# Directive 88/2006: European Union animal health requirements for aquaculture animals and products thereof

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**Alday-Sanz, V.** 2009. Directive 88/2006: European Union animal health requirements for aquaculture animals and products thereof. In M.G. Bondad-Reantaso, J.R. Arthur and R.P. Subasinghe (eds). Strengthening aquaculture health management in Bosnia and Herzegovina. *FAO Fisheries and Aquaculture Technical Paper.* No. 524. Rome, FAO. pp 17–25.

**ABSTRACT**

The European Union animal health legislation concerning aquaculture animals and products has been updated. Directives 91/67/EEC, 93/53/EEC and 95/70/EC have been replaced by Directive 88/2006, which came into effect on 1 July 2008. This new directive establishes the animal health requirements for the placing on the market, importation and transit of aquaculture animals and their products; the minimum measures to prevent diseases in aquaculture animals; and the minimum measures to be taken in response to suspected or established cases of certain diseases in these animals. The animals concerned are fish, molluscs and crustaceans and their products, not including ornamental animals bred in an aquarium not intended for sale, wild animals introduced directly into the food chain and animals intended for the production of fishmeal, fish oils and similar products. This directive states the need to designate Community Reference Laboratories for each of the listed diseases and National Reference Laboratories for each member country and establishes the functions and responsibilities of these laboratories.

## INTRODUCTION

Aquaculture has been recognized as an important economic activity in the European Union (EU) and an alternative to capture fisheries. Diseases have become one of the most important constraints to growth of the aquaculture sector and at the same time they represent a significant threat to wild populations. For this reason, the EU has adopted specific legislation on aquatic animal health in order to control and reduce the impact of diseases in farmed and wild populations and to prevent and effectively respond to new diseases that threaten animal health. Such measures are expected to reduce the constraints that diseases impose on the sustainability of animal production and improve the preservation of natural ecosystems.

The Community animal health legislation concerning aquaculture animals and their products has been updated. Directives 91/67/EEC, 93/53/EEC and 95/70/EC have been replaced by Directive 88/2006, which was implemented on 1 July 2008.[1] This new directive merges the three previous directives into a single one. The previous directives mainly took into account the farming of salmon, trout and oysters. Since they were enacted, the aquaculture industry has developed significantly, with additional species being cultured and new types of farming practices coming into use. Since the adoption of the first directive on this subject in 1991, the EU has ratified the Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) of the World Trade Organization (WTO). Therefore, this new directive takes into account the *Aquatic Animal Health Code* (OIE, 2008) and the *Manual of Diagnostic Tests for Aquatic Animals* (OIE, 2006) of the World Organisation for Animal Health (OIE). But the most significant changes in the new directive are related to a new strategy for animal health surveillance based on risk analysis, with emphasis on the traceability of all animal movements and considering especially the role of wild aquatic populations in spreading diseases. There is also a change in the way that diseases are listed, the new directive dividing them into exotic and non-exotic diseases depending on whether or not the diseases of interest have been reported as occurring within the EU. This paper summarizes the main issues raised in Directive 88/2006 of the EU.

## DEFINITIONS

There are a number of technical definitions that apply to this directive:

- *Aquaculture animal:* any aquatic animal at all its life stages, including eggs and sperm (gametes).
- *Ornamental aquatic animal:* any aquatic animal, which is kept, reared or placed on the market for ornamental purposes only.
- *"Placing on the market":* the sale, including offering for sale or any other form of transfer, whether free of charge or not, and any form of movement of aquaculture animals.
- *Compartment:* one or more farms under a common biosecurity system containing an aquatic animal population with a distinct health status with respect to a specific disease.
- *Zone:* a precise geographical area where the water body is naturally or artificially isolated, preventing the migration of wild animals.
- *Disease:* a clinical or non-clinical infection with one or more aetiological agents.
- *Infection:* the presence of a multiplying or developing or latent disease agent in or on a host.
- *Emerging diseases:* newly identified serious diseases or listed diseases in a new host species.
- *Susceptible species:* any species in which infection has been demonstrated by natural cases or by experimental infection that mimics the natural pathways.
- *Vector*: a species that is not susceptible to a disease but which is capable of spreading infection by conveying pathogens from one host to another (living mechanical vector).

## AQUACULTURE PRODUCTION BUSINESS AND AUTHORIZED PROCESSING ESTABLISHMENTS

All farms rearing or keeping fish or molluscs susceptible to listed diseases must be registered by the official service and keep records of mortality and movement of animals into and out of the farm. In case of suspicion of outbreak, the farm must be

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

investigated in order to confirm the presence of a pathogen and movements must be forbidden until the disease is ruled out or eradicated. An early detection system can reduce the spread of disease if strict restriction of animal movements is applied in order to reduce the transfer of pathogens and emergence of disease in other territories.

## INTRODUCTION OF AQUACULTURE ANIMALS AND PRODUCTS THEREOF INTO THE COMMUNITY FROM THIRD COUNTRIES

Only the countries listed or approved by the EU are allowed to export into the Community. To obtain that approval, the third country needs to demonstrate to the EU that the competent authority (CA) provides appropriate guarantees as regards compliance with the EU legislation. An inspection by EU may be required to confirm this.

The different issues that are taken into account are:

- The legislation of the third country.
- The organization of the CA and its inspection services, the powers of these services, the supervision to which they are subjected and the means at their disposal, including staff capacity to apply their legislation effectively.
- Health requirements in force that are applied to the production, manufacture, handling, storage and dispatch of live aquaculture animals intended for the EU.
- The experience of marketing from the third country and the results of any import controls carried out.
- The results of any EU assessment or the report submitted by the CAs of the third country on any inspections carried out.
- The health status of the farmed and wild aquatic animals in the third country, especially with regard to exotic diseases, and any aspect of general health that may pose a risk to the aquatic animal health in the Community.
- The regularity, speed and accuracy with which the third country supplies information on the existence of infectious diseases in its territory, particularly diseases listed by the OIE.
- The rules on the prevention and control of aquatic animal diseases in force in the third country and their implementation, including rules on imports from other countries.

## DISEASE STATUS

The health status of a country, aquaculture zones or compartments will be determined by the presence or absence of the listed pathogen in its aquaculture stocks and wild animals. The listed pathogens in Directive 88/2006 are given in Table 1. These have been divided as exotic or non-exotic diseases depending on whether or not they have been previously reported as occurring within the EU.

## DISEASE-FREE STATUS

A country shall be directly declared disease-free of one of more diseases if:

- none of the species susceptible to the disease in question is present in the territory, or
- the pathogen is not able to survive in the country and its water source.

If the susceptible species is present and the pathogen may survive in the country environment, the disease-free status may be achieved by two ways: (1) on historical grounds or (2) targeted surveillance.

- On historical grounds: a country with susceptible species, with no outbreak for at least 10 years from the time of application of disease status despite the existence of conditions that may lead to clinical expression where:
  - basic biosecurity has been in place for at least 10 years (disease is compulsorily notifiable, and there is an early detection system [recognition and communication]);

– infection is not known to be established in wild animals; and
– implementation of trade and import conditions.

- By targeted surveillance: a country where the last clinical outbreak was within 10 years before applying for disease-free status or where the infection status prior to targeted surveillance was unknown (for example because of the absence of conditions that may lead to clinical expression), may be considered disease-free if:
  – basic biosecurity is place (compulsory notification and availability of detection system); and
  – the appropriate targeted surveillance has been implemented for at least two years without detection of the agent.

When a neighbouring country or water area is not declared a disease-free zone, the country needs to establish within its territory a buffer zone. The limits of the buffer zone need to be such that they prevent the passive introduction of the disease.

TABLE 1
**European Union listed diseases, Directive 88/2006**

| | | **Exotic diseases** |
|---|---|---|
| | **Disease** | **Susceptible species** |
| Fish | Epizootic hematopoietic necrosis (EHN) | Perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*) |
| | Epizootic ulcerative syndrome (EUS) | Members of the genera *Channa, Mastacembelus, Puntius, Trichogaster, Catla, Mugil* and *Labeo*. |
| Molluscs | Infection with *Bonamia exitiosa* | Chilean flat oyster (*Ostrea chilensis*), Australian mud oyster (*O. angasi*) |
| | Infection with *Perkinsus marinus* | Pacific oyster (*Crassostrea gigas*), Eastern oyster (*C. virginica*) |
| | Infection with *Microcytos mackini* | Pacific oyster (*C. gigas*), Eastern oyster (*C. virginica*), Olympia oyster (*Ostrea conchaphila*), European flat oyster (*O. edulis*) |
| Crustaceans | Taura syndrome | Gulf white shrimp (*Penaeus setiferus*), Pacific blue shrimp (*P. stylirostris*), Pacific white shrimp (*P. vannamei*) |
| | Yellowhead disease | Gulf brown shrimp (*P. aztecus*), Gulf pink shrimp (*P. duorarum*), Kuruma prawn (*P. japonicus*), black tiger shrimp (*P. monodon*), Gulf white shrimp (*P. setiferus*), Pacific blue shrimp (*P. stylirostris*), Pacific white shrimp (*P. vannamei*) |
| | | **Non-exotic diseases** |
| | **Disease** | **Susceptible species** |
| Fish | Spring viremia of carp (SVC) | Bighead carp (*Aristichthys nobilis*), goldfish (*Carassius auratus*), Crucian carp (*C. carassius*), grass carp (*Ctenopharyngodon idellus*), common carp and koi carp (*Cyprinus carpio*), silver carp (*Hypophthalmichthys molitrix*), sheatfish (*Silurus glanis*), tench (*Tinca tinca*) |
| | Viral hemorrhagic septicemia (VHS) | Herring (*Clupea* spp.), whitefish (*Coregonus* sp.), pike (*Esox lucius*), haddock (*Gadus aeglefinus*), Pacific cod (*G. macrocephalus*), Atlantic cod (*G. morhua*), Pacific salmon (*Oncorhynchus* spp.) rainbow trout (*O. mykiss*), rockling (*Onos mustelus*), brown trout (*Salmo trutta*), turbot (*Scophthalmus maximus*), sprat (*Sprattus sprattus*), grayling (*Thymallus thymallus*) |
| | Infectious hematopoietic necrosis (IHN) | Chum salmon (*O. keta*), coho salmon (*O. kisutch*), Masou salmon (*O. masou*), rainbow or steelhead trout (*O. mykiss*), sockeye salmon (*O. nerka*), pink salmon (O. *rhodurus*), chinook salmon (*O. tshawytscha*), Atlantic salmon (*Salmo salar*) |
| | Koi herpes virus (KHV) | Common carp and koi carp (*Cyprinus carpio*). |
| | Infectious salmon anemia (ISA) | Rainbow trout (*O. mykiss*), Atlantic salmon (*S. salar*), brown and sea trout (*S. trutta*) |
| Molluscs | Infection with *Martelia refringens* | Australian mud oyster (*O. angasi*), Chilean flat oyster (*O. chilensis*), European flat oyster (*O. edulis*), Argentinian oyster (*O. puelchana*), blue mussel (*Mytilus edulis*), Mediterranean mussel (*M. galloprovincialis*) |
| | Infection with *Bonamia ostrea* | Australian mud oyster (*O. angasi*), Chilean flat oyster (*O. chilensis*), Olympia flat oyster (*O. conchaphila*), Asiatic oyster (*O. denselamellosa*), European flat oyster (*O. edulis*), Argentinian oyster (*O. puelchana*) |
| Crustaceans | White spot disease | All decapod crustaceans (Order Decapoda) |

### Maintenance of disease-free status

A declared disease-free country may stop surveillance as long as the conditions conducive to clinical expression exist and the other provisions are implemented. If the conditions conducive to clinical expression do not exist, surveillance must continue to confirm the absence of the pathogen.

### Suspension of disease-free status

When there is suspicion of loss of disease-free status, trade with susceptible species and vectors needs to be suspended with countries of higher health status. If the infection is confirmed, the disease-free status will be withdrawn. In order to restore the disease-free status, targeted surveillance needs to be carried out to confirm the absence of the pathogen.

The disease status of a country will determine the possibility of trade with the EU (see Table 2). Countries are classified into categories depending whether they are disease-free (Category I), under a surveillance programme (Category II), undetermined (Category III), under an eradication programme (Category IV) or infected (Category V). As a general rule, countries (zones or compartments) can introduce animals from countries with a higher sanitary status than themselves and can dispatch animals to countries with lower sanitary status.

## NOTIFICATION AND MINIMUM MEASURES FOR CONTROL OF DISEASES OF AQUATIC ANIMALS

Any suspicion or confirmation of the presence of a listed disease or an increase in mortality needs to be notified at the national level. The obligation to notify is applied to any professional that is aware of the situation (such as the owner or manager), any person to accompany the animals during transportation, veterinary practitioners or aquatic animal health professionals, official veterinarians and private laboratories.

In case of suspicion of a listed disease, appropriate sample collection and submission to a designated laboratory has to be carried out. While waiting for the results, the farm/area is placed under official surveillance and no aquatic animals are allowed in or out of the facilities/area. At this point, an epizootic investigation is performed with the aims of finding out the possible origin and means of contamination, the animal movement prior to notification, the health status of other farms and the establishment of a containment area appropriate to the disease in question, including a protection zone and a surveillance zone around the area.

TABLE 2
**Health status of aquaculture zones or compartments to be considered**

| Category | Health status | May introduce animals from | Health certification | | May dispatch animals to |
|---|---|---|---|---|---|
| | | | Introduction | Dispatching | |
| I | Disease-free | Only Category I | Yes | No when dispatched to category III or V<br>Yes when dispatched to categories I, II or IV | All categories |
| II | Surveillance programme | Only Category I | Yes | No | Categories III and V |
| III | Undetermined (not known to be infected but not subject to a programme for achieving disease-free status) | Categories I, II or III | No | No | Categories III and V |
| IV | Eradication programme | Only Category I | Yes | Yes | Only Category V |
| V | Infected | All Categories | No | Yes | Only Category V |

If a listed disease is confirmed, international notification is due to the OIE, trading partners and neighboring countries potentially at risk.

The control measures that need to be established will depend on the whether the disease is an exotic or non-exotic disease, whether it is established in wild animals, and whether it is an emerging disease or a non-listed disease. These measures should be maintained until eradication has been carried out and the appropriate sampling and surveillance for the disease has been carried out with negative results.

### Control measures in case of an outbreak of an exotic disease

In the case of an outbreak of an exotic disease, the farm/area is declared infected and a containment area, including a protection and surveillance zone around the area is established. No movement of aquatic animals into, outside or within the area should be allowed. Harvesting is possible if the animals have reached commercial size, but minimizing the risk of spread of the pathogen. The removal and disposal of dead animals and animals that show no clinical signs should be done in a safe way. Fallowing after empting and cleaning and disinfection, if appropriate, should follow.

### Control measures in case of a non-exotic disease

The control measures for a non-exotic disease are similar to those for an exotic disease but with the particularity that clinically healthy animals are allowed to continue growing till harvest size if no disease outbreak appears.

### Control measures in case of a listed disease in wild aquatic animals

When wild aquatic animals are infected or suspected of being infected with an exotic or non-exotic disease, the country needs to monitor the situation and take measures to reduce and prevent further spread of the disease.

### Control measures in case of emerging diseases

The country needs to take the appropriate control measures and prevent the spread of an emerging disease and inform the Commission, trading partners, OIE and neighbouring countries. Within four weeks of reporting, it should be brought to the attention of the Standing Committee on the Food Chain and Animal Health, who will decide if the measures taken need to be extended, amended or repealed.

### Control measures in case of non-listed diseases

If a non-listed disease has a significant risk for the animal health situation of aquaculture or wild aquatic animals, a country may take measures to prevent its introduction or to control the disease as long as these do not exceed the necessary requirements.

## CONTROL PROGRAMMES: SURVEILLANCE, ERADICATION AND CONTINGENCY PLANS

Depending on the disease status, countries need to have a surveillance or an eradication programme. In any case, the country should have a contingency plan in place.

### Surveillance and eradication programmes

Countries not known to be infected but not declared disease-free need to draw up a surveillance programme for achieving disease-free status. Countries known to be infected need to draw up an eradication programme for that particular disease. Both programmes need to contain at least:

- a description of the epidemiological situation of the disease before starting the programme,
- an analysis of the estimated cost and anticipated benefits of the programme,

- the duration of the programme and the objective at the time of its completion, and
- the description of the geographical and administrative area.

Vaccination is not allowed for exotic diseases as a control measure, unless for certain exceptions or as part of an eradication plan.

### Contingency plans

Every country needs to have a contingency plan to maintain a high level of disease awareness and preparedness and to ensure environmental protection. The contingency plan should ensure:

- legal powers to implement contingency plans and put into effect successful eradication campaigns;
- access to emergency funds and financial resources in order to cover all aspects to fight diseases;
- cooperation between veterinary and environmental authorities so that they are properly coordinated. Also communication with potentially affected neighbouring areas and trade partners;
- provision of adequate resources for a rapid and effective campaign, including personnel, equipment and laboratory capacity;
- establishment of a chain of command that guarantees a rapid and effective decision-making process, including a central decision-making unit charged with the overall direction of control strategies;
- availability of an up-to-date manual with a detailed and practical description of all actions, procedures, instructions and control measures to be employed in handling exotic or emergency diseases (it is recommended that the contingency plan is updated every five years);
- availability of detailed plans for emergency vaccination if necessary;
- regular training of staff in clinical signs, epidemiological enquiry and disease control;
- identification of a place for the disposal of carcasses and animal waste in the event of disease outbreak, taking into account that it causes the minimum risk to soil, air, surface and ground waters and minimizes noise, odours and adverse effects on nature.

## COMPETENT AUTHORITIES AND LABORATORIES

There is a series of general obligations for Member States:

- Each Member State shall designate its competent authorities (CAs) and notify the Commission.
- Each Member State shall ensure effective and continuous cooperation based on the free exchange of information between CAs and any of its other authorities involved in regulating aquaculture, aquatic animals and food or feed of aquaculture origin and between CAs of the different Member States.
- Each Member State shall ensure that the CAs have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology.

The requirements, standards and functions of the three types of laboratories are described: the Community Reference Laboratory (CRL), National Reference Laboratory (NRL) and Designated Laboratories (DL).

### Community Reference Laboratory

The CRL needs to comply with some requirements and follow some standards and is responsible for certain functions. CRLs are required to:

- have suitably qualified staff (i.e. properly trained personnel) available for emergency situations occurring within the Community;

- possess the equipment and products needed to carry out the tasks assigned to it;
- have an appropriate administrative infrastructure;
- ensure that the staff respect confidentiality;
- have sufficient knowledge of international standards and practices;
- have available an updated list of substances and reagents and a list of manufacturers and suppliers; and
- take into account research activities at national and community levels.

The CRL needs to operate, be assessed and accredited in accordance with the following standards:

- EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories" ;
- EN 45002 on "General criteria for the assessment of testing laboratories" ; and
- EN 45003 on "Calibration and testing laboratory accreditation system-General requirements for operation and recognition".

The functions of the CRL are to:

- coordinate the diagnostic methods employed:
  - typing, storing, supplying strains of pathogens; and
  - supplying standard sera and other reference reagents to the NRL in order to standardize the tests and reagents.
- organize periodic ring test with national laboratories;
- retain pertinent expertise on the relevant pathogens and others for a quick differential diagnosis;
- assist in the diagnosis of outbreak by providing confirmatory diagnosis;
- facilitate the training or retraining of experts in diagnosis with a view to harmonizing diagnostic techniques;
- collaborate with the CAs from third countries where listed diseases are prevalent;
- collaborate with OIE reference laboratories with regard to exotic diseases; and
- collate and forward information on exotic and endemic diseases that are potentially emerging in Community aquaculture.

### National Reference Laboratory

Each Member State needs to designate a NRL. It may be situated in another Member State and a single laboratory may be the NRL of more than one Member State.

- The NRL shall collaborate with any laboratory in the Member State.
- Member States shall ensure that any NRL is adequately equipped and staffed with the appropriate number of trained personnel.

The NRL shall be responsible for coordinating the diagnostic standards and methods within their field of responsibility in the Member State. The functions of the NRL are to:

- notify without delay the CA whenever the laboratory is aware of suspicion of any of the listed diseases;
- coordinate with the CRL the methods employed for diagnosing; and
- cooperate with the CRL and participate in the ring tests organized.

In addition, it performs functions similar to those undertaken by the CRL but at national level, and needs to be accredited by European standards.

### Designated Laboratories

The CA shall designate diagnostic laboratories within their territory that will fulfil the following requirements:

- notify without delay the CA whenever a laboratory is aware of a suspicion of any of the listed diseases;
- participate in the ring tests organized by the national laboratories ; and

- operate and be assessed and accredited in accordance with the European Standards referred to in the CRL.

The CA shall cancel the designation where the conditions are not fulfilled.

## CONCLUSIONS

The new EU Directive 88/2006 provides the requirements and specifications to establish a higher control on aquatic animal health and preserve the health status of aquaculture and wild populations. It also addresses the requirements for third countries to export into the EU, providing them with a framework to develop their own aquatic animal health strategies.

## REFERENCES

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