

Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

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THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

Whereas:

- (1) Aquaculture animals and products fall under the scope of Annex I to the Treaty as live animals, fish, molluscs and crustaceans. The breeding, rearing and the placing on the market of aquaculture animals and products thereof constitutes an important source of income for persons working in this sector.
- (2) In the context of the internal market, specific animal health rules were laid down for the placing on the market and introduction from third countries of the products concerned by Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products<sup>(2)</sup>.
- (3) Outbreaks of diseases in aquaculture animals could cause severe losses to the industry concerned. Minimum measures to be applied in case of outbreaks of the most important diseases in fish and molluscs were established by Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases<sup>(3)</sup> and Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs<sup>(4)</sup>.
- (4) Existing Community legislation was drafted mainly to take into account the farming of salmon, trout and oysters. Since that legislation was adopted, the Community aquaculture industry has developed significantly. A number of additional fish species, particularly marine species, are now used in aquaculture. New types of farming practices involving other fish species have also become increasingly common, particularly following the recent enlargement of the Community. Furthermore, farming of crustaceans, mussels, clams and abalones is becoming increasingly important.

- (5) All disease control measures have an economic impact on aquaculture. Inadequate controls may lead to a spread of pathogens, which may cause major losses and compromise the animal health status of fish, molluscs and crustaceans used in Community aquaculture. On the other hand, over-regulation could place unnecessary restrictions on free trade.
- (6) The Communication from the Commission to the Council and the European Parliament dated 19 September 2002 sets out a strategy for the sustainable development of European aquaculture. That Communication outlined a series of measures designed to create long-term employment in the aquaculture sector, including promoting high animal health and welfare standards, and environmental actions to ensure a sound industry. Those measures should be taken into account.
- (7) Since the adoption of Directive 91/67/EEC, the Community has ratified the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE). The animal health requirements for placing live aquaculture animals and products thereof on the market within the Community set out in Directive 91/67/EEC are more stringent than those standards. Therefore, this Directive should take into account the Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aquatic Animals of the OIE.
- (8) In order to ensure the rational development of the aquaculture sector and to increase productivity, aquatic animal health rules should be laid down at Community level. These rules are necessary, *inter alia*, in order to contribute to the completion of the internal market and to avoid the spread of infectious diseases. Legislation should be flexible to take into account the continuing developments in and diversity of the aquaculture sector, as well as the health status of aquatic animals within the Community.
- (9) This Directive should cover aquaculture animals, and those environments which may affect the health status of such animals. In general the provisions of this Directive should only apply to wild aquatic animals where the environmental situation may impinge on the health status of aquaculture animals, or where necessary in order to fulfil the purpose of other Community legislation, such as Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora<sup>(5)</sup> or to protect species referred to in the list drawn up by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). This Directive should not prejudice the adoption of more stringent rules on the introduction of non-native species.
- (10) The competent authorities designated for the purpose of this Directive should perform their functions and duties in accordance with the general principles laid down in Regulation (EC) No 854/2004 of European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>(6)</sup> and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>(7)</sup>.

- (11) It is necessary for the development of aquaculture in the Community to increase the awareness and preparedness of the competent authorities and aquaculture production business operators with respect to the prevention, control and eradication of aquatic animal diseases.
- (12) The competent authorities of Member States should have access to and apply state-of-the-art techniques and knowledge in the fields of risk analysis and epidemiology. This is of increasing importance because international obligations now focus on risk analysis in relation to the adoption of sanitary measures.
- (13) It is appropriate to introduce at Community level a system of authorisation of aquaculture production businesses. Such authorisation would enable the competent authorities to establish a complete overview of the aquaculture industry, which would assist in the prevention, control and eradication of aquatic animal diseases. Furthermore, authorisation allows the laying down of specific requirements that should be fulfilled by the aquaculture production business in order to operate. Such authorisation should, where possible, be combined with or included in an authorisation regime which the Member States may already have established for other purposes, for example under environmental legislation. Such authorisation should therefore not be an extra burden to the aquaculture industry.
- (14) Member States should refuse to issue an authorisation if the activity in question would pose an unacceptable risk of spreading diseases to other aquaculture animals or to wild stocks of aquatic animals. Before deciding to refuse an authorisation, consideration should be given to risk mitigation measures or alternative siting of the activity in question.
- (15) The rearing of aquaculture animals for the purpose of human consumption is defined as primary production in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs<sup>(8)</sup>. Obligations imposed on individual aquaculture production businesses under this Directive, such as record keeping, and internal systems enabling the aquaculture production business to demonstrate to the competent authority that the relevant requirements of this Directive are being fulfilled, should, where possible, be combined with the obligations laid down in Regulation (EC) No 852/2004.
- (16) More attention should be paid to preventing disease occurrence than to controlling the disease once it has occurred. It is therefore appropriate to lay down minimum measures of disease prevention and risk mitigation which should be applied to the whole production chain in aquaculture, from fertilisation and hatching of eggs to the processing of aquaculture animals for human consumption, including transportation.
- (17) In order to improve general animal health and assist in the prevention and control of animal disease through improved traceability, the movement of aquaculture animals should be recorded. Where appropriate, such movements should also be subject to animal health certification.
- (18) In order to have an overview of the disease situation, to facilitate a rapid reaction in the case of a suspicion of disease and to protect farms or mollusc farming areas having a

high animal health standard, a risk-based animal health surveillance should be applied in all such farms and mollusc farming areas.

- (19) It is necessary to ensure that the main aquatic animal diseases at Community level do not spread. Harmonised animal health provisions for placing on the market should therefore be laid down with specific provisions applicable to species susceptible to those diseases. Therefore a list of such diseases and species susceptible thereto should be laid down.
- (20) The prevalence of such aquatic animal diseases is not the same throughout the Community. Reference should therefore be made to the concept of Member States declared disease free, and when dealing with parts of the territory concerned, to the concept of zones or compartments. General criteria and procedures for the granting, maintenance, suspension, restoration and withdrawal of such status should be laid down.
- (21) Without prejudice to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market<sup>(9)</sup>, in order to maintain and improve the general aquatic animal health status in the Community, Member States, zones or compartments declared free of one or more of the diseases listed should be protected against the introduction of such disease.
- (22) Where necessary, Member States may take interim protective measures in accordance with Article 10 of Directive 90/425/EEC and Article 18 of Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC<sup>(10)</sup>.
- (23) In order to avoid the creation of unnecessary trade restrictions, the exchange of aquaculture animals between Member States, zones or compartments where one or more of such diseases are present should be allowed, provided that appropriate risk mitigation measures are taken, including during transport.
- (24) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread the disease, *inter alia* as a result of the discharge of effluents containing pathogens from processing plants. It is therefore necessary for the Member States to have access to processing establishments that have been duly authorised to undertake such slaughter and processing without jeopardising the health status of farmed and wild aquatic animals, including in respect of the discharge of effluents.
- (25) The designation of Community and national reference laboratories should contribute to the high quality and uniformity of diagnostic results. That objective can be achieved by activities such as the application of validated diagnostic tests and the organisation of comparative testing and training of staff from laboratories.
- (26) Laboratories involved in the examination of official samples should work in accordance with internationally approved procedures or criteria based on performance standards and should use diagnostic methods that have, as far as possible, been validated. For a number of activities related to such examination, the European Committee

for Standardisation (CEN), and International Organisation for Standardisation (ISO) have developed European Standards (EN Standards) and International Standards (ISO Standards) respectively, appropriate for the purpose of this Directive. Such standards relate in particular to the operation and assessment of laboratories and to the operation and accreditation of control bodies.

- (27) In order to ensure early detection of any possible outbreak of an aquatic animal disease, it is necessary to oblige those in contact with aquatic animals of susceptible species to notify any suspect case of disease to the competent authority. Routine inspections should be carried out in the Member States to ensure that aquaculture production business operators are familiar with, and apply, the general rules on disease control and biosecurity laid down in this Directive.
- (28) It is necessary to prevent the spread of non-exotic but serious diseases in aquaculture animals as soon as an outbreak occurs by carefully monitoring movements of live aquaculture animals and products thereof, and the use of equipment liable to be contaminated. The choice of the measures to be used by the competent authorities should depend on the epidemiological situation in the Member State concerned.
- (29) In order to advance the animal health status of the Community, it is appropriate that epidemiologically based programmes to control and eradicate certain diseases are submitted by Member States for recognition at Community level.
- (30) For diseases not subject to Community measures, but which are of local importance, the aquaculture industry should, with the assistance of the competent authorities of the Member States, take more responsibility for preventing the introduction of or controlling such diseases through self regulation and the development of 'codes of practice'. However, it may be necessary for the Member States to implement certain national measures. Such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect the trade between the Member States unless this is necessary in order to prevent the introduction of or to control the disease, and should be approved and regularly reviewed at Community level. Pending the establishment of such measures under this Directive, the additional guarantees granted in Commission Decision 2004/453/EC of 29 April 2004 implementing Council Directive 91/67/EEC as regards measures against certain diseases in aquaculture animals<sup>(11)</sup> should remain in force.
- (31) There is a continuous development in knowledge with respect to hitherto unknown diseases in aquatic animals. It may therefore be necessary for a Member State to apply control measures in the case of such emerging disease. Such measures should be swift and adapted to each individual case, but should not be maintained longer than necessary to achieve their goal. As such emerging diseases may also affect other Member States, all Member States and the Commission should be informed of the presence of an emerging disease and any control measures taken.
- (32) It is necessary and appropriate for the achievement of the basic objective of maintaining and, in the event of an outbreak, returning to a disease-free status in Member States, to lay down rules on the measures to increase disease preparedness. Outbreaks should be controlled as speedily as possible, if necessary by emergency vaccination, in order

to limit the adverse effects on the production of, and trade in, live aquaculture animals and products thereof.

- (33) Directive of the European Parliament and of the Council 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>(12)</sup> and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>(13)</sup> require that, with only minor exceptions, all veterinary medicinal products that are placed on the market within the Community are to hold a marketing authorisation. In general, all vaccines used in the Community should have a marketing authorisation. However, the Member States may permit the use of a product without a marketing authorisation in the event of a serious epidemic subject to certain conditions, in accordance with Regulation (EC) No 726/2004. Vaccines against exotic and emerging diseases in aquaculture animals may qualify for such derogation.
- (34) This Directive should lay down provisions to ensure the necessary level of preparedness to effectively tackle the emergency situations related to one or more outbreaks of serious exotic or emerging diseases affecting aquaculture, in particular by drawing up contingency plans to combat them. Such contingency plans should be reviewed and updated regularly.
- (35) Where the control of a serious aquatic animal disease is subject to harmonised Community eradication measures, Member States should be allowed to make use of financial contribution from the Community under Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund<sup>(14)</sup>. Any application for Community support should be subject to scrutiny as regards compliance with control provisions laid down in this Directive.
- (36) Live aquaculture animals and products thereof imported from third countries should not present an animal health hazard for aquatic animals in the Community. To that end, this Directive should set out measures for the prevention of the introduction of epizootic diseases.
- (37) It is necessary in order to safeguard the aquatic animal health situation in the Community to further ensure that consignments of live aquaculture animals transiting through the Community comply with the relevant animal health requirements applicable to the species concerned.
- (38) The placing on the market of ornamental aquatic animals involves a wide variety of species, often tropical species, solely for ornamental purposes. Those ornamental aquatic animals are normally kept in private aquariums or ponds, garden centres, or in exhibition aquariums, not in direct contact with Community waters. Consequently, ornamental aquatic animals held under such conditions do not pose the same risk to other sectors of Community aquaculture or to wild stocks. It is therefore appropriate to lay down special provisions applicable to the placing on the market, transit and import of ornamental aquatic animals, kept under such conditions.

- (39) However, where ornamental aquatic animals are kept outside closed systems or aquariums, in direct contact with the natural waters of the Community, they could pose a significant risk to Community aquaculture or wild stocks. That is particularly the case for the populations of carp (*Cyprinidae*), as popular ornamental fish such as koi carp are susceptible to some diseases affecting other carp species farmed in the Community or found in the wild. In such cases, the general provisions of this Directive should apply.
- (40) The setting up of electronic means of information exchange is vital for simplification, for the benefit of the aquaculture industry and of the competent authorities. In order to meet that obligation, common criteria need to be introduced.
- (41) Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (42) In accordance with paragraph 34 of the Interinstitutional agreement on better law-making<sup>(15)</sup>, Member States are encouraged to draw up, for themselves and in the interest of the Community, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures and to make them public.
- (43) Since the objectives of this Directive, namely to provide for the approximation of the concepts, principles and procedures forming a common basis for aquatic animal health legislation in the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of this Directive, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (44) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(16)</sup>.
- (45) It is appropriate to update Community animal health legislation concerning aquaculture animals and products thereof. Accordingly, Directives 91/67/EEC, 93/53/EEC and 95/70/EC should be repealed and replaced by this Directive,

HAS ADOPTED THIS DIRECTIVE:

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*Status: This is the original version (as it was originally adopted).*

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- (1) [OJ C 88, 11.4.2006, p. 13.](#)
- (2) [OJ L 46, 19.2.1991, p. 1.](#) Directive as last amended by Regulation (EC) No 806/2003 ([OJ L 122, 16.5.2003, p. 1.](#)).
- (3) [OJ L 175, 19.7.1993, p. 23.](#) Directive as last amended by the 2003 Act of Accession.
- (4) [OJ L 332, 30.12.1995, p. 33.](#) Directive as last amended by the 2003 Act of Accession.
- (5) [OJ L 206, 22.7.1992, p. 7.](#) Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1.](#)).
- (6) [OJ L 139, 30.4.2004, p. 206,](#) corrected by [OJ L 226, 25.6.2004, p. 83.](#) Regulation as last amended by Commission Regulation (EC) No 2076/2005 ([OJ L 338, 22.12.2005, p. 83.](#)).
- (7) [OJ L 165, 30.4.2004, p. 1,](#) corrected by [OJ L 191, 28.5.2004, p. 1.](#) Regulation as last amended by Commission Regulation (EC) No 776/2006 ([OJ L 136, 24.5.2006, p. 3.](#)).
- (8) [OJ L 139, 30.4.2004, p. 1,](#) corrected by [OJ L 226, 25.6.2004, p. 3.](#)
- (9) [OJ L 224, 18.8.1990, p. 29](#) Directive as last amended by Directive 2002/33/EC of the European Parliament and of the Council ([OJ L 315, 19.11.2002, p. 14.](#)).
- (10) [OJ L 268, 24.9.1991, p. 56.](#) Directive as last amended by the 2003 Act of Accession.
- (11) [OJ L 156, 30.4.2004, p. 5,](#) as corrected by [OJ L 202, 7.6.2004, p. 4.](#) Decision as last amended by Commission Decision 2006/272/EC ([OJ L 99, 7.4.2006, p. 31.](#)).
- (12) [OJ L 311, 28.11.2001, p. 1.](#) Directive as last amended by Directive 2004/28/EC ([OJ L 136, 30.4.2004, p. 58.](#)).
- (13) [OJ L 136, 30.4.2004, p. 1.](#)
- (14) [OJ L 223, 15.8.2006, p. 1.](#)
- (15) [OJ C 321, 31.12.2003, p. 1.](#) Corrected version in [OJ C 4, 8.1.2004, p. 7.](#)
- (16) [OJ L 184, 17.7.1999, p. 23.](#) Decision as last amended by Decision 2006/512/EC ([OJ L 200, 22.7.2006, p. 11.](#)).