	**1087**
Bighead carp - Hypophthalmichthys nobil		750					1							277			1										**1029**
Marine fishes nei - Osteichthyes						924													6								**930**
Grass carp (= White amur) - Ctenopharyngodon idella		291											3	470			5			11	1						**781**
Flathead grey mullet - Mugil cephalus						298	6			254																	**558**
Salmonoids nei - Salmonoidei (								507									11										**518**
Wels (=Som)catfish - Silurus glanis		60						360						87			2			2							**511**
Sea mussels nei - Mytilidae																			424								**424**
Atlantic halibut - Hippoglossus hippoglossu																								187	120		**307**
Torpedo-shaped catfish - Clarias spp																		300									**300**
Brook trout - Salvelinus fontinalis		77	10														188			19	5						**299**
Pollan(=Powan) - Coregonus lavaretus		42																				193					**235**

Tilapias nei - Oreochromis+Saratherodon	150						40																						**190**
Mullets nei - Mugilidae							175												4										**179**
Flat and cupped oysters - Ostreidae																			172										**172**
Northern pike - Esox lucius		91										4	9	40				2			2	1							**149**
Siberian sturgeon - Acipenser baeri								112																					**112**
Common scallop - Pecten maximus									67																39				**106**
Palaemonid shrimps - Palaemonidae							87																						**87**
Indian white prawn - Penaeus indicus											77																		**77**
Kuruma prawn - Penaeus japonicus						4	39	20		13																			**76**
Pike-perch - Stizostedion lucioperca		42												27				2			2								**73**
Goldfish - Carassius auratus										38												18							**56**
Carpet shell - Tapes pullastra							50																						**50**
Porgies + seabreams+ etc - Sparidae										49																			**49**
Soles nei - Soleidae							38																						**38**
Crayfishes - Astacus spp+ Cambarus sp								20										1						6					**27**
European perch - Perca fluviatilis		24																											**24**
Common pandora - Pagellus erythrinus						19																							**19**
Queen scallop - Chlamys opercularis																									19				**19**
Octopuses - Octopus spp							14																						**14**
Crucian carp - Carassius carassius												9									1								**10**
Common sole - Solea vulgaris							4												6										**10**
Venus clams - Veneridae						9																							**9**
Whitefishes nei - Coregonus spp																		9											**9**
Drums - Sciaena spp							5																						**5**
Red porgy(=Common seabr - Sparus pagrus											5																		**5**
Sturgeon - Acipenser sturio												3																	**3**
Red (=Blackspot) seabream - Pagellus bogaraveo							2																						**2**
Grayling - Thymallus thymallus																					2								**2**
Warty venus - Venus verrucosa							2																						**2**
Shi drum(=Corb) - Umbrina cirrosa											1																		**1**
Orfe(=Ide) - Leuciscus(=Idus)idus (tons																						1							**1**
Huchen - Hucho hucho																		1											**1**
Signal crayfish - Pacifastacus leniusculus							1																						**1**
SUM Country	**1350**	**19210**	**31750**	**49852**	**257**	**87864**	**263742**	**249349**	**62568**	**190575**	**1871**	**430**	**1710**	**10696**	**1116**	**51836**	**2333**	**32709**	**8437**	**1290**	**829**	**15132**	**5103**	**179036**		**3559**	**553480**	**1826084**	**1826084**
Rank	**21**	**12**	**11**	**9**	**26**	**6**	**2**	**3**	**7**	**4**	**19**	**25**	**20**	**14**	**23**	**8**	**18**	**10**	**15**	**22**	**24**	**13**	**16**	**5**		**17**	**1**		

Part III
Structure of EU (25) + EFTA/EEA (2) aquaculture

Data from EuroStat and survey done by Community Reference Laboratories for fish and mollusc diseases

Member State	Fish farming												Mollusc farming		
	No of farmsrelated to size (tons production)				No of farms related to species							Comments	No of farms hatcheries)	No of farms or farming areas	Comments
	<5	5>100	>100	Total	Salmonides	Carps	Eel	Flatfish	Bream Bass	Other Marine	Other Fresh-water				
Austria	339	47	0	386	172	150					64		0	0	No production
Belgium	76	27	1	131	110	10					9		1	1 farm	The farms is the same as the hatchery
Czech Republic	10	20	2	176	82	54	1				32		0	0	No production
Cyprus				17	8				9				0	0	No production
Denmark	30	225	169	435	401	3	12	4			6		1	3 farms	
Estonia	19	10	1	30	14	4	1						0	0	No production
Finland		370		383	373	2	1				5		0	0	No production
France				ND									10	4113 farming areas	
Germany	2680	620	36	10788	4.135	5.897	11			155	590		0	1 farm	Mytilus harvested from wild beds
Greece	31	94	295	435	94	12	10	0	308		11		ND	566 farms	
Hungary		150	6	157	3	150	1				3		0	0	No production
Ireland	18	29	24	72	70	1		1					8	71 farming areas with 473 farms	
Italy				945	589	ND	74		79		203		3	436	
Latvia	51	5		62	6								0	0	No production
Lithuania		14	6	20		219							0	0	No production
Malta				11									0	0	No production
Poland				450	155	ND							0	0	No production

Portugal	6	21	4	37	36	1							ND	ND	
Slovakia				ND									0	0	No production
Slovenia	140	60	2	203	43	30							0	2 farms	
Spain	38	99	100	483	177	3	3	30	83	45	142		>10	133 farming areas	
Sweden	35	35	70	174	144	1	2				3		0	0	No production
The Netherlands				>180	46	2	78	1	1		55		1	200 farms	
United Kingdom	156	195	220	599	987	176	1	18	1	26	11	987 represents sites	5	810 farms	
Iceland	8	27	5	50									ND	ND	
Norway				1.692	1.148		21	138		413			3	400 farms	
Total	17.916 does not include France and Slovakia				8.793	6.715	216	192	481	639	1.134		39	2952 farms + 4113 farming areas in France	No data on number of farms/operators in the 4113 farming areas in France