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# **DRAFT REPORT**

on the proposal for a Council directive on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (COM(2005)0362 - C6-0281/2005 - 2005/0153(CNS))

Committee on Fisheries

Rapporteur: Heinz Kindermann

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| Symbols for procedures   |  |
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| Consultation procedure   |  |
| majority of the votes cast   |  |
| Cooperation procedure (first reading)                              |  |
| majority of the votes cast   |  |
| Cooperation procedure (second reading)                             |  |
| majority of the votes cast, to approve the common position         |  |
| majority of Parliament's component Members, to reject or amend     |  |
| the common position  |  |
| Assent procedure   |  |
| majority of Parliament's component Members except in cases         |  |
| covered by Articles 105, 107, 161 and 300 of the EC Treaty and     |  |
| Article 7 of the EU Treaty<br>Codecision procedure (first reading) |  |
| majority of the votes cast   |  |
| Codecision procedure (second reading)                              |  |
| majority of the votes cast, to approve the common position         |  |
| majority of Parliament's component Members, to reject or amend     |  |
| the common position  |  |
| Codecision procedure (third reading)                               |  |
| majority of the votes cast, to approve the joint text              |  |
| e of procedure depends on the legal basis proposed by the sion.)   |  |
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# Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in *bold italics*. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

# CONTENTS

|  | Page |
|--|------|
| DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION | 5    |
| EXPLANATORY STATEMENT                            |      |

# DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(COM(2005)0362 - C6-0281/2005 - 2005/0153(CNS))

### (Consultation procedure)

#### The European Parliament,

- having regard to the Commission proposal to the Council  $(COM(2005)0362)^1$ ,
- having regard to Article 37 of the EC Treaty, pursuant to which the Council consulted Parliament (C6-0281/2005),
- having regard to Rule 51 of its Rules of Procedure,
- having regard to the report of the Committee on Fisheries and the opinion of the Committee on Budgets (A6-0000/2006),
- 1. Approves the Commission proposal as amended;
- 2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;
- 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
- 4. Asks the Council to consult Parliament again if it intends to amend the text submitted for consultation substantially;
- 5. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1 Article 4, paragraph 2, subparagraph 1

2. Member States shall ensure that *a sufficient number of* processing *establishments on their territory are authorised for the* slaughtering *and processing of* aquaculture animals *being harvested and slaughtered* for disease

2. Member States shall ensure that *every* processing *establishment* slaughtering aquaculture animals for disease control purposes in accordance with *Article 33 of* Chapter V *is duly authorised by the competent authority in accordance with* 

<sup>&</sup>lt;sup>1</sup> Not yet published in OJ.

control purposes, in accordance with Chapter V.

Article 5.

#### Justification

Member States should not be required to ensure a sufficient number of processing establishments. The use of processing establishments in other Member States should also be permitted.

*Limitation to processing establishments for the slaughtering of aquaculture animals makes the provisions more practicable and transparent.* 

The inclusion of article references makes the text more precise.

Amendment 2 Article 4, paragraph 2, subparagraph 2

#### deleted

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

# Justification

See justification in respect of amendment 1 (Article 4(2), first subparagraph).

# Amendment 3 Article 4, paragraph 4

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

# 4. Member States may require *only the registration by the competent authority of the following:*

(a) installations other than aquaculture production businesses, where aquatic animals are kept without the intention of being placed on the market;

(b) put and take fisheries;

(c) aquaculture production businesses which place aquaculture animals on the market solely for human consumption as In *that case*, the provisions of this Directive shall apply *mutatis mutandis* taking into account the nature, characteristics and situations of the installation *or* put and take fishery concerned and the risk of spreading aquatic animal diseases to other populations of aquatic animals as a result of its operation.

#### described in Article 1(3), point (c) of Regulation (EC) No 853/2004.

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

# Justification

This amendment means that certain 'small businesses' will be required only to be registered, not authorised. Supervision and inspection of the large number of small businesses and hobby farms would not be practicable. It is appropriate to refer to the hygiene regulation (Regulation (EC) No 853/2004), which provides for a similar exemption for the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.

#### Amendment 4 Article 8, title

Recording obligations

Recording obligations - Traceability

Justification

The Commission proposal lays down provisions on traceability in Chapter III, Article 14 (Traceability and certification). This amendment brings together traceability with the provisions on recording obligations.

Amendment 5 Article 8, paragraph 3 a (new)

> 3a. Without prejudice to specific provisions on traceability, Member States shall ensure that all movements of animals recorded by the aquaculture production business operators as provided for in paragraph 1, point (a) are registered in such a way that the tracing of the place of origin and destination can be guaranteed.

Member States may require such

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Justification

The Commission proposal lays down provisions on traceability in Chapter III, Article 14 (Traceability and certification). This amendment brings together traceability with the provisions on recording obligations. Member States are being allowed here to adopt procedures for ensuring traceability of consignments that are suited to the circumstances of the respective country.

### Amendment 6 Article 14, title

Traceability and certification

Animal health certification

*Justification* 

This amendment makes the text more precise. Provisions on traceability should appear elsewhere. See rapporteur's amendments 4 and 5 to Article 8.

> Amendment 7 Article 14, paragraph 1

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

1. Member States shall ensure that *the* placing on the market of aquaculture animals *is subject to animal health* certification when the animals are introduced into a Member State, zone or compartment declared disease-free in accordance with Article 49 and 50 for:

(a) farming and restocking purposes;

(b) human consumption in accordance with point (a) of Article 18(1), point (a) of Article 18(2) and Article 19(2).

Justification

As it is preferable for traceability to be dealt with in the context of Chapter II, Article 8, the provisions on traceability laid down here are deleted, and more detailed provisions on the issuing of animal health certification are laid down.

#### Amendment 8 Article 14, paragraph 2

2. Paragraph 1 of this Article shall also apply to aquaculture animals placed on the market for human consumption in accordance with point (a) of Article 18(1), point (a) of Article 18(2) and Article 19(2). 2. Paragraph 1 shall also apply to *diseases* and the species susceptible thereto not listed in Part II of Annex III for which national measures have been taken to control the disease in question and which are approved at Community level in accordance with Article 43(3).

#### Justification

The amendment makes it clear that animal health certification is also required for deliveries to or from areas where a national control programme is in place.

#### Amendment 9 Article 14, paragraph 3

deleted

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

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

# Justification

This amendment follows from the rapporteur's proposed amendment to Article 14 (1).

# Amendment 10 Article 14, paragraph 4

4. Member States shall ensure that introduction of aquaculture animals for farming and restocking purposes into other Member States, zones or compartments declared disease-free in accordance with Articles 49 and 50 are 3. Member States shall *also* ensure that *the placing on the market* of aquaculture animals *is* subject to animal health certification *when the animals are allowed to leave an area subject to the control provisions provided for in sections 3, 4, 5* 

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subject to animal health certification.

and 6 of Chapter V.

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

# Justification

Animal health certification is also required for placing on the market.

Amendment 11 Article 14, paragraph 5

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

# Justification

This amendment follows from the rapporteur's proposed amendment to Article 14 (4).

# Amendment 12 Article 15, paragraph 1, subparagraph 1

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

# Justification

Strict application of the '31 day rule' here seems too rigid, and would significantly complicate the dispatching of animals. The decisive factor is, rather, that the animals are healthy at the time of dispatch.

#### Amendment 13 Article 17, title

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

Introduction of aquaculture animals of *potentially* susceptible **or** *vector* species into disease-free areas

#### Justification

The title should be amended to make the text more precise.

Amendment 14 Article 17, paragraph 1, introductory part

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

Justification

This amendment makes the wording more precise.

#### Amendment 15 Article 17, paragraph 2

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

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

#### Justification

This amendment makes the wording more precise.

Amendment 16 Article 17, paragraph 3

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

Justification

This amendment makes the wording more precise.

Amendment 17 Article 17, paragraph 3 a (new)

> 3a. Where a Member State can substantiate the risk of disease introduction by a species not referred to as susceptible to the disease in question, the justification should be forwarded to the Commission. Pending a decision on inclusion of that species on the list referred to in paragraph 3, the Commission may decide that the Member States shall apply the measures provided for in paragraph 1.

Justification

This new paragraph 3a makes it clear that a Member State must provide evidence of the risk posed by a species not previously regarded as a susceptible species or a vector species; this is in accordance with the WTO Agreement.

#### Amendment 18 Article 50, paragraph 1, introductory part

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

#### Justification

The procedure for declaring a compartment or zone disease-free should be set out in detail in a separate article; see rapporteur's amendment to Article 50 (1a).

#### Amendment 19 Article 50, paragraph 1 a (new)

1a. A Member State shall notify the declaration referred to in paragraph 1 to the Standing Committee on the Food Chain and Animal Health in accordance with the following procedure:

(a) the declaration shall be supported by evidence in a form to be determined by the procedure referred to in Article 62(2) and shall be accessible by electronic means to the Commission and Member States in accordance with the requirements of Article 59;

(b) the Commission shall add the notification of the declaration to the agenda of the next meeting of the Standing Committee on the Food Chain and Animal Health as an information point. The declaration shall take effect 30 days after the date of that meeting;

(c) within that period, the Commission or Member States may seek clarification or additional information on the supporting evidence from the Member State making the declaration;

(d) where written comments are made by at least one Member State, indicating significant objective concerns related to the supporting evidence, the Commission and Member States concerned shall together examine the submitted evidence in order to resolve the dispute. In that event, the period referred to in point (b) may be prolonged for 30 days;

(e) in the absence of any resolution of the dispute by the means referred to in point
(d), the Commission may decide to carry out an on-the-spot inspection in

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accordance with Article 58 in order to verify the compliance of the declaration submitted with the criteria set out in paragraph 1, unless the declaring Member State withdraws its declaration;

(f) where necessary in the light of the results achieved, a decision may be taken in accordance with the procedure referred to in Article 62(2) to suspend the selfdeclaration of the disease-free status of the zone or compartment concerned.

#### Justification

This amendment sets out in detail the procedure to be followed for declaring a compartment or zone disease-free. In order to enable adjustments to be made, if necessary, to the procedure, reference is made to Chapter X, Article 62.

# Amendment 20 Article 59, paragraph 1

1. Member States shall, by *1 January 2007* at the latest, ensure that all procedures and formalities relating to making the information provided for in Article 6, Article 51(1), and Article 56(2) available by electronic means, are in place. 1. Member States shall, by *30 June 2007* at the latest, ensure that all procedures and formalities relating to making the information provided for in Article 6, *Article 50(1a)*, Article 51(1) and Article 56(2) available by electronic means, are in place.

# Justification

The draft submitted by the Commission is not due to be adopted before the middle of 2006. As experience suggests that a period of 12 to 18 months is needed to transpose a directive of this kind, 30 June 2007 seems a more realistic date. Article 50(1a) fleshes out the proposed procedure for declaring a compartment disease-free.

#### Amendment 21 Article 61, paragraph 1

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

1. *Article 50(1a)* may be amended in accordance with the procedure referred to in Article 62(2), after consultation of the appropriate scientific committee.

#### Justification

*Article 50 (1a) provides for the possibility of amending the procedure for declaring a compartment or zone disease-free, using the regulatory committee procedure.* 

#### Amendment 22 Annex V, Part II, paragraph 3, heading

(Does not affect English version.)

3. Compartments comprising one or more individual farms where the disease status is independent of the disease status of the surrounding natural waters

Justification

(Does not affect English version.)

Amendment 23 Annex V, Part II, paragraph 3, point 3.2. (a)

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

(a) Through a water treatment plant *inactivating* the relevant pathogen *in order to reduce the risk of disease introduction to an acceptable level*.

Justification

This amendment makes the wording clearer.

Amendment 24 Annex V, Part II, paragraph 3, point 3.6. a (new)

> 3.6a. Implementing measures concerning paragraph 3.2 (a) shall be laid down in accordance with the procedure referred to in Article 62(2).

# Justification

Details relating to the supply of water to compartments should be laid down in implementing measures.

# **EXPLANATORY STATEMENT**

# **INTRODUCTION**

Aquaculture is a very important industry in the Community, particularly in rural and coastal areas. According to the European Commission, EU aquaculture produced fish, molluscs and crustaceans worth more than  $\notin 2.5$  billion in 2004. However, financial losses due to disease (high mortality, reduced growth and reduced quality) are estimated to represent 20 % of the production value. The proposal aims to introduce modern and targeted legislation that will reduce these costs. Reducing them by just 20% would result in an added value of  $\notin 100$  million per year. The aim is also to minimise the risks to wild aquatic animals posed by the aquaculture industry.

There are at present three separate directives laying down animal health conditions governing trade in aquaculture animals and products and minimum Community measures for the control of certain fish diseases and of certain diseases affecting bivalve molluscs (91/67/EEC; 93/53/EEC; 95/70/EEC). The current legislation protects those aquaculture sectors which were the main ones in the Community when the legislation was adopted, in particular salmonid (trout and salmon) and oyster farming. As aquaculture has developed and become more diversified, the legislation now needs to be updated to reflect the broader range of aquaculture structures and to take account of the significant developments within the industry, the experience gained through 15 years of applying the existing legislation, as well as scientific advances in this field. The rules must also be updated to bring EU rules in line with the international agreements and standards of the World Trade Organization (WTO) and the World Organisation for Animal Health (OIE).

# **OBJECTIVE OF THE PROPOSAL**

The main purpose of this proposal is to improve the competitiveness of EU aquaculture producers.

To that end, the three existing directives laying down animal health conditions for placing on the market and minimum measures for the control of diseases are to be consolidated and at the same time extended and adapted to today's requirements. The objective is also to treat aquatic animal diseases in the same way as terrestrial animal diseases.

The legal instrument of the directive has been deliberately chosen in order to allow the Member States wider scope and to delegate to them greater responsibility with regard to implementation, so as to better reflect the different conditions and structures in European aquaculture. This is in line with the subsidiarity principle.

# SUBSTANCE OF THE PROPOSAL

The proposal contains 11 chapters and eight annexes.

**Chapter I** lays down the subject matter and scope of the Directive. In addition, it defines important terms relating to the aquaculture industry. Further technical definitions are given in Annex I.

**Chapter II** lays down rules on the authorisation of aquaculture production businesses and processing establishments and also provisions on the keeping of records, registration and supervision by the competent authority and the animal health surveillance scheme.

**Chapter III** covers animal health requirements for the placing on the market of aquaculture animals and products. In addition to general provisions, specific provisions are laid down relating to aquaculture animals intended for farming and restocking, animals and products intended for human consumption, release of wild aquatic animals and the placing on the market of ornamental aquatic animals.

**Chapter IV** lays down rules on the introduction of aquaculture animals and products into the Community from third countries. It contains provisions on how lists of third countries and parts of third countries from which the introduction of aquaculture animals and products is permitted should be drawn up and what documents are needed for entry.

**Chapter V** lays down rules on disease notification and minimum measures for control of exotic and non-exotic diseases of aquatic animals listed in Part II of Annex III in aquaculture animals and in wild aquatic animals. Measures for controlling emerging diseases and diseases not listed in Part II of Annex III are also set out.

**Chapter VI** lays down rules on the drawing up and approval of control and eradication programmes and on their content and period of application. Member States are called upon to draw up contingency plans for emerging and exotic diseases. Vaccination of aquatic animals is prohibited except where it is carried out in connection with control measures and eradication programmes or with contingency plans.

**Chapter VII** lays down provisions on the disease-free status of Member States, zones and compartments. A list of disease-free Member States, zones and compartments is required to be drawn up and updated. Provisions relating to the maintenance, suspension and restoration of disease-free status are also laid down.

**Chapter VIII** contains provisions on designating competent authorities and Community and national reference laboratories, and lays down the conditions governing them and their duties. It also lays down provisions on diagnostic methods.

**Chapter IX** contains provisions relating to on-the-spot inspections and audits by Commission experts, communication of information by electronic means between Member States and the Commission, and appropriate and effective penalties for infringements of the Directive.

**Chapter X** lays down provisions on the procedure for amending the Annexes and detailed rules for the implementation of the Directive. The Commission is to be assisted by the Standing Committee on the Food Chain and Animal Health.

**Chapter XI** covers transitional and final provisions. The three existing directives (91/67/EEC; 93/53/EEC; 95/70/EC) are to be repealed following the expiry of a transitional period. The chapter provides for the possibility of transitional provisions, and there are Articles on transposition and entry into force of the Directive.

**Annex I** contains technical definitions, which are in addition to the definitions in Chapter I. **Annex II** sets out the information required to be kept in the official register of aquaculture production businesses and processing establishments authorised in accordance with Chapter II.

Annex III lists exotic and non-exotic diseases of fish, molluscs and crustaceans and the species susceptible to them, and lays down the criteria for listing diseases.

Annex IV specifies the type of health surveillance and frequency of inspections of farms and mollusc farming areas, according to the level of risk and disease status.

Annex V sets out the requirements for declaring a Member State, zone or compartment disease-free pursuant to Chapter VII.

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**Annex VI** lays down the functions and duties of Community and national reference laboratories and of laboratories providing diagnostic services pursuant to Chapter VIII. **Annex VII** lays down the criteria and requirements for national contingency plans pursuant to Chapter VI.

Annex VIII shows the correlation between Articles in this proposal for a Directive and Articles in the three Directives currently in force (91/67/EEC; 93/53/EEC; 95/70/EC).

# ASSESSMENT OF THE PROPOSAL

Your rapporteur supports the Commission's proposal to bring together and simplify the current complex legislation. He particularly welcomes the fact that the legislative provisions are to be brought together in the form of a directive, as this should make it possible to reflect the very different conditions in aquaculture across Europe.

The directive can be expected to have an impact in the following ways:

- shift of emphasis away from preventing the spread of disease and towards preventing the occurrence of disease;
- Member States will be able to decide for themselves what disease prevention measures are best suited to regional circumstances;
- risk-based animal health surveillance will enable a significantly better overview of the disease situation to be gained;
- the administrative burden on Member States and aquaculture production businesses should be limited, and Community financial support may be provided in the event of slaughter and eradication measures being taken.

# AMENDMENTS PROPOSED

The aim of the amendments to **Chapter II** (aquaculture production businesses and authorised processing establishments) proposed by your rapporteur is to make the provisions more practicable and transparent. It makes sense for traceability to be brought together with the provisions on recording obligations. Member States are also being allowed to adopt procedures for ensuring traceability of consignments that are suited to the circumstances of the respective country. The amendments proposed to **Chapter III** (Animal health requirements for placing on the market of aquaculture animals and products) make the wording of the Directive more precise and make the provisions more practicable. For example, animal health certification is required for deliveries to or from an area where a national control programme or control measures apply.

Your rapporteur's proposed amendments to **Chapter VII** (disease-free status), **Chapter IX** (inspections, communication of information by electronic means and penalties) and **Chapter X** (amendments, detailed rules and committee procedure) reflect the need on the part of Member States for the procedure for declaring a zone or compartment disease-free to be laid down more clearly and at the same time for the possibility of reviewing these detailed rules to be provided. The deadline for implementation proposed by the Commission should, bearing in mind that a transposition period of 12 to 18 months is normally needed, be deferred by six months, to 30 June 2007. An amendment to Annex V (Requirements for declaring a Member State, zone or compartment disease-free) relating to the supply of water to compartments

makes the text clearer.

# CONCLUSIONS

Overall, the Commission proposal is a very good one. However, the text of the Directive still needs to be amended in the interests of practicability and transparency. Amendments contained in this report are also intended to take account of the concerns of aquaculture production businesses and Member States.