Basic information

2005/0153(CNS) CNS - Consultation procedure Directive	Procedure completed
Aquaculture animals: animal health requirements, prevention and control of certain diseases Repealing Directive 95/70/EC 1994/0213(CNS) Repealed by 2013/0136(COD) **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.05 Animal diseases 3.15.02 Aquaculture	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
PECH Fisheries	KINDERMANN Heinz (PSE)	15/09/2005

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	20/09/2004
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2758	2006-10-24

European Commission

Commission DG	Commissioner
Health and Food Safety	KYPRIANOU Markos

Key events

Date	Event	Reference	Summary
23/08/2005	Legislative proposal published	COM(2005)0362	Summary
27/09/2005	Committee referral announced in Parliament		

21/03/2006	Vote in committee		Summary
27/03/2006	Committee report tabled for plenary, 1st reading/single reading	A6-0091/2006	
27/04/2006	Decision by Parliament	T6-0153/2006	Summary
27/04/2006	Results of vote in Parliament		
24/10/2006	Act adopted by Council after consultation of Parliament		
24/10/2006	End of procedure in Parliament		
24/11/2006	Final act published in Official Journal		

Technical information

Procedure reference	2005/0153(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Repealing Directive 95/70/EC 1994/0213(CNS) Repealed by 2013/0136(COD)
Legal basis	EC Treaty (after Amsterdam) EC 037
Stage reached in procedure	Procedure completed
Committee dossier	PECH/6/30035

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE362.794	06/01/2006	
Amendments tabled in committee		PE370.109	22/02/2006	
Committee report tabled for plenary, 1st reading/single reading		A6-0091/2006	27/03/2006	
Text adopted by Parliament, 1st reading/single reading		T6-0153/2006	27/04/2006	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2005)0362	23/08/2005	Summary
Document attached to the procedure	SEC(2005)1047	23/08/2005	Summary
Commission response to text adopted in plenary	SP(2006)2095	11/05/2006	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0233/2006	14/02/2006	

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Directive 2006/0088 OJ L 328 24.11.2006, p. 0014-0056	Summary

Aquaculture animals: animal health requirements, prevention and control of certain diseases

2005/0153(CNS) - 24/10/2006 - Final act

PURPOSE: to update, recast and consolidate the animal health rules in relation to the trade in aquaculture products.

LEGISLATIVE ACT: 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.

BACKGROUND: in 2004, the European aquaculture industry was estimated to be worth more than EUR 2.5 billion. However, financial loses due to disease are estimated to be 20% of the production value. A reduction in diseases by 20% could equate into savings worth EUR 100 million per annum.

Previous Community aquaculture provisions served an EU consisting of twelve Member States only and focused essentially on the factors mostly affecting the industry of the then twelve, namely salmonid (trout and salmon) and oyster farming. That legislation was developed over two decades ago and it can no longer usefully support the EU's aquaculture industry.

CONTENT: the purpose of this Directive, therefore, is to introduce modern and targeted legislation, which seeks to address the most pressing issues facing aquaculture products across the Community today. Such an approach will allow the regulatory framework of the EU's aquaculture industry to meet 21st Century challenges as well as simplifying and modernising existing rules. EU regulatory provisions have been updated to reflect the broader range of aquaculture practises and species that are found in an expanded EU.

The new Directive takes account of significant developments in the industry, which have taken place in recent years. It also takes account of experience gained through 15 years of application of the present legislation, as well as scientific advances in this field. Moreover, the rules have been updated to bring the EU in line with international agreements and standards (like WTO/SPS and OIE).

In agreeing to the new Directive existing primary legislation has been repealed to be replaced by this one Council Directive. One intention of the new Directive is to generate greater flexibility and to delegate more operational responsibility to the Member States, thereby allowing local or regional authorities greater powers to prevent and contain aquatic diseases.

The Directive introduces the principle that aquatic animal diseases should receive the same treatment as terrestrial animal diseases. This obliges the Community to offer financial contributions under Community law in cases where a slaughter/eradication policy needs to be carried out. (see also CNS /2005/0154). In addition, the Directive allows for the application of more stringent rules where this is necessary for the protection of species from an environmental or conservation point of view. Thus, the Directive does not conflict with the EU Directive on the conservation of natural habitats and of wild fauna and flora. Indeed, it is hoped that a shift in policy towards Member State responsibility for disease will help overall conservation and environmental efforts.

More specifically speaking, the Directive sets out the following provisions:

- General requirements for production and processing, including authorisations and provisions relating to operations.
- Animal health provisions for placing aquatic animals and related products on the market.

- Animal health provisions for introducing third-country aquatic animals into the EU.
- Provisions for notification and control of certain diseases in aquatic animals.
- Control programmes and vaccinations.
- Provisions relating to a declaration of a ‘disease free’ status.
- Requirements relating to the relevant Member State authorities and laboratories.
- Technical requirements and guidelines specified in the Annexes.

TRANSPOSITION: Member States must adopt and publish by 1 May 2008 the laws, regulations and administrative provisions needed to comply with this Directive. They must comply with the Directive before 14 December 2008.

APPLY FROM: 1 August 2008.

ENTRY INTO FORCE: 14 December 2006.

Aquaculture animals: animal health requirements, prevention and control of certain diseases

2005/0153(CNS) - 23/08/2005

COMMISSION'S IMPACT ASSESSMENT

For further information concerning the background to this issue, please refer to the summary of the Commission's initial proposals of 23 August 2005 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 - COM(2005)0362 and for a Council Decision amending Decision 90/424/EEC on expenditure in the veterinary field (please refer to procedure reference CNS 2005/0154).

1- POLICY OPTIONS AND IMPACTS

1.1- Option 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, the zero-option is not discussed.

1.2- Type of legislation for regulating animal health conditions for trade :

1.2.1- Option 2 : Regulation: Regulations have direct application in the Member States and are binding in their entirety. By choosing a Regulation, and thereby avoiding the need for Member States to transpose the act into national law, the time needed to have the legislation fully applicable would be significantly reduced compared to a Directive.

However, the Commission acknowledges 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 influence 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 shrimp farms measured in hectares.

1.2.2- Option 3 : Intra-Community Trade Directive: with an Intra Community Trade Directive, the Community legislation will lay down the animal health conditions for cross-border 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 the aim 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.

1.2.3- Option 4 : Placing on the market Directive: this option 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 comitology procedures.

CONCLUSION: As a consequence of the discussion under points 1.2.1 and 1.2.2, **according to the Commission, the best legislative option is to propose a Directive relating to placing on the market.IMPACT**

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

- § Positive impacts will arise from an updated Community legislative framework that takes into account current scientific knowledge and the structure of today's aquaculture industry in the Community. There will be a positive shift in focus away from preventing the spread of disease and towards the occurrence of disease. Significant resources are now being used to maintain disease-free status in farms and zones that have been declared disease-free. The proposal would allow the Member State to re-allocate some of these resources to disease preventive activities. The proposal implements the philosophy that the best solution is often found closest to the problem, and delegates more operational responsibility to the Member States. By introducing general risk-based animal health surveillance, a better overview of the disease situation can be achieved. At the same time, the risk of spreading diseases to farms or areas where the disease has not yet been found is reduced. It takes into account the potential for exchange of disease agents between farmed and wild aquatic animals. The new legislation will be consistent with the International Aquatic Animal Health Code of the World Organisation for Animal Health (OIE), and will reduce existing trade barriers between third countries, including developing countries, and the Community.

- § The negative impact will be limited, as the proposal will to a large extent be founded on the existing legislation. Some new elements and requirements will have an administrative and economic impact on the Member States and on the industry. The proposal for authorisation of aquaculture production business will cause extra work for the competent authorities in the Member States. However, since all mollusc farms and the majority of fish farms are already registered, the authorisation requirement is achievable for the Member States. The introduction of general risk-based animal health surveillance in all farms or farming areas is an extension of the requirements in the present mollusc legislation, under which all Member States must have a monitoring and sampling programme.

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.

2- FOLLOW-UP

Member States have to adopt and publish their implementing legislation by the date laid down in the Directive.

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.

Aquaculture animals: animal health requirements, prevention and control of certain diseases

2005/0153(CNS) - 27/04/2006 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Heinz KINDERMANN (PES, DE), subject to some technical amendments. (Please see the summary of 21/03/2006.)

Aquaculture animals: animal health requirements, prevention and control of certain diseases

2005/0153(CNS) - 23/08/2005 - Legislative proposal

PURPOSE: to update, recast and consolidate the animal health rules in relation to the trade in aquaculture products.

PROPOSED ACT: Council Directive.

CONTENT: in 2004, the European aquaculture industry was estimated to be worth more than EUR 2.5 billion. However, financial loses due to disease are estimated to be 20% of the production value. The purpose of this proposal, therefore, is to introduce modern and targeted legislation, which seeks to reduce these high costs. A reduction in diseases by 20% could equate into savings worth EUR 100 million per annum.

Given that existing legislation was initially developed over two decades ago, it can no longer usefully support the EU's aquaculture industry. When initially approved, the EU's aquaculture provisions served an EU consisting of twelve Member States only and focused essentially on the factors mostly affecting the industry of the then twelve, namely salmonid (trout and salmon) and oyster farming. EU regulatory provisions now need to be updated to reflect the broader range of aquaculture practises and species that are found in an expanded EU.

The current proposal takes account of significant developments in the industry, which have taken place in recent years. It also takes account of experience gained through 15 years of application of the present legislation, as well as scientific advances in this field. Moreover, the rules have been updated to bring the EU in to line with international agreements and standards (like WTO/SPS and OIE).

This proposal will repeal existing primary legislation and merge the current three Directives into one. Such an approach will allow the regulatory framework of the EU's aquaculture industry to meet 21st Century challenges as well as simplifying and modernising existing rules. Further objectives of the revision are to generate greater flexibility and to delegate more operational responsibility to the Member States, thereby allowing local or regional authorities greater powers to prevent and contain aquatic diseases.

It is important to stress that the general principles laid down in the three Directives will be maintained. In addition to the current three Directives there are 13 implementing Decisions, which have been adopted pursuant to those Directives. These implementing Decisions will remain in force until they are repealed by a specific Decision, or replaced by a Decision adopted pursuant to this proposal.

The proposed Directive introduces the principle that aquatic animal diseases should receive the same treatment as terrestrial animal diseases. This would oblige the Community to offer financial contributions under Community law in cases where a slaughter/eradication policy needs to be carried out. In addition, the Directive allows for the application of more stringent rules where this is necessary for the protection of species from an environmental or conservation point of view. Thus, the Directive would not conflict with the EU Directive on the conservation of natural habitats and of wild fauna and flora. Indeed, it is hoped that a shift in policy towards Member State responsibility for disease will help overall conservation and environmental efforts.

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

More specifically speaking, the proposed Directive would include the following legal elements:

- General requirements for production and processing, including authorisations and provisions relating to operations.
- Animal health provisions for placing aquatic animals and related products on the market.
- Animal health provisions for introducing third-country aquatic animals into the EU.
- Provisions for notification and control of certain diseases in aquatic animals.
- Provisions relating to a declaration of a 'disease free' status.
- Requirements relating to the relevant Member State authorities and laboratories.
- Technical requirements and guidelines specified in the Annexes.

As far as the budget is concerned the Commission proposes that the economic impact on the Community budget is limited. Financing should focus on two areas. Firstly offering economic compensation in the case of disease control and secondly, offering financial support for the implementation of primary legislation and the adoption of secondary legislation. In terms of the first area, it is being proposed that financial contributions for aquatic animal diseases and the control thereof should be financed through the European Fisheries Fund. As yet, however, it is difficult for the Commission to assess the exact impact this will have on the EFF, as much will depend on the size of the farms affected, the value of the animals kept at the farms etc. On the second point, the Commission deems it necessary to draw up, adopt and maintain secondary legislation relating to the control of aquatic diseases. Activities under this heading include, for example, the organisation of working-groups and meetings with stake-holders. In addition, following the entry into force of the Directive, FVO inspections of Member State implementation will be necessary in 2008/09 – an estimated 13 or 14 per year.

For further information concerning the financial implications of this measure, please refer to the financial statement.