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## I

(Acts whose publication is obligatory)

**REGULATION (EC) No 1692/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 24 October 2006**

**establishing the second 'Marco Polo' programme for the granting of Community financial assistance to improve the environmental performance of the freight transport system (Marco Polo II) and repealing Regulation (EC) No 1382/2003**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 71(1) and 80(2) thereof,

Having regard to the proposal from the Commission,

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

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(2)</sup>,

Whereas:

(1) The Commission White Paper on the Common Transport Policy of September 2001 stresses the development of intermodality as a practical and effective means to achieve a balanced transport system, and proposes not only the development of Motorways of the Sea, high-quality integrated intermodal maritime options, but also the more intensive use of rail and inland waterway transport as key elements in this strategy. At its meeting in Gothenburg on 15 and 16 June 2001 the European Council declared that shifting the balance between the modes of transport is at the heart of the sustainable development strategy. Furthermore, at its meeting in Barcelona on 15 and 16 March 2002 the European Council stressed the necessity of reducing congestion in the traffic bottlenecks in several regions, mentioning in particular the Alps, the Pyrenees and the Baltic Sea – an indication that the maritime lines of the Motorways of the Sea are an integral and important part of the Trans-European Transport

Network. A market-driven funding programme for intermodality is a central instrument to further develop intermodality and should specifically support the set-up of Motorways of the Sea, ensuring, *inter alia*, an improvement in economic, social and territorial cohesion, and in rail and inland waterway transport.

(2) If no decisive action is taken, total road freight transport in Europe is set to grow by more than 60 % by 2013. The effect would be an estimated growth in international road freight for the period 2007 to 2013 of 20,5 billion tonne-kilometres per year for the 25 Member States of the European Union, with negative consequences in terms of additional road infrastructure costs, accidents, congestion, local and global pollution, the reliability of the supply chain and of logistics processes and environmental damage.

(3) In order to cope with this growth in road freight transport, short sea shipping, rail and inland waterways must be used even more than today, and it is necessary to stimulate further powerful initiatives from the transport and logistics sector, for instance the development of technical innovations in rolling stock, to decrease road congestion.

(4) The programme established by Regulation (EC) No 1382/2003 of the European Parliament and of the Council of 22 July 2003 on the granting of Community financial assistance to improve the environmental performance of the freight transport system (the Marco Polo Programme) <sup>(3)</sup> should therefore be enhanced by new actions, aimed at an actual reduction in international road transport. The Commission therefore has proposed a stronger programme, hereinafter referred to as the 'Marco Polo II Programme', or 'the Programme', to enhance intermodality, reduce road congestion and improve the environmental performance of the freight transport system within the Community. To achieve this objective, the Programme should support actions in the freight transport, logistics

<sup>(1)</sup> OJ C 234, 22.9.2005, p. 19.

<sup>(2)</sup> Opinion of the European Parliament of 17 May 2006 (not yet published in the Official Journal) and Decision of the Council of 12 October 2006.

<sup>(3)</sup> OJ L 196, 2.8.2003, p. 1. Regulation as amended by Regulation (EC) No 788/2004 (OJ L 138, 30.4.2004, p. 17).

- and other relevant markets, taking into account the needs of small and medium-sized enterprises (SMEs). It should help to shift at least the expected aggregate increase in international road freight traffic, but preferably more, to short sea shipping, rail and inland waterway transport or to a combination of modes of transport in which road journeys are as short as possible. The Marco Polo Programme established by Regulation (EC) No 1382/2003 should therefore be replaced.
- (5) The Marco Polo II Programme features different types of action which should contribute to a measurable and sustained modal shift and better cooperation in the inter-modal market. Furthermore, actions under the Marco Polo II Programme should also contribute to an actual reduction in international road freight transport.
- (6) Actions to be funded under the Marco Polo II Programme should be international in geographic scope. In order to reflect the European dimension of the actions, projects should be submitted by undertakings established in different countries, in the form of a consortium submitting an action. Public law entities should be entitled to participate in such a consortium, when engaging in economic activities, in accordance with their national laws.
- (7) Applicants should be able to submit new or, where appropriate, existing projects which best match current market needs. Suitable projects, in particular those taking into account the needs of SMEs, should not be discouraged by any over-rigid definition of eligible actions.
- (8) There may be cases in which the benefits of developing an existing service are at least equal in terms of additional modal shift, quality and environmental and viability advantages to those of starting up a new service involving considerable expense.
- (9) To be transparent, objective and clearly delimited, aid for the launch of modal shift actions, for example, should be based on cost savings for society brought about by the use of short sea shipping, rail and inland waterway transport instead of road transport alone. For this reason, this Regulation should provide for an indicative amount of financial assistance by reference to tonne-kilometres of road freight shifted.
- (10) Community financial assistance based on tonne-kilometres shifted from road to short sea shipping, rail or inland waterways or based on the avoidance of tonne-kilometres or vehicle-kilometres of road freight should be adjustable so as to reward high quality projects or projects demonstrating a real environmental benefit.
- (11) Special attention should also be paid to sensitive and metropolitan areas within the geographic scope of the Programme when allocating funding.
- (12) The results of all actions of the Programme should be adequately disseminated, in order to ensure publicity and transparency and the exchange of best practices.
- (13) During the selection procedure and during the lifetime of actions, it is necessary to ensure that the actions chosen make real contributions to the common transport policy and do not cause distortions of competition contrary to the common interest. The Commission should therefore evaluate the implementation of both Programmes. It should present the evaluation report on the results achieved by the Marco Polo Programme for the period 2003 to 2006 not later than 30 June 2007.
- (14) Actions should not cause distortions of competition, in particular, between modes of transport other than road transport or within each alternative mode, to an extent contrary to the common interest. Special care should be taken to avoid such distortions, so that actions contribute to shifting freight from road transport to alternative modes, rather than withdrawing freight from an existing rail, short sea shipping or inland waterway service.
- (15) Since the objective of the Marco Polo II Programme cannot be sufficiently achieved by the Member States and can therefore, by reason of the scope of the Programme, 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 Regulation does not go beyond what is necessary in order to achieve that objective.
- (16) The measures necessary for the implementation of this Regulation 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>(1)</sup>.
- (17) This Regulation lays down for the entire duration of the Programme, a financial envelope constituting the prime reference, within the meaning of point 37 of the Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management <sup>(2)</sup>, for the budgetary authority during the annual budgetary procedure.
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- <sup>(1)</sup> 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).
- <sup>(2)</sup> OJ C 139, 14.6.2006, p. 1.

- (18) In order to safeguard the continuity and transparency of the Marco Polo Programme, transitional provisions should be laid down concerning contracts and the selection procedure,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### Article 1

##### Subject matter

This Regulation establishes a financing instrument, hereinafter referred to as 'the Marco Polo II Programme' or 'the Programme' in order to reduce congestion, to improve the environmental performance of the transport system and to enhance intermodal transport, thereby contributing to an efficient and sustainable transport system which provides EU added value without having a negative impact on economic, social or territorial cohesion. The duration of the Programme shall be from 1 January 2007 to 31 December 2013 in order to achieve, by the end of the Programme, a traffic shift that is a substantial part of the expected yearly aggregate increase in international road freight traffic, measured in tonne-kilometres, to short sea shipping, rail and inland waterway transport or to a combination of modes of transport in which road journeys are as short as possible.

#### Article 2

##### Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'action' means any project executed by undertakings which contributes to reducing congestion in the road freight transport system and/or to improving the environmental performance of the transport system in the territories of the Member States or participating countries; catalyst actions, modal shift actions and common learning actions may comprise several coordinated projects;
- (b) 'catalyst action' means any innovative action aimed at overcoming significant structural barriers in the Community freight transport market which impede the efficient functioning of the markets, the competitiveness of short sea shipping, rail, or inland waterway transport, and/or the efficiency of transport chains making use of these modes, including the modification or creation of ancillary infrastructure; for the purpose of this definition, such structural barriers shall mean any non-regulatory, factual and non-temporary impediment to the proper functioning of the freight transport chain;
- (c) 'Motorways of the Sea action' means any innovative action directly shifting freight from road to short sea shipping or a combination of short sea shipping with other modes of transport in which road journeys are as short as possible; actions of this kind may include the modification or creation of the ancillary infrastructure required in order to implement a very large-volume, high-frequency inter-modal maritime transport service, including, preferably, the use of the most environmentally-friendly transport modes, such as inland waterways and rail, for hinterland freight transport and integrated door-to-door services; if possible, the resources of the outermost regions should also be integrated;
- (d) 'modal shift action' means any action directly, measurably, substantially and immediately shifting freight from road to short sea shipping, rail, inland waterways or a combination of modes of transport in which road journeys are as short as possible, without being a catalyst action; this includes, where appropriate, actions where modal shift is brought about by the development of an existing service; the Commission shall examine the possibility of supporting ancillary infrastructure projects;
- (e) 'traffic avoidance action' means any innovative action integrating transport into production logistics to avoid a large percentage of freight transport by road without adversely affecting production output or workforce; actions of this kind may include the modification or creation of ancillary infrastructure and equipment;
- (f) 'common learning action' means any action aimed at improving cooperation for structurally optimising working methods and procedures in the freight transport chain, taking into account the requirements of logistics;
- (g) 'innovative action' means any action which features elements which have hitherto not existed in a given market;
- (h) 'ancillary infrastructure' means the necessary and sufficient infrastructure to achieve the goals of actions, including freight-passenger installations;
- (i) 'accompanying measure' means any measure which seeks to prepare for or to support current or future actions, including dissemination activities and project monitoring and evaluation, and the collection and analysis of statistical data; measures devoted to the commercialisation of products, processes or services, marketing activities and sales promotion are not accompanying measures;
- (j) 'preparatory measure' means any measure taken in preparation for a catalyst, Motorways of the Sea or traffic avoidance action, such as technical, operational or financial feasibility studies and equipment tests;

- (k) 'undertaking' means any entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed;
- (l) 'consortium' means any arrangement by which at least two undertakings execute together and share the risk relating to an action;
- (m) 'tonne-kilometre' means the transport of a tonne of freight, or its volumetric equivalent, over a distance of one kilometre;
- (n) 'vehicle-kilometre' means the movement of a truck, loaded or empty, over a distance of one kilometre;
- (o) 'close third country' means any country not a member of the European Union with a common border with the European Union or with a coastline on a closed or semi-closed sea neighbouring the European Union.

### Article 3

#### Scope

1. The Programme shall cover actions:
  - (a) involving the territory of at least two Member States,
  - or
  - (b) involving the territory of at least one Member State and the territory of a close third country.
2. Where an action involves the territory of a third country, costs arising in the territory of that country shall not be covered by the Programme, except in the circumstances set out in paragraphs 3 and 4.
3. The Programme shall be open to participation by countries which are candidates for accession to the European Union. Participation shall be governed by the conditions laid down in the Association Agreements with those countries, and on the basis of the rules laid down in the decision of the Association Council for each country concerned.
4. The Programme shall also be open to participation by EFTA and EEA countries and close third countries, on the basis of supplementary appropriations in accordance with procedures to be agreed with those countries.

## CHAPTER II

### ELIGIBLE APPLICANTS AND ACTIONS

#### Article 4

##### Eligible applicants

1. Actions shall be submitted by a consortium of two or more undertakings, established in at least two different Member States or in at least one Member State and one close third country, or

may in the case of a transport link with a close third country, in exceptional cases, be submitted by a single undertaking established in a Member State.

2. Undertakings established outside the participating countries referred to in Article 3(3) and (4) may be associated with a project, but may under no circumstances receive Community funding under the Programme.

### Article 5

#### Eligible actions and funding conditions

1. The following actions shall be eligible for funding under the Programme:

- (a) catalyst actions; those aimed at improving synergies in the rail, inland waterways and short sea shipping, including Motorways of the Sea, sectors by better use of existing infrastructures in particular deserve specific attention;
- (b) Motorways of the Sea actions; within the European Union such actions shall use the trans-European networks defined in Decision No 1692/96/EC of the European Parliament and Council of 23 July 1996 on Community guidelines for the development of the trans-European transport network <sup>(1)</sup>;
- (c) modal shift actions;
- (d) traffic avoidance actions;
- (e) common learning actions.

2. The specific funding conditions and other requirements for the various actions are set out in Annex I. The funding conditions for ancillary infrastructures within the meaning of Article 2(h) are set out in Annex II.

3. Community financial assistance shall be based on contracts to be negotiated by the Commission and the beneficiary. The terms and conditions of those contracts shall, as far as possible, keep financial and administrative burdens to a minimum, for example by facilitating business-friendly bank guarantees, as contemplated by applicable rules and regulations, especially Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities <sup>(2)</sup>, so as to achieve maximum administrative efficiency and flexibility.

<sup>(1)</sup> OJ L 228, 9.9.1996, p. 1. Decision as last amended by Decision No 884/2004/EC (OJ L 167, 30.4.2004, p. 1, as corrected in OJ L 201, 7.6.2004, p. 1).

<sup>(2)</sup> OJ L 248, 16.9.2002, p. 1.



4. Without prejudice to the overall policy objectives referred to in Article 1, annual priorities in the call for applications relating to catalyst actions and common learning actions shall be established and, if necessary, reviewed, by the Commission, assisted by the Committee referred to in Article 10 and in accordance with the procedure referred to in Article 10(2).

#### *Article 6*

##### **Detailed rules**

Detailed rules concerning the procedure for submission and selection of actions under the Programme shall be adopted in accordance with the procedure referred to in Article 10(2).

#### *Article 7*

##### **State aid**

Community financial assistance for the actions covered by the Programme shall not prevent those actions from being granted State aid at national, regional or local level, insofar as such aid is compatible with the State-aid arrangements laid down in the Treaty and within the cumulative limits established for each type of action set out in Annex I. The total aid granted in the form of State aid and Community financial assistance in respect of ancillary infrastructure shall not exceed 50 % of eligible costs.

#### CHAPTER III

##### **SUBMISSION AND SELECTION OF ACTIONS**

#### *Article 8*

##### **Submission of actions**

Actions shall be submitted to the Commission in accordance with the detailed rules issued under Article 6. Submissions shall contain all the information necessary to enable the Commission to make its selection in accordance with Article 9.

#### *Article 9*

##### **Selection of actions for financial assistance**

Submitted actions shall be evaluated by the Commission. When selecting actions for financial assistance under the Programme, the Commission shall take account of the following:

- (a) the objectives referred to in Article 1;
- (b) the conditions set out in Annexes I and II, as appropriate;

- (c) the contribution of the actions to reducing road congestion;
- (d) the relative environmental merits of the actions, including their contribution to reducing negative environmental effects caused by short sea shipping, rail and inland waterway transport. Specific attention will be paid to projects going beyond legally binding environmental requirements;
- (e) the overall sustainability of the actions.

The decision to grant financial assistance shall be adopted in accordance with the procedure referred to in Article 10(2).

The Commission shall inform the beneficiaries of its decision.

#### CHAPTER IV

##### **FINAL PROVISIONS**

#### *Article 10*

##### **Committee**

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

#### *Article 11*

##### **Budget**

The financial envelope for the implementation of the Marco Polo II Programme, for the period 1 January 2007 to 31 December 2013, shall be EUR 400 million <sup>(1)</sup>.

Annual appropriations shall be authorised by the budgetary authority within the limits of the financial framework.

#### *Article 12*

##### **Reserve for accompanying measures and Programme evaluation**

Up to 5 % of the budget provided for in this Regulation shall be set aside for accompanying measures and independent evaluation of the implementation of Article 5.

<sup>(1)</sup> This amount is based on 2004 figures and shall be subject to technical adjustment to take account of inflation.

*Article 13***Protection of the European Communities' financial interests**

1. The Commission shall ensure that, when actions financed under this Regulation are implemented, the financial interests of the European Communities are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by means of effective checks and the recovery of any amounts unduly paid and, if irregularities are detected, by means of effective, proportional and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests <sup>(1)</sup>, Council Regulation (Euratom, EC) No 2185/96, of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities <sup>(2)</sup>, and with Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) <sup>(3)</sup>.

2. For the actions financed under this Regulation, the notion of irregularity referred to in Article 1 of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Community law or any breach of a contractual obligation resulting from an act or omission by an economic operator, which has, or might have, the effect of prejudicing the general budget of the European Union or budgets managed by it, by an unjustified item of expenditure.

3. Contracts and agreements as well as agreements with participating third countries resulting from this Regulation shall provide in particular for supervision and financial control by the Commission or any representative authorised by it and audits by the Court of Auditors, if necessary on-the-spot.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 24 October 2006.

*For the European Parliament*  
*The President*  
J. BORELL FONTELLES

*Article 14***Evaluation**

1. The Commission shall inform the Committee at least twice a year concerning the financial execution of the Programme and give an update of the status of all actions financed under the Programme.

The Commission shall carry out both mid-term and final evaluations of the Programme in order to assess its contribution to the objectives of Community transport policy and the effective use made of the appropriations.

2. The Commission shall present to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions an evaluation report on the results achieved by the Marco Polo Programme for the period 2003 to 2006 by 30 June 2007. If this report reveals a need to adjust the Marco Polo II Programme, the Commission shall submit proposals accordingly.

*Article 15***Repeal**

Regulation (EC) No 1382/2003 is hereby repealed, with effect from 14 December 2006.

Contracts relating to actions within the framework of Regulation (EC) No 1382/2003 shall continue to be governed by that Regulation until their operational and financial closure. The entire evaluation and selection procedure for the year 2006 shall also be governed by Regulation (EC) No 1382/2003, even if that procedure ends in the year 2007.

*Article 16***Entry into force**

This Regulation shall enter into force on 14 December 2006.

*For the Council*  
*The President*  
P. LEHTOMÄKI

<sup>(1)</sup> OJ L 312, 23.12.1995, p. 1.

<sup>(2)</sup> OJ L 292, 15.11.1996, p. 2.

<sup>(3)</sup> OJ L 136, 31.5.1999, p. 1.

## ANNEX I

## Funding conditions and requirements according to Article 5(2)

Type of action	A. Catalyst	B. Motorways of the sea	C. Modal shift	D. Traffic avoidance	E. Common learning
	Article 5(1)(a)	Article 5(1)(b)	Article 5(1)(c)	Article 5(1)(d)	Article 5(1)(e)
1. Funding conditions	(a) the catalyst action will achieve its objectives within a period of a maximum of 60 months, and stay viable after that period, as forecast by a realistic business plan;	(a) the motorways of the sea (MoS) action will achieve its objectives within a period of a maximum of 60 months, and stay viable after that period, as forecast by a realistic business plan;	(a) the modal shift action will achieve its objectives within a period of a maximum of 36 months, and stay viable after that period, as forecast by a realistic business plan;	(a) the traffic avoidance action will achieve its objectives within a period of a maximum of 60 months, and stay viable after that period, as forecast by a realistic business plan;	(a) the common learning action will lead to the improvement of commercial services in the market, and in particular promote and/or facilitate road traffic avoidance or modal shift off the road to short sea shipping, rail and inland waterways, through improving cooperation and sharing of know-how; it will last for a maximum of 24 months;
	(b) the catalyst action is innovative on a European level, in terms of logistics, technology, methods, equipment, products, infrastructure or services rendered;	(b) the MoS action is innovative on a European level, in terms of logistics, technology, methods, equipment, products, infrastructure or services rendered; account will also be taken of high quality of service, simplified procedures and inspections, meeting safety and security standards, good access to the ports, efficient hinterland connections, and flexible and efficient port services;	(b) the modal shift action will not lead to distortions of competition in the relevant markets, in particular between alternative modes of transport to road transport alone or within each mode, contrary to the common interest;	(b) the traffic avoidance action is innovative on a European level, in terms of integration of production logistics into transport logistics;	(b) the action is innovative on a European level;



Type of action	A. Catalyst	B. Motorways of the sea	C. Modal shift	D. Traffic avoidance	E. Common learning
	Article 5(1)(a)	Article 5(1)(b)	Article 5(1)(c)	Article 5(1)(d)	Article 5(1)(e)
	(c) the catalyst action is expected to lead to an actual, measurable and sustainable modal shift from road to short sea shipping, rail, inland waterways;	(c) the MoS action aims at encouraging very large volume, high frequency intermodal services for freight transport by short sea shipping, including combined freight-passenger services as appropriate, or a combination of short sea shipping with other modes of transport in which road journeys are as short as possible; the action should preferably include integrated hinterland freight transport services by rail and/or inland waterways;	(c) the modal shift action proposes a realistic plan setting out the specific stages by which it seeks to achieve its objectives;	(c) the traffic avoidance action aims at encouraging higher efficiency in international freight transport in the European markets without impeding economic growth by focusing on modification of the production and/or distribution processes; thereby achieving shorter distances, higher loading factors, less empty runs, reduction of waste flows, reduction of volume and/or weight or any other effect leading to a significant reduction of freight traffic on the road, but not adversely affecting production output or workforce;	(c) the action will not lead to distortions of competition in the relevant markets, in particular between modes of transport alternative to road transport alone or within each mode to an extent contrary to the common interest;
	(d) the catalyst action proposes a realistic plan setting out the specific stages by which it seeks to achieve its objectives and identifies the need for Commission steering assistance;	(d) the MoS action is expected to lead to an actual, measurable and sustainable modal shift higher than the predicted growth rate of freight transport on the road route, from road to short sea shipping, inland waterways or rail;	(d) when the action requires reliance on services provided by third parties not part of the consortium, the applicant submits proof of a transparent, objective and non-discriminatory procedure for selection of the relevant services;	(d) the traffic avoidance action is expected to lead to an actual, measurable and sustainable traffic avoidance of at least 10 percent of the freight volume measured in tonnes-kilometres or vehicle-kilometres;	(d) the common learning action proposes a realistic plan setting out the specific stages by which it seeks to achieve its objectives and identifies the need for Commission steering assistance;
	(e) the catalyst action will not lead to distortions of competition in the relevant markets, in particular between modes of transport alternative to road transport alone or within each mode, to an extent contrary to the common interest;	(e) the MoS action proposes a realistic plan setting out the specific stages by which it seeks to achieve its objectives and identifies the need for Commission steering assistance;		(e) the traffic avoidance action proposes a realistic plan setting out the specific stages by which it seeks to achieve its objectives and identifies the need for Commission steering assistance;	

Type of action	A. Catalyst	B. Motorways of the sea	C. Modal shift	D. Traffic avoidance	E. Common learning
	Article 5(1)(a)	Article 5(1)(b)	Article 5(1)(c)	Article 5(1)(d)	Article 5(1)(e)
	(f) when the action requires reliance on services provided by third parties not part of the consortium, the applicant submits proof of a transparent, objective and non-discriminatory procedure for selection of the relevant services;	(f) the MoS action will not lead to distortions of competition in the relevant markets, in particular between modes of transport alternative to road transport alone or within each mode, to an extent contrary to the common interest;		(f) the traffic avoidance action will not lead to distortions of competition in the relevant markets, in particular concerning modes of transport alternative to road transport, to an extent contrary to the common interest;	
		(g) when the MoS action requires reliance on services provided by third parties not part of the consortium, the applicant submits proof of a transparent, objective and non-discriminatory procedure for selection of the relevant services;		(g) When the traffic avoidance action requires reliance on services provided by third parties not part of the consortium, the applicant submits proof of a transparent, objective and non-discriminatory procedure for selection of the relevant services;	
2. Funding intensity and scope	(a) Community financial assistance for catalyst actions shall be limited to a maximum of 35 % of the total expenditure necessary to achieve the objectives of the action and incurred as a result of the action, including preparatory measures and ancillary infrastructure. Such expenditure shall be eligible for Community financial assistance, to the extent to which it relates directly to the implementation of the action;	(a) Community financial assistance for MoS actions shall be limited to a maximum of 35 % of the total expenditure necessary to achieve the objectives of the action and incurred as a result of the action, including preparatory measures and ancillary infrastructure. Such expenditure shall be eligible for Community financial assistance, to the extent to which it relates directly to the implementation of the action;	(a) Community financial assistance for modal shift actions shall be limited to a maximum of 35 % of the total expenditure necessary to achieve the objectives of the action and incurred as a result of the action. Such expenditure shall be eligible for Community financial assistance to the extent to which it relates directly to the implementation of the action;	(a) Community financial assistance for traffic avoidance actions shall be limited to a maximum of 35 % of the total expenditure necessary to achieve the objectives of the action and incurred as a result of the action, including preparatory measures and ancillary infrastructure and equipment. Such expenditure shall be eligible for Community financial assistance, to the extent to which it relates directly to the implementation of the action;	(a) Community financial assistance for common learning actions shall be limited to a maximum of 50 % of the total expenditure necessary to achieve the objectives of the action and incurred as a result of the action. Such expenditure shall be eligible for Community financial assistance, to the extent to which it relates directly to the implementation of the action;

Type of action	A. Catalyst	B. Motorways of the sea	C. Modal shift	D. Traffic avoidance	E. Common learning
	Article 5(1)(a)	Article 5(1)(b)	Article 5(1)(c)	Article 5(1)(d)	Article 5(1)(e)
	Expenditure incurred on or after the date of the submission of an application under the selection procedure shall be eligible for Community financial assistance provided that final approval for Community funding is given. A contribution towards the costs of movable assets shall be contingent on the obligation to use such assets for the duration of the assistance, principally for the action, as defined by the subsidy agreement;	Expenditure incurred on or after the date of the submission of an application under the selection procedure shall be eligible for Community financial assistance provided that final approval for Community funding is given. A contribution towards the costs of movable assets shall be contingent on the obligation to use such assets for the duration of the assistance, principally for the action, as defined by the subsidy agreement;	Expenditure incurred on or after the date of the submission of an application under the selection procedure shall be eligible for Community financial assistance provided that final approval for Community funding is given. A contribution towards the costs of movable assets shall be contingent on the obligation to use such assets for the duration of the assistance, principally for the action, as defined by the subsidy agreement;	Expenditure incurred on or after the date of the submission of an application under the selection procedure shall be eligible for Community financial assistance provided that final approval for Community funding is given. A contribution towards the costs of movable assets shall be contingent on the obligation to use such assets for the duration of the assistance, principally for the action, as defined by the subsidy agreement;	Expenditure incurred on or after the date of the submission of an application under the selection procedure shall be eligible for Community financial assistance provided that final approval for Community funding is given;
				(b) Community financial assistance for traffic avoidance actions must not be used to support business or production activities which bear no direct relation to transport or distribution;	
	(b) The funding conditions for ancillary infrastructure are set out in Annex II;	(b) The Community financial assistance, except for preparatory measures and ancillary infrastructure, determined by the Commission on the basis of the tonne-kilometres shifted from road to short sea shipping, rail, inland waterways, shall initially be set at EUR 1 for each shift of 500 tonne-kilometres of road freight. This indicative amount could be adjusted, in particular, in accordance with the quality of the project or the real environmental benefit obtained;	(b) The Community financial assistance, except for ancillary infrastructure, determined by the Commission on the basis of the tonne-kilometres shifted from road to short sea shipping, rail, inland waterways shall initially be set at EUR 1 for each shift of 500 tonne-kilometres of road freight. This indicative amount could be adjusted, in particular, in accordance with the quality of the project or the real environmental benefit obtained;	(c) The Community financial assistance, except for preparatory measures, ancillary infrastructure and equipment, shall initially be set at EUR 1 for every avoidance of 500 tonne-kilometres or 25 vehicle-kilometres of road freight. This indicative amount could be adjusted, in particular, in accordance with the quality of the project or the real environmental benefit obtained;	(b) The funding conditions for ancillary infrastructure: not applicable;

Type of action	A. Catalyst	B. Motorways of the sea	C. Modal shift	D. Traffic avoidance	E. Common learning
	Article 5(1)(a)	Article 5(1)(b)	Article 5(1)(c)	Article 5(1)(d)	Article 5(1)(e)
		(c) In accordance with the procedure referred to in Article 10(2), the Commission may re-examine, from time to time as necessary, the developments concerning the items on which this calculation is based and, if necessary, adapt the amount of Community financial assistance accordingly;	(c) In accordance with the procedure referred to in Article 10(2), the Commission may re-examine, from time to time as necessary, the developments concerning the items on which this calculation is based and, if necessary, adapt the amount of Community financial assistance accordingly;	(d) In accordance with the procedure referred to in Article 10(2), the Commission may re-examine, from time to time as necessary, the developments concerning the items on which this calculation is based and, if necessary, adapt the amount of Community financial assistance accordingly;	
		(d) The funding conditions for ancillary infrastructure are set out in Annex II;	(d) The funding conditions for ancillary infrastructure, insofar as they are applicable, are set out in Annex II;	(e) The funding conditions for ancillary infrastructure are set out in Annex II;	
3. Form and duration of subsidy agreement	Community financial assistance for catalyst actions shall be granted on the basis of subsidy agreements, with appropriate provisions for steering and monitoring. As a rule, the maximum duration of these agreements shall be 62 months;	Community financial assistance for MoS actions shall be granted on the basis of subsidy agreements, with appropriate provisions for steering and monitoring. As a rule, the maximum duration of these agreements shall be 62 months;	Community financial assistance for modal shift actions shall be granted on the basis of subsidy agreements. As a rule, the maximum duration of these agreements shall be 38 months;	Community financial assistance for traffic avoidance actions shall be granted on the basis of subsidy agreements, with appropriate provisions for steering and monitoring. As a rule, the maximum duration of these agreements shall be 62 months;	Community financial assistance for common learning actions shall be granted on the basis of subsidy agreements, with appropriate provisions for steering and monitoring. As a rule, the maximum duration of these agreements shall be 26 months;
	Community financial assistance shall not be renewable beyond the stipulated maximum period of 62 months;	Community financial assistance shall not be renewable beyond the stipulated maximum period of 62 months;	Community financial assistance shall not be renewable beyond the stipulated maximum period of 38 months;	Community financial assistance shall not be renewable beyond the stipulated maximum period of 62 months;	Community financial assistance shall not be renewable beyond the stipulated maximum period of 26 months;
4. Contract value threshold	The minimum indicative subsidy threshold per catalyst action shall be EUR 2 000 000;	The minimum indicative subsidy threshold per MoS action shall be 1,25 billion tonne-kilometres or its volumetric equivalent of modal shift or, in proportion to the indicative amount per euro of financial assistance, EUR 2 500 000;	The minimum indicative subsidy threshold per modal shift action shall be 250 million tonne-kilometres or its volumetric equivalent of modal shift or, in proportion to the indicative amount per euro of financial assistance, EUR 500 000;	The minimum indicative subsidy threshold per traffic avoidance action shall be 500 million tonne-kilometres or 25 million vehicle-kilometres of freight traffic avoided or, in proportion to the indicative amount per euro of financial assistance, EUR 1 000 000;	The minimum indicative subsidy threshold per common learning action shall be EUR 250 000;

Type of action	A. Catalyst	B. Motorways of the sea	C. Modal shift	D. Traffic avoidance	E. Common learning
	Article 5(1)(a)	Article 5(1)(b)	Article 5(1)(c)	Article 5(1)(d)	Article 5(1)(e)
5. Dissemination	The results and methods of catalyst actions shall be disseminated, and the exchange of best practices shall be encouraged, as specified in a dissemination plan, in order to help achieve the objectives of this Regulation.	The results and methods of MoS actions shall be disseminated, and the exchange of best practices shall be encouraged, as specified in a dissemination plan, in order to help achieve the objectives of this Regulation.	Specific dissemination activities for modal shift actions are not foreseen.	The results and methods of traffic avoidance actions shall be disseminated and the exchange of best practices shall be encouraged, as specified in a dissemination plan, in order to help achieve the objectives of this Regulation.	The results and methods of common learning actions shall be disseminated and the exchange of best practices shall be encouraged, as specified in a dissemination plan, in order to help achieve the objectives of this Regulation.

## ANNEX II

**FUNDING CONDITIONS FOR ANCILLARY INFRASTRUCTURE ACCORDING TO ARTICLE 2(H) AND 5(2)**

1. Ancillary infrastructure shall be eligible for funding under the Programme provided that the following conditions are satisfied:
    - (a) the action requires infrastructure works for the timely implementation of a transport service shifting freight off the road, or, avoiding freight traffic on the road;
    - (b) the infrastructure works are completed within 24 months from the starting date of the action;
    - (c) the transport service or traffic avoidance starts within 3 months from the completion of the infrastructure works; additionally for traffic avoidance actions the agreed total avoidance is achieved within the duration of the subsidy agreement;
    - (d) the respect of relevant Community legislation, in particular concerning the environment.
  2. The maximum duration of the contract established for each type of action referred to in Article 5 may be extended by the time required to complete the infrastructure works, but in any case not longer than a total period of 74 months.
  3. Where funding for infrastructure has been requested under the Programme, funding from other Community programmes, and specifically funding under Decision No 1692/96/EC, for the same infrastructure item is excluded.
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**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**

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.

<sup>(1)</sup> OJ C 88, 11.4.2006, p. 13.

<sup>(2)</sup> 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).

<sup>(3)</sup> OJ L 175, 19.7.1993, p. 23. Directive as last amended by the 2003 Act of Accession.

<sup>(4)</sup> OJ L 332, 30.12.1995, p. 33. Directive as last amended by the 2003 Act of Accession.

- (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>(1)</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>(2)</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>(3)</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>(4)</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.

<sup>(1)</sup> 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).

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

- (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>(1)</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>(2)</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>(3)</sup> should remain in force.

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 268, 24.9.1991, p. 56. Directive as last amended by the 2003 Act of Accession.

<sup>(3)</sup> 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.).

- (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>(1)</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>(2)</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>(3)</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.

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 136, 30.4.2004, p. 1.

<sup>(3)</sup> OJ L 223, 15.8.2006, p. 1.



- (42) In accordance with paragraph 34 of the Interinstitutional agreement on better law-making <sup>(1)</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>(2)</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:

## CHAPTER I

### SUBJECT MATTER, SCOPE AND DEFINITIONS

#### Article 1

##### Subject matter

1. This Directive lays down:
  - (a) the animal health requirements to be applied for the placing on the market, the importation and the transit of aquaculture animals and products thereof;
  - (b) minimum preventive measures aimed at increasing the awareness and preparedness of the competent authorities, aquaculture production business operators and others related to this industry, for diseases in aquaculture animals;

<sup>(1)</sup> OJ C 321, 31.12.2003, p. 1. Corrected version in OJ C 4, 8.1.2004, p. 7.

<sup>(2)</sup> 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).

- (c) minimum control measures to be applied in the event of a suspicion of, or an outbreak of certain diseases in aquatic animals.

2. Member States shall remain free to take more stringent measures in the field covered by Article 13 of Chapter II, and Chapter V, provided that such measures do not affect trade with other Member States.

#### Article 2

##### Scope

1. This Directive shall not apply to:
  - (a) ornamental aquatic animals reared in non-commercial aquaria;
  - (b) wild aquatic animals harvested or caught for direct entry into the food chain;
  - (c) aquatic animals caught for the purpose of production of fish-meal, fish feed, fish oil and similar products.
2. Chapter II, Sections 1 to 4 of Chapter III, and Chapter VII shall not apply where ornamental aquatic animals are kept in pet shops, garden centres, garden ponds, commercial aquaria, or with wholesalers:
  - (a) without any direct contact with natural waters in the Community;

or

  - (b) which are equipped with an effluent treatment system reducing the risk of transmitting diseases to the natural waters to an acceptable level.
3. This Directive shall apply without prejudice to provisions on the conservation of species or the introduction of non-native species.

#### Article 3

##### Definitions

1. For the purposes of this Directive, the following definitions shall apply:
  - (a) 'aquaculture' means the rearing or cultivation of aquatic organisms using techniques designed to increase the production of those organisms beyond the natural capacity of the environment and where the organisms remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting;

- (b) 'aquaculture animal' means any aquatic animal at all its life stages, including eggs and sperm/gametes, reared in a farm or mollusc farming area, including any aquatic animal from the wild intended for a farm or mollusc farming area;
- (c) 'aquaculture production business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to the rearing, keeping or cultivation of aquaculture animals;
- (d) 'aquaculture production business operator' means any natural or legal person responsible for ensuring that the requirements of this Directive are met within the aquaculture production business under their control;
- (e) 'aquatic animal' means:
- (i) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes* and *Osteichthyes*;
  - (ii) mollusc belonging to the Phylum *Mollusca*;
  - (iii) crustacean belonging to the Subphylum *Crustacea*;
- (f) 'authorised processing establishment' means any food business approved in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin <sup>(1)</sup>, for processing aquaculture animals for food purposes, and authorised in accordance with Articles 4 and 5 of this Directive;
- (g) 'authorised processing establishment operator' means any natural or legal person responsible for ensuring that the requirements of this Directive are met within the authorised processing establishment under their control;
- (h) 'farm' means any premises, enclosed area, or installation operated by an aquaculture production business in which aquaculture animals are reared with a view to their being placed on the market, with the exception of those where wild aquatic animals harvested or caught for the purpose of human consumption are temporarily kept awaiting slaughter without being fed;
- (i) 'farming' means the rearing of aquaculture animals in a farm or in a mollusc farming area;
- (j) 'mollusc farming area' means a production area or relaying area in which all aquaculture production businesses operate under a common biosecurity system;
- (k) 'ornamental aquatic animal' means an aquatic animal which is kept, reared, or placed on the market for ornamental purposes only;
- (l) 'placing on the market' means 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;
- (m) 'production area' means any freshwater, sea, estuarine, continental or lagoon area containing natural beds of molluscs or sites used for the cultivation of molluscs, and from which molluscs are taken;
- (n) 'put and take fisheries' means ponds or other installations where the population is maintained only for recreational fishing by restocking with aquaculture animals;
- (o) 'relaying area' means any freshwater, sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live molluscs;
- (p) 'wild aquatic animal' means an aquatic animal which is not an aquaculture animal.
2. For the purposes of this Directive, the following definitions shall also apply:
- (a) the technical definitions laid down in Annex I;
  - (b) as appropriate, the definitions laid down respectively in:
    - (i) Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(2)</sup>;
    - (ii) Article 2 of Regulation (EC) No 852/2004;
    - (iii) Article 2 of Regulation (EC) No 853/2004;
    - (iv) Article 2 of Regulation (EC) No 882/2004.

## CHAPTER II

AQUACULTURE PRODUCTION BUSINESSES AND  
AUTHORISED PROCESSING ESTABLISHMENTS

## Article 4

Authorisation of aquaculture production businesses and  
processing establishments

1. Member States shall ensure that each aquaculture production business is duly authorised by the competent authority in accordance with Article 5.

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 55.

<sup>(2)</sup> OJ L 31, 1.2.2002, p. 1.



Where appropriate, such authorisation may cover several aquaculture production businesses for molluscs in a mollusc farming area.

However, dispatch centres, purification centres or similar businesses located inside a mollusc farming area shall have an individual authorisation.

2. Member States shall ensure that each 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 Article 5.

3. Member States shall ensure that each aquaculture production business and authorised processing establishment has a unique authorisation number.

4. By way of derogation from the authorisation requirement in paragraph 1, 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 in accordance with of Article 1(3)(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.

5. In the case of non-compliance with the provisions of this Directive, the competent authority shall act in accordance with Article 54 of Regulation (EC) No 882/2004.

#### Article 5

##### Authorisation conditions

1. Member States shall ensure that authorisations, as provided for in Article 4(1) and (2), are only granted by the competent authority if the aquaculture production business operator or authorised processing establishment operator:

- (a) fulfils the relevant requirements of Articles 8, 9 and 10;
- (b) has a system in place which enables the operator to demonstrate to the competent authority that those relevant requirements are being fulfilled;
- and
- (c) remains under the supervision of the competent authority, which shall perform the duties laid down in Article 54(1).

2. Authorisation shall not be granted if the activity in question were to lead to an unacceptable risk of spreading diseases to farms, mollusc farming areas or to wild stocks of aquatic animals in the vicinity of the farm or mollusc farming area.

However, before a decision to refuse authorisation is taken, consideration shall be given to risk-mitigation measures, including possible alternative siting of the activity in question.

3. Member States shall ensure that the aquaculture production business operator or authorised processing establishment operator submits all relevant information in order to allow the competent authority to assess that the conditions for authorisation are fulfilled, including the information required in accordance with Annex II.

#### Article 6

##### Register

The Member States shall establish, keep up to date and make publicly available a register of aquaculture production businesses and authorised processing establishments containing at least the information set out in Annex II.

#### Article 7

##### Official controls

1. In accordance with Article 3 of Regulation (EC) No 882/2004, official controls on aquaculture production businesses and authorised processing establishments shall be carried out by the competent authority.

2. The official controls provided for in paragraph 1 shall at least consist of regular inspections, visits, audits, and where appropriate, sampling, for each aquaculture production business, taking account of the risk the aquaculture production business and authorised processing establishment poses in relation to the contracting and spreading of diseases. Recommendations for the frequencies of such controls, depending on the health status of the concerned zone or compartment, are laid down in Part B of Annex III.

3. Detailed rules for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 62(2).

#### Article 8

##### Recording obligations - Traceability

1. Member States shall ensure that aquaculture production businesses keep a record of:

- (a) all movements of aquaculture animals and products thereof into and out of the farm or mollusc farming area;

- (b) the mortality in each epidemiological unit as relevant for the type of production;

and

- (c) the results of the risk-based animal health surveillance scheme provided for in Article 10.

2. Member States shall ensure that authorised processing establishments keep a record of all movement of aquaculture animals and products thereof into and out of such establishments.

3. Member States shall ensure that when aquaculture animals are transported, transporters keep a record of:

- (a) mortality during transport, as practicable for the type of transport and the species transported;
- (b) farms, mollusc farming areas and processing establishments visited by the means of transport;

and

- (c) any water exchange during transport, in particular the sources of new water and site of release of water.

4. 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(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 movements to be recorded on a national register and kept in a computerised form.

#### *Article 9*

### **Good hygiene practice**

Member States shall ensure that aquaculture production businesses and authorised processing establishments implement good hygiene practice, as relevant for the activity concerned, to prevent the introduction and spreading of diseases.

#### *Article 10*

### **Animal health surveillance scheme**

1. Member States shall ensure that a risk-based animal health surveillance scheme is applied in all farms and mollusc farming areas, as appropriate for the type of production.

2. The risk-based animal health surveillance scheme referred to in paragraph 1 shall aim at the detection of:

- (a) any increased mortality in all farms and mollusc farming areas as appropriate for the type of production;

and

- (b) the diseases listed in Part II of Annex IV, in farms and mollusc farming areas where species susceptible to those diseases are present.

3. Recommendations for the frequencies of such animal health surveillance schemes, depending on the health status of the concerned zone or compartment, are laid down in Part B of Annex III. This surveillance shall apply without prejudice to the sampling and surveillance carried out in accordance with Chapter V or Article 49(3), Article 50(4) and Article 52.

4. The risk-based animal health surveillance scheme referred to in paragraph 1 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2).

5. In the light of the outcome of official controls carried out in accordance with Article 7 and of the outcome of Community controls carried out in accordance with Article 58, and of any other relevant information, the Commission shall submit to the Council a report on the overall operation of risk-based animal health surveillance in Member States. This report may, where appropriate, be accompanied by an appropriate proposal, in accordance with the procedure referred to in Article 62(2) laying down detailed rules for the implementing of this Article.

## **CHAPTER III**

### **ANIMAL HEALTH REQUIREMENTS FOR PLACING ON THE MARKET OF AQUACULTURE ANIMALS AND PRODUCTS THEREOF**

#### **SECTION 1**

### **General Provisions**

#### *Article 11*

### **Scope**

1. Unless otherwise provided, this Chapter shall apply only to the diseases and the species susceptible thereto listed in Part II of Annex IV.

2. Member States may allow the placing on the market for scientific purposes of aquaculture animals and products thereof, which do not comply with this Chapter under the strict supervision of the competent authority.

The competent authority shall ensure that such placing on the market does not jeopardise the health status with regard to the diseases listed in Part II of Annex IV of aquatic animals at the place of destination or at places of transit.

Any such movements between Member States shall not take place without prior notification of the competent authorities of the Member States concerned.

#### Article 12

##### **General requirements for the placing of aquaculture animals on the market**

1. Member States shall ensure that the placing on the market of aquaculture animals and products thereof does not jeopardise the health status of aquatic animals at the place of destination with regard to the diseases listed in Part II of Annex IV.

2. Detailed rules on the movement of aquaculture animals are laid down in this Chapter, in particular relating to movements between Member States, zones and compartments with different health statuses, as referred to in Part A of Annex III.

#### Article 13

##### **Disease prevention requirements in relation to transport**

1. Member States shall ensure that:

(a) the necessary disease prevention measures are applied during the transport of aquaculture animals in order not to alter the health status of those animals during transport, and to reduce the risk of spreading diseases;

and

(b) aquaculture animals are transported under conditions which neither alter their health status nor jeopardise the health status of the place of destination, and where appropriate, of places of transit.

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

2. Member States shall ensure that any water exchanges during transport are carried out at places and under conditions which do not jeopardise the health status of:

(a) the aquaculture animals being transported;

(b) any aquatic animals at the place of water exchange;

and

(c) aquatic animals at the place of destination.

#### Article 14

##### **Animal health certification**

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 Articles 49 and 50 or subject to surveillance, or eradication programme in accordance with Article 44(1) or (2) for:

(a) farming and restocking purposes;

or

(b) further processing before human consumption, unless:

(i) as regards fish, they are slaughtered and eviscerated before dispatch;

(ii) as regards molluscs and crustaceans, they are dispatched as unprocessed or processed products.

2. 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 and 6 of Chapter V.

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

3. The following movements shall be subject to notification under the computerised system provided for in Article 20(1) of Directive 90/425/EEC:

(a) movements of aquaculture animals between Member States where animal health certification is required in accordance with paragraphs 1 or 2 of this Article;

and

(b) all other movements of live aquaculture animals for farming or restocking purposes between Member States where no animal health certification is required under this Directive.

4. Member States may decide to use the computerised system provided for in paragraph 3 to trace movements taking place entirely within their territory.

## SECTION 2

***Aquaculture animals intended for farming and restocking****Article 15***General requirements for the placing of aquaculture animals on the market for farming and restocking**

1. Without prejudice to the provisions laid down in Chapter V, Member States shall ensure that aquaculture animals placed on the market for farming are:

(a) clinically healthy;

and

(b) do not come from a farm or mollusc farming area where there is any unresolved increased mortality.

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

2. By way of derogation from paragraph 1(b), Member States may allow such placing on the market, based on an assessment of risk, provided that the animals originate from a part of the farm or mollusc farming area independent of the epidemiological unit where the increased mortality has occurred.

3. Member States shall ensure that aquaculture animals intended for destruction or slaughter in accordance with the disease control measures provided for in Chapter V are not placed on the market for farming and restocking purposes.

4. Aquaculture animals may only be released into the wild for restocking purposes or into put and take fisheries if they:

(a) comply with the requirements in paragraph 1;

and

(b) come from a farm or mollusc farming area with a health status as referred to in Part A of Annex III, at least equivalent to the health status of the waters in which they are to be released.

However, Member States may decide that the aquaculture animals shall come from a zone or compartment declared disease-free in accordance with Articles 49 or 50. Member States may also decide to apply this paragraph to programmes drawn up and applied in accordance with Article 43.

*Article 16***Introduction of aquaculture animals of species susceptible to a specific disease into areas free of that disease**

1. In order to be introduced for farming or restocking into a Member State, zone or compartment declared free of a specific disease in accordance with Articles 49 or 50, aquaculture animals of species susceptible thereto shall originate from another Member State, zone or compartment also declared free of that disease.

2. Where it can be scientifically justified that species susceptible to the specific disease at certain life stages do not transmit that disease, paragraph 1 shall not apply to those life stages.

A list of species and life stages to which the first subparagraph may 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).

*Article 17***Introduction of live aquaculture animals of vector species into disease-free areas**

1. Where scientific data or practical experience substantiates that species other than those referred to in Part II of Annex IV may be responsible for the transmission of a specific disease by acting as vector species, Member States shall ensure that where introduced for farming or restocking purposes into a Member State, zone or compartment declared free of that specific disease in accordance with Articles 49 or 50, such vector species shall:

(a) originate from another Member State, zone or compartment declared free of that specific disease;

or

(b) be held in quarantine facilities in water free of the pathogen in question, for an appropriate period of time, where, in the light of the scientific data or practical experience provided, this proves to be sufficient to reduce the risk of transmission of the specific disease to a level acceptable for preventing the transmission of the disease concerned.

2. A list of vector species and life stages of such species to which this Article applies and, where appropriate, the conditions under which those species can transmit a disease shall be adopted, and when necessary amended taking into account scientific and technological developments in accordance with the procedure referred to in Article 62(2).

3. Pending the possible inclusion of a species on the list referred to in paragraph 2, the Commission may decide in accordance with the procedure referred to in Article 62(3), to allow Member States to apply the provisions provided for in paragraph 1.

#### SECTION 3

##### ***Aquaculture animals and products thereof intended for human consumption***

#### Article 18

##### **Aquaculture animals and products thereof placed on the market for further processing before human consumption**

1. Member States shall ensure that aquaculture animals of species susceptible to one or more of the non-exotic diseases listed in Part II of Annex IV, and products thereof, may only be placed on the market for further processing in a Member State, zone or compartment declared free of those diseases in accordance with Articles 49 or 50, if they comply with one of the following conditions:

- (a) they originate from another Member State, zone or compartment declared free of the disease in question;
- (b) they are processed in an authorised processing establishment under conditions which prevent the spreading of diseases;
- (c) as regards fish, they are slaughtered and eviscerated before dispatch;
- or
- (d) as regards molluscs and crustaceans, they are dispatched as unprocessed or processed products.

2. Member States shall ensure that live aquaculture animals of species susceptible to one or more of the non-exotic diseases listed in Part II of Annex IV which are placed on the market for further processing in a Member State, zone or compartment declared free of those diseases in accordance with Articles 49 or 50, may only be temporarily stored at the place of processing if:

- (a) they originate from another Member State, zone, or compartment declared free of the disease in question;
- or
- (b) they are temporarily kept in dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.

#### Article 19

##### **Aquaculture animals and products thereof placed on the market for human consumption without further processing**

1. This section shall not apply where aquaculture animals of species susceptible to one or more of the diseases listed in Part II of Annex IV, or products thereof, are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for packaging and labelling provided for in Regulation (EC) No 853/2004.

2. Where live molluscs and crustaceans of species susceptible to one or more of the diseases listed in Part II of Annex IV are temporarily relayed in Community waters, or introduced into dispatch centres, purification centres or similar businesses, they shall comply with Article 18(2).

#### SECTION 4

##### **Wild aquatic animals**

#### Article 20

##### **Release of wild aquatic animals in Member States, zones or compartments declared disease-free**

1. Wild aquatic animals of species susceptible to one or more of the diseases listed in Part II of Annex IV caught in a Member State or zone or compartment not declared disease-free in accordance with Articles 49 or 50 shall be placed in quarantine under the supervision of the competent authority in suitable facilities, for a period of time sufficient to reduce to an acceptable level the risk of transmission of the disease, before they may be released into a farm or mollusc farming area situated in a Member State, zone, or compartment declared free from that disease in accordance with Articles 49 or 50.

2. The Member States may allow traditional extensive lagoon aquaculture practice, without the quarantine provided for in paragraph 1, provided a risk assessment is undertaken and that the risk is considered not higher than what is expected from the application of paragraph 1.

#### SECTION 5

##### **Ornamental aquatic animals**

#### Article 21

##### **Placing on the market of ornamental aquatic animals**

1. Member States shall ensure that the placing on the market of ornamental aquatic animals does not jeopardise the health status of aquatic animals with regard to the diseases listed in Part II of Annex IV.



2. This Article shall apply also in relation to diseases not listed in Part II of Annex IV.

#### CHAPTER IV

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

#### Article 22

#### **General requirements for introduction of aquaculture animals and products thereof from third countries**

Member States shall ensure that aquaculture animals and products thereof are introduced into the Community only from third countries or parts of third countries that appear on a list drawn up and updated in accordance with the procedure referred to Article 62(2).

#### Article 23

#### **Lists of third countries and parts of third countries from which introduction of aquaculture animals and products thereof is permitted**

1. A third country, or a part of a third country, shall appear on the list provided for in Article 22 only if a Community assessment of that country, or that part of a third country, has demonstrated that the competent authority provides appropriate guarantees as regards compliance with the relevant animal health requirements of Community legislation.

2. The Commission may decide if an inspection as referred to in Article 58(2) is necessary to complete the assessment of the third country, or part of the third country, provided for in paragraph 1.

3. When drawing up or updating the lists provided for in Article 22, particular account shall be taken of:

- (a) the legislation of the third country;
- (b) the organisation of the competent authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and the means at their disposal, including staff capacity, to apply their legislation effectively;
- (c) the aquatic animal health requirements in force that apply to the production, manufacture, handling, storage and dispatch of live aquaculture animals intended for the Community;
- (d) the assurances which the competent authority of the third country may give regarding compliance or equivalence with the relevant aquatic animal health conditions;

- (e) any experience of marketing live aquaculture animals from the third country and the results of any import controls carried out;
- (f) the results of the Community assessment, in particular the results of the assessment carried out by the competent authorities of the third country concerned or, where the Commission so requests, the report submitted by the competent authorities of the third country on any inspections carried out;
- (g) the health status of farmed and wild aquatic animals in the third country, with particular regard to exotic animal diseases and any aspects of the general aquatic animal health situation in the country which might pose a risk to aquatic animal health in the Community;
- (h) the regularity, speed and accuracy with which the third country supplies information on the existence of infectious or contagious aquatic animal diseases in its territory, particularly the notifiable diseases, listed by the World Organisation for Animal Health (OIE);

and

- (i) 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.

4. The Commission shall arrange for all lists to be drawn up or updated in accordance with Article 22 and made available to the public.

5. Lists drawn up in accordance with Article 22 may be combined with other lists drawn up for animal and public health purposes.

#### Article 24

#### **Documents**

1. All consignments of aquaculture animals and products thereof shall be accompanied by a document containing an animal health certificate upon their entry into the Community.

2. The animal health certificate shall certify that the consignment satisfies:

- (a) the requirements laid down for such commodities under this Directive;

and

- (b) any special import conditions established in accordance with Article 25(a).

3. The document may include details required under other provisions of Community public and animal health legislation.



*Article 25***Detailed rules**

Where necessary, detailed rules for the application of this Chapter may be established in accordance with the procedure referred to in Article 62(2). These rules may concern in particular:

- (a) special import conditions for each third country, parts thereof or group of third countries;
- (b) the criteria for classifying third countries and parts thereof with regard to aquatic animal diseases;
- (c) the use of electronic documents;
- (d) model animal health certificates and other documents;  
and
- (e) procedures and certification for transit.

## CHAPTER V

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

## SECTION 1

**Disease notification***Article 26***National notification**

1. Member States shall ensure that:
  - (a) when there are any reasons to suspect the presence of a disease listed in Part II of Annex IV, or the presence of such disease is confirmed in aquatic animals, the suspicion and/or the confirmation is immediately notified to the competent authority;  
  
and
  - (b) when increased mortality occurs in aquaculture animals, the mortality is immediately notified to the competent authority or a private veterinarian for further investigations.
2. Member States shall ensure that the obligations to notify the matters referred to in paragraph 1 are imposed on:
  - (a) the owner and any person attending aquatic animals;
  - (b) any person accompanying aquaculture animals during transport;
  - (c) veterinary practitioners and other professionals involved in aquatic animal health services;

- (d) official veterinarians, senior staff of veterinary or other official or private laboratories;

and

- (e) any other person with an occupational relationship to aquatic animals of susceptible species or to products of such animals.

*Article 27***Notification of the other Member States, the Commission and EFTA Member States**

Member States shall notify the other Member States, the Commission and EFTA Member States within 24 hours in case of confirmation of:

- (a) an exotic disease listed in Part II of Annex IV;
- (b) a non-exotic disease listed in Part II of Annex IV where the Member State concerned, zone, or compartment has been declared free of that disease.

## SECTION 2

**Suspicion of a listed disease – Epizootic investigation***Article 28***Initial control measures**

Member States shall ensure that, in the case of a suspicion of an exotic disease listed in Part II of Annex IV or, in the case of suspicion of a non-exotic disease listed in Part II of Annex IV in Member States, zones or compartments with a health status of either category I or III as referred to in Part A of Annex III, for that disease:

- (a) appropriate samples are taken and examined in a laboratory designated in accordance with Article 57;
- (b) pending the result of the examination provided for in point (a):
  - (i) the farm, or mollusc farming area, in which the disease is suspected, is placed under official surveillance and relevant control measures are implemented to prevent the spreading of the disease to other aquatic animals;
  - (ii) no aquaculture animals are allowed to leave or enter the affected farm or mollusc farming area in which the disease is suspected, unless authorised by the competent authority;
  - (iii) the epizootic investigation provided for in Article 29 is initiated.

*Article 29***Epizootic investigation**

1. Member States shall ensure that the epizootic investigation initiated in accordance with Article 28(b)(iii) is carried out where the examination provided for in Article 28(a) shows the presence of:

- (a) an exotic disease listed in Part II of Annex IV in any Member State;

or

- (b) a non-exotic disease listed in Part II of Annex IV in Member States, zones or compartments with a health status of either category I or III, as referred to in Part A of Annex III, for the disease in question.

2. The epizootic investigation provided for in paragraph 1 shall be aimed at:

- (a) determining the possible origin and means of contamination;
- (b) investigating whether aquaculture animals have left the farm or mollusc farming area during the relevant period preceding the notification of the suspicion provided for in Article 26(1);
- (c) investigating whether other farms have been infected.

3. Where the epizootic investigation provided for in paragraph 1 shows that the disease may have been introduced into one or more farms, mollusc farming areas or unenclosed waters, the Member State concerned shall ensure that the measures provided for in Article 28 are applied in such farms, mollusc farming areas or unenclosed waters.

In the case of extensive water catchment areas or coastal areas, the competent authority may decide to limit the application of Article 28 to a less extensive area in the vicinity of the farm or the mollusc farming area suspected of being infected, where it considers that such less extensive area is sufficiently large to guarantee that the disease does not spread.

4. Where necessary, the competent authority of neighbouring Member States or third countries shall be informed of the suspected case of disease.

In that event, the competent authorities of the Member States involved shall take appropriate action to apply the measures provided for in this Article within their territory.

*Article 30***Lifting restrictions**

The competent authority shall lift the restrictions provided for in Article 28(b) where the examination provided for in point (a) of that Article fails to demonstrate the presence of the disease.

*SECTION 3****Minimum control measures in the case of confirmation of exotic diseases in aquaculture animals****Article 31***Introductory provision**

This Section shall apply in the case of confirmation of an exotic disease listed in Part II of Annex IV in aquaculture animals.

*Article 32***General measures**

Member States shall ensure that:

- (a) the farm or mollusc farming area is officially declared infected;
  - (b) a containment area appropriate to the disease in question is established, including a protection zone and surveillance zone, around the farm or mollusc farming area declared infected;
  - (c) no restocking takes place and no aquaculture animals are moved into, within, and out of the containment area unless authorised by the competent authority;
- and
- (d) any additional measures necessary to prevent the further spread of the disease are implemented.

*Article 33***Harvesting and further processing**

1. Aquaculture animals which have reached commercial size and show no clinical sign of disease may be harvested under the supervision of the competent authority for human consumption, or for further processing.

2. Harvesting, introduction into dispatch centres or purification centres, further processing and any other related operations involved in the preparation of the aquaculture animals for entry into the food chain shall be carried out under conditions which prevent the spread of the pathogen responsible for causing the disease.

3. Dispatch centres, purification centres or similar businesses shall be equipped with an effluent treatment system inactivating the pathogen responsible for causing the disease, or the effluent shall be subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.

4. Further processing shall be performed in authorised processing establishments.

#### Article 34

##### Removal and disposal

1. Member States shall ensure that dead fish and crustaceans, as well as live fish and crustaceans showing clinical signs of disease, are removed and disposed of under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption <sup>(1)</sup>, as soon as possible in accordance with the contingency plan provided for in Article 47 of this Directive.

2. Aquaculture animals which have not reached commercial size and do not show clinical signs of disease shall, in an appropriate timeframe taking into account the type of production and the risk such animals pose for further spread of the disease, be removed and disposed of under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002, and the contingency plan provided for in Article 47 of this Directive.

#### Article 35

##### Fallowing

Where possible, infected farms or mollusc farming areas shall undergo an appropriate period of fallowing after being emptied and, where appropriate, cleansed and disinfected.

For farms or mollusc farming areas rearing aquaculture animals not susceptible to the disease in question, decisions on fallowing shall be based on a risk assessment.

#### Article 36

##### Protection of aquatic animals

Member States shall take the necessary measures to prevent the spreading of diseases to other aquatic animals.

<sup>(1)</sup> OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).

#### Article 37

##### Lifting measures

The measures provided for in this Section shall be maintained until:

- (a) the eradication measures provided for in this Section have been carried out;
- (b) sampling and surveillance as appropriate for the disease in question and the types of aquaculture production businesses affected has been carried out in the containment area with negative results.

#### SECTION 4

##### **Minimum control measures in the case of confirmation of non-exotic diseases in aquaculture animals**

#### Article 38

##### General provisions

1. In the case of confirmation of a non-exotic disease listed in Part II of Annex IV in a Member State, zone or compartment declared free of that disease, the Member State concerned shall either:

- (a) apply the measures provided for in Section 3 in order to regain such disease-free status,

or

- (b) draw up an eradication programme in accordance with Article 44(2).

2. By way of derogation from Article 34(2), where a Member State decides to apply the measures provided for in Section 3, it may allow clinically healthy animals to be raised to market size before slaughter for human consumption or to be moved to another infected zone or compartment. In such cases, measures shall be taken to reduce and as far as possible, prevent the further spreading of the disease.

3. Where the Member State concerned does not wish to regain disease-free status, Article 39 shall apply.

#### Article 39

##### Containment measures

In the case of confirmation of a non-exotic disease listed in Part II of Annex IV in a Member State, zone or compartment not declared free of that disease, the Member State concerned shall take measures to contain the disease.

Those measures shall at least consist of:

- (a) declaring the farm or mollusc farming area to be infected;
- (b) establishing a containment area appropriate to the disease in question, including a protection zone and surveillance zone around the farm or mollusc farming area declared infected;
- (c) restricting the movement of aquaculture animals from the containment area to the effect that such animals may only be:
  - (i) introduced into farms or mollusc farming areas in accordance with Article 12(2);
  - or
  - (ii) harvested and slaughtered for human consumption in accordance with Article 33(1);
- (d) the removal and disposal of dead fish and crustaceans, under the supervision of the competent authority in accordance with Regulation (EC) No 1774/2002, in an appropriate time-frame taking into account the type of production and the risk such dead animals pose for further spread of the disease.

#### SECTION 5

##### **Minimum control measures in the case of confirmation of diseases listed in Part II of Annex IV in wild aquatic animals**

###### Article 40

##### **Control of diseases listed in Part II of Annex IV in wild aquatic animals**

1. Where wild aquatic animals are infected or suspected of being infected with exotic diseases listed in Part II of Annex IV, the Member State concerned shall monitor the situation, and take measures to reduce and, as far as possible, to prevent the further spreading of the disease.
2. Where wild aquatic animals are infected or suspected of being infected with non-exotic diseases listed in Part II of Annex IV in a Member State, zone or compartment declared free of that disease, the Member State shall also monitor the situation and take measures to reduce, and as far as possible, to prevent the further spreading of the disease.

3. Member States shall inform the Commission and the other Member States within the Committee referred to in Article 62(1) of the measures they have taken in accordance with paragraphs 1 and 2.

#### SECTION 6

##### **Control measures in case of emerging diseases**

###### Article 41

##### **Emerging diseases**

1. Member States shall take appropriate measures to control an emerging disease situation and prevent that disease from spreading, where the emerging disease in question has the potential to jeopardise the health situation of aquatic animals.
2. In the case of an emerging disease situation, the Member State concerned shall inform the Member States, the Commission and EFTA Member States without delay thereof, where the findings are of epidemiological significance to another Member State.
3. Within four weeks of informing the other Member States, the Commission and EFTA Member States as required in paragraph 2, the matter shall be brought to the attention of the Committee referred to in Article 62(1). The measures taken by the Member State concerned pursuant to paragraph 1 of this Article may be extended, amended or repealed in accordance with the procedure referred to in Article 62(2).
4. Where appropriate, the list set out in Part II of Annex IV shall be amended in accordance with the procedure referred to in Article 62(2) to include the emerging disease in question or a new susceptible host species to a disease already listed in that Annex.

#### SECTION 7

##### **Alternative measures and national provisions**

###### Article 42

##### **Procedure for adoption of ad hoc epidemiological measures for diseases listed in Part II of Annex IV**

A decision may be adopted in accordance with the procedure referred to in Article 62(2) to authorise the implementation of ad hoc measures for a limited period of time, under conditions appropriate to the epidemiological situation where:

- (a) the measures provided for in this chapter are found not to be suited to the epidemiological situation;
- or
- (b) the disease appears to be spreading despite the measures taken in accordance with this chapter.

*Article 43***Provisions for limiting the impact of diseases not listed in Part II of Annex IV**

1. Where a disease not listed in Part II of Annex IV constitutes a significant risk for the animal health situation of aquaculture or wild aquatic animals in a Member State, the Member State concerned may take measures to prevent the introduction of or to control that disease.

Member States shall ensure that these measures do not exceed the limits of what is appropriate and necessary to prevent the introduction of or to control the disease.

2. Member States shall notify to the Commission any measures referred to in paragraph 1 that may affect trade between Member States. Those measures shall be subject to approval in accordance with the procedure referred to in Article 62(2).

3. Approval referred to in paragraph 2 shall only be granted where the establishment of intra-Community trade restrictions is necessary to prevent the introduction of or to control the disease, and shall take into account the provisions laid down in Chapters II, III, IV and V.

## CHAPTER VI

**CONTROL PROGRAMMES AND VACCINATION**

## SECTION 1

***Surveillance and eradication programmes****Article 44***Drawing up and approval of surveillance and eradication programmes**

1. Where a Member State not known to be infected but not declared free (category III as referred to in Part A of Annex III) of one or more of the non-exotic diseases listed in Part II of Annex IV draws up a surveillance programme for achieving disease-free status for one or more of those diseases, it shall submit that programme for approval in accordance with the procedure referred to in Article 62(2).

Such programmes may also be amended or terminated in accordance with that procedure.

The specific requirements for surveillance, sampling and diagnostic shall be those provided for in Article 49(3).

However, where a programme provided for in this paragraph is to cover individual compartments or zones, which comprise less than 75 % of the territory of the Member State, and the zone or compartment consists of a water catchment area not shared with another Member State or third country, the procedure referred to in Article 50(2) shall apply for any approval, or amendment or termination of such programme.

2. Where a Member State known to be infected (category V as referred to in Part A of Annex III) by one or more of the non-exotic diseases listed in Part II of Annex IV, draws up an eradication programme for one or more of those diseases, it shall submit that programme for approval in accordance with the procedure referred to in Article 62(2).

Such programmes may also be amended or terminated in accordance with that procedure.

3. An overview of the programmes approved in accordance with paragraphs 1 and 2 of this Article shall be made available at Community level in accordance with the procedures provided for in Article 51.

4. From the date of approval of the programmes referred to in this Article, the requirements and measures provided for in Article 14, Sections 2, 3, 4 and 5 of Chapter III, Section 2 of Chapter V, and Article 38(1) in relation to areas declared disease-free shall apply to the areas which are covered by the programmes.

*Article 45***Content of programmes**

Programmes shall not be approved unless they contain at least the following:

- (a) a description of the epidemiological situation of the disease before the date of commencement of the programme;
  - (b) an analysis of the estimated costs and the anticipated benefits of the programme;
  - (c) the likely duration of the programme and the objective to be attained by the completion date of the programme;
- and
- (d) a description and demarcation of the geographical and administrative area in which the programme is to be applied.

*Article 46***Period of application of programmes**

1. Programmes shall continue to be applied until:

- (a) the requirements laid down in Annex V have been fulfilled, and the Member State, zone or compartment is declared free of the disease;
- or
- (b) the programme is withdrawn, namely if it no longer fulfils its purpose, by the competent authority of the Member State concerned, or by the Commission.



2. If the programme is withdrawn as provided for in paragraph 1(b), the Member State concerned shall apply the containment measures in Article 39 from the date of withdrawal of the programme.

## SECTION 2

### **Contingency plan for emerging and exotic diseases**

#### Article 47

#### **Contingency plan for emerging and exotic diseases**

1. Each Member State shall draw up a contingency plan specifying the national measures required to maintain a high level of disease awareness and preparedness and to ensure environmental protection.

2. The contingency plan shall:

- (a) provide the competent authority with the authority and means to access all facilities, equipment, personnel and other appropriate materials necessary for the rapid and efficient eradication of an outbreak;
- (b) ensure coordination and compatibility with neighbouring Member States and encourage cooperation with neighbouring third countries;

and

- (c) where relevant, give a precise indication of the vaccine requirements and vaccination conditions considered necessary in the event of emergency vaccination.

3. Member States shall comply with the criteria and requirements laid down in Annex VII when drawing up contingency plans.

4. Member States shall submit the contingency plans for approval in accordance with the procedure referred to in Article 62(2).

Every five years, each Member State shall update its contingency plan and submit the updated plan for approval in accordance with that procedure.

5. The contingency plan shall be implemented in the event of an outbreak of emerging diseases and of exotic diseases listed in Part II of Annex IV.

## SECTION 3

### **Vaccination**

#### Article 48

#### **Vaccination**

1. Member States shall ensure that vaccination against the exotic diseases listed in Part II of Annex IV is prohibited unless such vaccination is approved in accordance with Articles 41, 42 or 47.

2. Member States shall ensure that vaccination against the non-exotic diseases listed in Part II of Annex IV is prohibited in any parts of their territory declared free of the diseases in question in accordance with Article 49 or 50, or covered by a surveillance programme, approved in accordance with Article 44(1).

Member States may allow such vaccination in parts of their territory not declared free from the diseases in question, or where vaccination is a part of an eradication programme approved in accordance with Article 44(2).

3. Member States shall ensure that the vaccines used are authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004.

4. Paragraphs 1 and 2 shall not apply to scientific studies for the purpose of developing and testing vaccines under controlled conditions.

During such studies, Member States shall ensure that the appropriate measures are taken to protect other aquatic animals from any adverse effect of the vaccination carried out within the framework of the studies.

## CHAPTER VII

### **DISEASE-FREE STATUS**

#### Article 49

#### **Disease-free Member State**

1. A Member State shall be declared free of one or more of the non-exotic diseases listed in Part II of Annex IV in accordance with the procedure referred to in Article 62(2), if paragraph 2 of this Article is complied with and:

- (a) none of the species susceptible to the disease(s) in question is present in its territory;

or

- (b) the pathogen is known not to be able to survive in the Member State, and in its water source;

or

- (c) the Member State meets the conditions laid down in Part I of Annex V.

2. Where neighbouring Member States, or water catchment areas shared with neighbouring Member States, are not declared disease-free, the Member State shall establish appropriate buffer zones in its territory. The demarcation of buffer zones shall be such that they protect the disease-free Member State from passive introduction of the disease.



3. The specific requirements for surveillance, buffer zones, sampling and diagnostic methods that shall be used by Member States to grant disease-free status in accordance with this Article shall be adopted in accordance with the procedure referred to in Article 62(2).

#### Article 50

##### **Disease-free zone or compartment**

1. A Member State may declare a zone or a compartment within its territory free of one or more of the non-exotic diseases listed in Part II of Annex IV, where:

(a) none of the species susceptible to the disease(s) in question is present in the zone or compartment, and where relevant in its water source;

or

(b) the pathogen is known not to be able to survive in the zone or compartment, and where relevant in its water source;

or

(c) the zone or compartment complies with the conditions laid down in Part II of Annex V.

2. A Member State shall submit the declaration referred to in paragraph 1 to the Standing Committee on 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 in accordance with the procedure referred to in Article 62(2) and 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 Committee referred to in Article 62(1) as an information point. The declaration shall take effect 60 days after the date of the meeting;

(c) within this 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, or the Commission, within the period referred to in point (b) indicating significant objective concerns related to the supporting evidence, the Commission and the Member States concerned shall together examine the submitted evidence in order to resolve the concerns. In that case, the period referred to in point (b) may be prolonged for 30 days. Such comments shall be submitted to the declaring Member State and to the Commission;

(e) if the arbitration referred to in point (d) fails, the Commission may decide to make an on-the-spot inspection in accordance with Article 58 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 in accordance with the procedure referred to in Article 62(2) shall be taken, to suspend the self-declaration of the disease-free status of the zone or compartment concerned.

3. Where the zone(s) or compartment(s) referred to in paragraph 1 comprise more than 75 % of the territory of the Member State, or if the zone or compartment consists of a water catchment area shared by another Member State or third country, the procedure referred to in paragraph 2 shall be replaced by the procedure referred to in Article 62(2).

4. The specific requirements of the surveillance, sampling and diagnostic methods used by Member States to obtain disease-free status in accordance with this Article shall be laid down in accordance with the procedure referred to in Article 62(2).

#### Article 51

##### **Lists of disease-free Member States, zones or compartments**

1. Each Member State shall establish and maintain an updated list of zones and compartments declared disease-free in accordance with Article 50(2). Such lists shall be made publicly available.

2. The Commission shall draw up and update a list of Member States, zones or compartments declared disease-free in accordance with Articles 49 or 50(3), and shall make the list publicly available.

#### Article 52

##### **Maintenance of disease-free status**

A Member State that is declared free from one or more non-exotic diseases listed in Part II of Annex IV in accordance with Article 49 may discontinue targeted surveillance and maintain its disease-free status provided that the conditions conducive to clinical expression of the disease in question exist, and the relevant provisions of this Directive are implemented.

However, for disease-free zones or compartments in Member States not declared disease-free, and in all cases where conditions are not conducive to clinical expression of the disease in question, targeted surveillance shall be continued in accordance with the methods provided for in Articles 49(3) or 50(4) as appropriate, but at a level commensurate with the degree of risk.

#### Article 53

##### **Suspension and restoration of disease-free status**

1. Where a Member State has reason to believe that any of the conditions for maintaining its status as a disease-free Member State, zone or compartment have been breached, that Member State shall immediately suspend trade in susceptible species and vector species to other Member States, zones or compartments with a higher health status for the disease in question as laid down in Part A of Annex III and apply the provisions of Sections 2 and 4 of Chapter V.

2. Where the epizootic investigation provided for in Article 29(1) confirms that the suspected breach has not taken place, the disease-free status of the Member State, zone or compartment shall be restored.

3. Where the epizootic investigation confirms a significant likelihood that infection has occurred, the disease-free status of the Member State, zone or compartment shall be withdrawn, in accordance with the procedure under which that status was declared. The requirements laid down in Annex V shall be complied with before the disease-free status is restored.

#### CHAPTER VIII

##### **COMPETENT AUTHORITIES AND LABORATORIES**

#### Article 54

##### **General obligations**

1. Each Member State shall designate its competent authorities for the purposes of this Directive and notify the Commission thereof.

The competent authorities shall operate and perform their duties in accordance with Regulation (EC) No 882/2004.

2. Each Member State shall ensure that effective and continuous cooperation based on the free exchange of information relevant to the implementation of this Directive is established between the competent authorities it designates for the purposes of this Directive and any of its other authorities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin.

Information shall also, to the extent necessary, be exchanged between the competent authorities of the different Member States.

3. Each Member State shall ensure that the competent authorities have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology, and that there is a free exchange of any information relevant to the implementation of this Directive between the competent authorities and laboratories.

#### Article 55

##### **Community reference laboratories**

1. Community reference laboratories for the aquatic animal diseases relevant to this Directive shall be designated in accordance with the procedure referred to in Article 62(2) for a period to be defined in accordance with that procedure.

2. Community reference laboratories for aquatic animal diseases shall comply with the functions and duties laid down in Part I of Annex VI.

3. The Commission shall review the designation of the Community reference laboratories by the end of the period referred to in paragraph 1 at the latest, in the light of their compliance with the functions and duties referred to in paragraph 2.

#### Article 56

##### **National reference laboratories**

1. Member States shall arrange for the designation of a national reference laboratory for each of the Community reference laboratories referred to in Article 55.

Member States may designate a laboratory situated in another Member State or EFTA Member State, and a single laboratory may be the national reference laboratory for more than one Member State.

2. Member States shall communicate the name and address of each designated national reference laboratory to the Commission, the relevant Community reference laboratory and other Member States, including any updates hereto.

3. The national reference laboratory shall liaise with the relevant Community reference laboratory provided for in Article 55.

4. In order to ensure an efficient diagnostic service throughout the territory of a Member State in accordance with the requirements of this Directive, the national reference laboratory shall collaborate with any laboratory designated in accordance with Article 57 situated in the territory of the same Member State.

5. Member States shall ensure that any national reference laboratory on their territory is adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with this Directive and to comply with the functions and duties laid down in Part II of Annex VI.

#### *Article 57*

### **Diagnostic services and methods**

Member States shall ensure that:

- (a) laboratory examinations for the purposes of this Directive are carried out in laboratories designated for such purpose by the competent authority;
- (b) laboratory examinations in the case of suspicion and to confirm the presence of the diseases listed in Part II of Annex IV are carried out by diagnostic methods to be established in accordance with the procedure referred to in Article 62(2);

and

- (c) laboratories designated for diagnostic services in accordance with this Article shall comply with the functions and duties laid down in Part III of Annex VI.

## **CHAPTER IX**

### **INSPECTIONS, ELECTRONIC MANAGEMENT AND PENALTIES**

#### *Article 58*

### **Community inspections and audits**

1. Experts from the Commission may carry out on-the-spot inspections, including audits, in cooperation with the competent authorities of the Member States, insofar as they are necessary for the uniform application of this Directive.

The Member States in the territory of which such inspections and audits are made shall provide the experts with all the assistance necessary for carrying out their duties.

The Commission shall inform the competent authority of the results of any such inspections and audits.

2. Experts from the Commission may also carry out on-the-spot inspections, including audits, in third countries, in cooperation with the competent authorities of the third country concerned, in order to verify conformity with or equivalence to Community aquatic animal health rules.

3. Where a serious animal health risk is identified during a Commission inspection, the Member State concerned shall immediately take all measures necessary to safeguard animal health.

Where such measures are not taken, or where they are considered to be insufficient, the measures necessary to safeguard animal health shall be adopted in accordance with the procedure referred to in Article 62(3) and the Member State concerned shall be informed thereof.

#### *Article 59*

### **Electronic management**

1. Member States shall, by 1 August 2008 at the latest, ensure that all procedures and formalities relating to making the information provided for in Article 6, Article 50(2) Article 51(1) and Article 56(2) available by electronic means are in place.

2. The Commission shall, in accordance with the procedure referred to in Article 62(2), adopt detailed rules for the implementation of paragraph 1 in order to facilitate the interoperability of information systems and use of procedures by electronic means between Member States.

#### *Article 60*

### **Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 65(1) at the latest and shall notify it without delay of any subsequent amendment affecting them.

## **CHAPTER X**

### **AMENDMENTS, DETAILED RULES AND COMMITTEE PROCEDURE**

#### *Article 61*

### **Amendments and detailed rules**

1. Article 50(2) may be amended in accordance with the procedure referred to in Article 62(2).

2. The Annexes to this Directive may be amended in accordance with the procedure referred to in Article 62(2).

3. The measures necessary for the implementation of this Directive shall be adopted in accordance with the procedure referred to in Article 62(2).

#### *Article 62*

### **Committee procedure**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health (hereinafter referred to as the Committee).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

4. The Committee shall adopt its Rules of Procedure.

#### CHAPTER XI

#### TRANSITIONAL AND FINAL PROVISIONS

##### Article 63

##### Repeal

1. Directives 91/67/EEC, 93/53/EEC and 95/70/EC shall be repealed as from 1 August 2008.

2. References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table laid down in Annex VIII.

3. However, Commission Decision 2004/453/EC shall continue to apply for the purpose of this Directive pending the adoption of the necessary provisions in accordance with Article 43 of this Directive, which shall be adopted not later than 3 years after the entry into force of this Directive.

##### Article 64

##### Transitional provisions

Transitional provisions may be adopted in accordance with the procedure referred to in Article 62(2) for a period of four years from 14 December 2006.

##### Article 65

##### Transposition

1. Member States shall adopt and publish, not later than 1 May 2008, the laws, regulations and administrative provisions necessary to comply with this Directive before 14 December 2008. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 August 2008.

When they are adopted by Member States, these measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

##### Article 66

##### Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

##### Article 67

##### Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 24 October 2006.

*For the Council*

*The President*

J. KORKEAOJA

## ANNEX I

## DEFINITIONS

In addition to the definitions in Article 3, the following technical definitions shall apply:

- (a) 'compartment' means 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;
- (b) 'common biosecurity system' means that the same aquatic animal health surveillance, disease prevention, and disease control measures are applied;
- (c) 'containment area' means an area around an infected farm or mollusc farming area where disease control measures are applied with the purpose of preventing the spread of the disease;
- (d) 'disease' means a clinical or non-clinical infection with one or more aetiological agents in aquatic animals;
- (e) 'disease-free zones or compartments' means zones or compartments declared disease-free in accordance with Articles 49 or 50;
- (f) 'emerging disease' means a newly identified serious disease, the cause of which may or may not yet be established, that has the potential to be spread within and between populations, such as by way of trade in aquatic animals and/or aquatic animal products. It also means a listed disease identified in a new host species not yet included in Part II of Annex IV as a susceptible species;
- (g) 'epidemiological unit' means a group of aquatic animals that share approximately the same risk of exposure to a disease agent within a defined location. This risk may be because they share a common aquatic environment, or because management practices make it likely that a disease agent in one group of animals would quickly spread to another group of animals;
- (h) 'fallowing' means, for disease management purposes, an operation where a farm is emptied of aquaculture animals susceptible to the disease of concern or known to be capable of transferring the disease agent, and, where feasible, of the carrying water;
- (i) 'further processing' means processing of aquaculture animals before human consumption by any type of measures and techniques affecting anatomical wholeness, such as bleeding, gutting/evisceration, heading, slicing and filleting, which produces waste or by-products and could cause a risk of spreading diseases;
- (j) 'increased mortality' means unexplained mortalities significantly above the level of what is considered to be normal for the farm or mollusc farming area in question under the prevailing conditions. What is considered to be increased mortality shall be decided in cooperation between the farmer and the competent authority;
- (k) 'infection' means the presence of a multiplying, or otherwise developing, or latent disease agent in, or on, a host;
- (l) 'infected zone or compartment' means zones or compartments where the infection is known to occur;
- (m) 'quarantine' means maintaining a group of aquatic animals in isolation with no direct or indirect contact with other aquatic animals, in order to undergo observation for a specified length of time and, where appropriate, testing and treatment, including proper treatment of the effluent waters;
- (n) 'susceptible species' means any species in which infection by a disease agent has been demonstrated by natural cases or by experimental infection that mimics the natural pathways;

- (o) 'vector' means a species that is not susceptible to a disease but which is capable of spreading infection by conveying pathogens from one host to another;
  - (p) 'zone' means a precise geographical area with a homogeneous hydrological system comprising part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area, an entire water catchment area from its source(s) to its estuary, or more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.
-



## ANNEX II

**Information required in the official register of aquaculture production businesses and authorised processing establishments****PART I****Authorised aquaculture production business**

1. The following minimum information on each aquaculture production business shall be kept by the competent authority in a register, as provided for in Article 6:
  - (a) the name and addresses of the aquaculture production business, and contact details (telephone, facsimile, e-mail);
  - (b) the registration number and particulars of the authorisation delivered, (i.e. dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisation(s));
  - (c) the geographical position of the farm defined by a suitable system of coordinates of all farm-sites (if possible, GIS coordinates);
  - (d) the purpose, type (i.e. type of culture system, or facilities such as land-based facilities, sea cages, earth ponds) and maximum volume of production where this is regulated;
  - (e) for continental farms, dispatch centres and purification centres, details on the farm's water supply and discharges;
  - (f) the species of aquaculture animals reared at the farm (for multi-species farms or ornamental farms, it shall as a minimum be registered whether any of the species are known to be susceptible to diseases listed in Part II of Annex IV, or known vectors of such diseases);
  - (g) updated information on the health status (i.e. if the farm is disease-free (located in a Member State, zone or compartment), where the farm is under a programme with a view of achieving such status, or where the farm is declared infected by a disease referred to in Annex IV).
2. Where an authorisation is granted to a mollusc farming area in accordance with the second subparagraph of Article 4(1), the data required pursuant to point 1(a) of this part shall be recorded for all aquaculture production businesses which operate within the mollusc farming area. The data required pursuant to points 1(b) to 1(g) of this part shall be recorded at mollusc farming area level.

**PART II****Authorised processing establishments**

The following minimum information on each authorised processing establishment shall be kept by the competent authority in a register, as provided for in Article 6:

- (a) the name and addresses of the authorised processing establishment, and contact details (telephone, facsimile, e-mail);
  - (b) the registration number and particulars of the authorisation delivered (i.e. dates for specific authorisations, identification codes or numbers, specified conditions for production, any other matter relevant to the authorisation(s));
  - (c) the geographical position of the processing establishment defined by a suitable system of coordinates (if possible GIS coordinates);
  - (d) details on the authorised processing establishment's water effluent treatment systems;
  - (e) the species of aquaculture animals handled in the authorised processing establishment.
-

## ANNEX III

## PART A

## Health status of aquaculture zones or compartments to be considered for the application of Article 12

## Aquaculture animals for farming and restocking

Category	Health status	May introduce animals from	Health certification		May dispatch animals to
			Introduction	Dispatching	
I	Disease-free (Articles 49 or 50)	Only category I	YES	NO when dispatched to category III or V  YES when dispatched to categories I, II or IV	All categories
II	Surveillance Programme (Article 44(1))	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 (Article 44(2))	Only category I	YES	YES	Only category V
V	Infected (Article 39)	All categories	NO	YES	Only category V

PART B

Recommended surveillance and inspections on farms and mollusc-farming areas

Species present	Health status as referred to in Part A	Risk level	Surveillance	Recommended inspection frequency by the competent authority (Article 7)	Recommended inspection frequency by qualified aquatic animal health services (Article 10)	Specific requirements for inspections, sampling and surveillance necessary to maintain the health status	Comments
No species susceptible to the diseases listed in Annex IV	Category I Declared disease-free in accordance with Article 49(1)(a) or (b) or Article 50(1)(a) or (b).	Low	Passive	1 every 4 years	1 every 4 years	Specific requirements for the maintenance of the disease-free status in accordance with Article 52.	The recommended inspection frequencies shall apply without prejudice to the specific requirements mentioned for each health status.
Species susceptible to one or more of the diseases listed in Annex IV	Category I Declared disease-free in accordance with of Article 49(1)(c) or of Article 50(1)(c).	High	Active, targeted or passive	1 every year	1 every year		
		Medium		1 every 2 years	1 every 2 years		
		Low		1 every 4 years	1 every 2 years		
	Category II Not declared disease-free but subject to a surveillance programme approved in accordance with Article 44(1).	High	Targeted	1 every year	1 every year	Specific requirements in accordance with Article 44(1).	The aim of inspections by the competent authority is to check compliance with this Directive in accordance with Article 7.  The aim of inspections by qualified aquatic animal health services is to check the health status of the animals, to advise the aquaculture production business operator on aquatic animal health issues, and where necessary, undertake the necessary veterinary measures.
		Medium		1 every 2 years	1 every 2 years		
		Low		1 every 4 years	1 every 2 years		
	Category III Not known to be infected but not subject to surveillance programme for achieving disease-free status.	High	Active	1 every year	3 every year		
		Medium		1 every year	2 every year		
		Low		1 every 2 years	1 every year		
Category IV Known to be infected but subject to an eradication programme approved in accordance with Article 44(2).	High	Targeted	1 every year	1 every year	Specific requirements in accordance with Article 44(2).		
	Medium		1 every 2 years	1 every 2 years			
	Low		1 every 4 years	1 every 2 years			
Category V Known to be infected. Subject to minimum control measures as provided for in Chapter V.	High	Passive	1 every 4 years	1 every year	Specific requirements in accordance with Chapter V.		
	Medium		1 every 4 years	1 every 2 years			
	Low		1 every 4 years	1 every 4 years			

### **Risk levels**

A high-risk farm or mollusc farming area is a farm or mollusc farming area which:

- (a) has a high risk of spreading diseases to or contracting diseases from other farms or wild stocks;
- (b) operates under farming conditions which could increase the risk of disease outbreaks (high biomass, low water quality), taking into account the species present;
- (c) sells live aquatic animals for further farming or restocking.

A medium-risk farm or mollusc farming area is a farm or mollusc farming area which:

- (a) has medium risk of spreading diseases to or contracting diseases from other farms or wild stocks;
- (b) operates under farming conditions which would not necessarily increase the risk of disease outbreaks (medium biomass and water quality), taking into account the species present;
- (c) sells live aquatic animals mainly for human consumption.

A low-risk farm or mollusc farming area is a farm or mollusc farming area which:

- (a) has a low risk of spreading diseases to or contracting diseases from other farms or wild stocks;
- (b) operates under farming conditions which would not increase the risk of disease outbreaks (low biomass, good water quality), taking into account the species present;
- (c) sells live aquatic animals for human consumption only.

### **Types of health surveillance**

Passive surveillance shall include mandatory immediate notification of the occurrence or suspicion of specified diseases or of any increased mortalities. In such cases investigation in accordance with Section 2 of Chapter V shall be required.

Active surveillance shall include:

- (a) routine inspection by the competent authority or by other qualified health services on behalf of the competent authorities;
- (b) examination of the aquaculture animal population on the farm or in the mollusc farming area for clinical disease;
- (c) diagnostic samples to be collected on suspicion of a listed disease or observed increased mortality during inspection;
- (d) mandatory immediate notification of occurrence or suspicion of specified diseases or of any increased mortalities.

Targeted surveillance shall include:

- (a) routine inspection by the competent authority or by other qualified health services on behalf of the competent authorities;
  - (b) prescribed samples of aquaculture animals to be taken and tested for specific pathogen(s) by specified methods;
  - (c) mandatory immediate notification of occurrence or suspicion of specified diseases or of any increased mortalities.
-

## ANNEX IV

**Disease listing****PART I****Criteria for listing diseases**

- A. Exotic diseases shall meet the following criteria laid down in point 1 and either point 2 or 3.
1. The disease is exotic to the Community, i.e. the disease is not established in Community aquaculture, and the pathogen is not known to be present in Community waters.
  2. It has potential for significant economic impact if introduced into the Community, either by production losses in Community aquaculture or by restricting the potential for trade in aquaculture animals and products thereof.
  3. It has potential for detrimental environmental impact if introduced into the Community, to wild aquatic animal populations of species, which are an asset worth protecting by Community law or international provisions.
- B. Non-exotic diseases shall meet the following criteria laid down in points 1, 4, 5, 6, 7, and 2 or 3.
1. Several Member States, or regions in several Member States, are free of the specific disease.
  2. It has potential for significant economic impact if introduced into a Member State free of the disease, either by production losses, and annual costs associated with the disease and its control exceeding 5 % of the value of the production of the susceptible aquaculture animal species production in the region, or by restricting the possibilities for international trade in aquaculture animals and products thereof.
  3. The disease has shown, where it occurs, to have a detrimental environmental impact if introduced into a Member State free of the disease, to wild aquatic animal populations of species that is an asset worth protecting under Community law or international provisions.
  4. The disease is difficult to control and contain at farm or mollusc farming area level without stringent control measures and trade restrictions.
  5. The disease may be controlled at Member State level, experience having shown that zones or compartments free of the disease may be established and maintained, and that this maintenance is cost-beneficial.
  6. During placing on the market of aquaculture animals, there is a risk that the disease will establish itself in a previously uninfected area.
  7. Reliable and simple tests for infected aquatic animals are available. The tests must be specific and sensitive and the testing method harmonised at Community level.

## PART II

## Listed diseases

EXOTIC DISEASES		
	DISEASE	SUSCEPTIBLE SPECIES
FISH	Epizootic haematopoietic necrosis	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) and redfin perch ( <i>Perca fluviatilis</i> )
	Epizootic ulcerative syndrome	Genera: <i>Catla</i> , <i>Channa</i> , <i>Labeo</i> , <i>Mastacembelus</i> , <i>Mugil</i> , <i>Puntius</i> and <i>Trichogaster</i> .
MOLLUSCS	Infection with <i>Bonamia exitiosa</i>	Australian mud oyster ( <i>Ostrea angasi</i> ) and Chilean flat oyster ( <i>O. chilensis</i> )
	Infection with <i>Perkinsus marinus</i>	Pacific oyster ( <i>Crassostrea gigas</i> ) and Eastern oyster ( <i>C. virginica</i> )
	Infection with <i>Microcytos mackini</i>	Pacific oyster ( <i>Crassostrea gigas</i> ), Eastern oyster ( <i>C. virginica</i> ), Olympia flat oyster ( <i>Ostrea conchaphila</i> ) and European flat oyster ( <i>O. edulis</i> )
CRUSTACEANS	Taura syndrome	Gulf white shrimp ( <i>Penaeus setiferus</i> ), Pacific blue shrimp ( <i>P. stylirostris</i> ), and Pacific white shrimp ( <i>P. vannamei</i> )
	Yellowhead disease	Gulf brown shrimp ( <i>Penaeus aztecus</i> ), Gulf pink shrimp ( <i>P. duorarum</i> ), Kuruma prawn ( <i>P. japonicus</i> ), black tiger shrimp ( <i>P. monodon</i> ), Gulf white shrimp ( <i>P. setiferus</i> ), Pacific blue shrimp ( <i>P. stylirostris</i> ), and Pacific white shrimp ( <i>P. vannamei</i> )
NON-EXOTIC DISEASES		
	DISEASE	SUSCEPTIBLE SPECIES
FISH	Spring viraemia of carp (SVC)	Bighead carp ( <i>Aristichthys nobilis</i> ), goldfish ( <i>Carassius auratus</i> ), crucian carp ( <i>C. carassius</i> ), grass carp ( <i>Ctenopharyngodon idellus</i> ), common carp and koi carp ( <i>Cyprinus carpio</i> ), silver carp ( <i>Hypophthalmichthys molitrix</i> ), sheatfish ( <i>Silurus glanis</i> ) and tench ( <i>Tinca tinca</i> )
	Viral haemorrhagic septicaemia (VHS)	Herring ( <i>Clupea</i> spp.), whitefish ( <i>Coregonus</i> spp.), pike ( <i>Esox lucius</i> ), haddock ( <i>Gadus aeglefinus</i> ), Pacific cod ( <i>G. macrocephalus</i> ), Atlantic cod ( <i>G. morhua</i> ), Pacific salmon ( <i>Oncorhynchus</i> spp.), rainbow trout ( <i>O. mykiss</i> ), rockling ( <i>Onos mustelus</i> ), brown trout ( <i>Salmo trutta</i> ), turbot ( <i>Scophthalmus maximus</i> ), sprat ( <i>Sprattus sprattus</i> ) and grayling ( <i>Thymallus thymallus</i> )
	Infectious haematopoietic necrosis (IHN)	Chum salmon ( <i>Oncorhynchus keta</i> ), coho salmon ( <i>O. kisutch</i> ), Masou salmon ( <i>O. masou</i> ), rainbow or steelhead trout ( <i>O. mykiss</i> ), sockeye salmon ( <i>O. nerka</i> ), pink salmon ( <i>O. rhodurus</i> ) chinook salmon ( <i>O. tshawytscha</i> ), and Atlantic salmon ( <i>Salmo salar</i> )
	Koi herpes virus (KHV) disease	Common carp and koi carp ( <i>Cyprinus carpio</i> ).
	Infectious salmon anaemia (ISA)	Rainbow trout ( <i>Oncorhynchus mykiss</i> ), Atlantic salmon ( <i>Salmo salar</i> ), and brown and sea trout ( <i>S. trutta</i> ).
MOLLUSCS	Infection with <i>Marteilia refringens</i>	Australian mud oyster ( <i>Ostrea angasi</i> ), Chilean flat oyster ( <i>O. chilensis</i> ), European flat oyster ( <i>O. edulis</i> ), Argentinian oyster ( <i>O. puelchana</i> ), blue mussel ( <i>Mytilus edulis</i> ) and Mediterranean mussel ( <i>M. galloprovincialis</i> )
	Infection with <i>Bonamia ostreae</i>	Australian mud oyster ( <i>Ostrea angasi</i> ), Chilean flat oyster ( <i>O. chilensis</i> ), Olympia flat oyster ( <i>O. conchaphila</i> ), Asiatic oyster ( <i>O. dense-lammellosa</i> ), European flat oyster ( <i>O. edulis</i> ), and Argentinian oyster ( <i>O. puelchana</i> ).
CRUSTACEANS	White spot disease	All decapod crustaceans (order <i>Decapoda</i> ).



## ANNEX V

**Requirements for declaring a Member State, zone or compartment disease-free****PART I****Disease-free Member State****1. On historical grounds**

1.1. A Member State where susceptible species are present, but where there has not been any observed occurrence of the disease for at least for a period of 10 years before the date of application for the disease-free status despite conditions that are conducive to its clinical expression may be considered disease-free where:

- (a) basic biosecurity measure conditions have been in place continuously for at least a period of 10 years before the date of application for the disease-free status;
- (b) infection is not known to be established in wild populations;
- (c) the implementation of trade and imports conditions to prevent the introduction of the disease into the Member State is effective.

A Member State wishing to benefit from a disease-free status, shall submit an application in accordance with Article 49 before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

**1.2. The basic biosecurity measures referred to in point 1.1(a) shall consist, as a minimum, of the following:**

- (a) the disease is compulsorily notifiable to the competent authority, including notification of suspicion;
- (b) an early detection system is in place throughout the Member State, enabling the competent authority to undertake effective disease investigation and reporting, and ensuring in particular:
  - (i) the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or molluscs farming areas, and in the wild;
  - (ii) the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay.

**1.3. The early detection system referred to in point 1.2(b) shall include at least the following:**

- (a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians or aquatic animal health specialists in detecting and reporting unusual disease occurrence;
- (b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- (c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

2. Based on targeted surveillance

A Member State where the last known clinical occurrence was within 10 years before the date of application for the disease-free status or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free of the specific disease where:

- (a) the Member State meets the basic disease control conditions laid down in point 1.2;

and

- (b) targeted surveillance in accordance with methods adopted pursuant to Article 49(3), has been in place for at least a period of two years without detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.

Where there are parts of the Member State in which the number of farms, or molluscs farming areas is limited, and consequently targeted surveillance in these parts do not provide sufficient epidemiological data, but in which there are wild populations of any of the susceptible species, those wild populations shall be included in the targeted surveillance.

## PART II

### Disease-free zone or compartment

1. Zones

1.1. A zone may comprise:

- (a) an entire water catchment area from its source to its estuary;

or

- (b) part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area;

or

- (c) more than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

The geographical demarcation of the zone shall be clearly identified on a map.

- 1.2. Where a zone extends over more than one Member State, it may not be declared a disease-free zone unless the conditions outlined in points 1.3, 1.4 and 1.5 apply to all areas of that zone. In that case both Member States concerned shall apply for approval for the part of the zone situated in their territory.

- 1.3. A zone where susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of application for the disease-free status, despite conditions that are conducive to its clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.1.

A Member State wishing to benefit from a disease-free status shall notify its intention in accordance with Article 50(2) before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

- 1.4. A zone where the last known clinical occurrence was within a period of 10 years before the date of application for the disease-free status or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free where it complies *mutatis mutandis* with the requirements laid down in Part I.2.
- 1.5. A buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease.

2. Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status regarding that disease of surrounding natural waters

2.1. A compartment may comprise one or more farms, a group or cluster of farms or a mollusc farming area that may be considered as one epidemiological unit due to its geographical localisation and distance from other groups or clusters of farms or mollusc farming areas, provided that all farms comprising the compartment fall within a common biosecurity system. The geographical demarcation of a compartment shall be clearly identified on a map.

2.2. A compartment where susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of application for the disease-free status despite conditions that are conducive to its clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements in Part I.1 of this Annex.

Member States wishing to benefit from this provision shall notify their intention in accordance with Article 50(2) before 1 November 2008. After this date, disease-free status may only be granted in accordance with Part I.2.

2.3. A compartment where the last known clinical occurrence was within 10 years before the date of application for the disease-free status, or where the infection status in the compartment or in the waters surrounding the compartment prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, may be considered disease-free if it complies *mutatis mutandis* with the requirements laid down in Part I.2.

2.4. Each farm or mollusc farming area in a compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring programme is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.

3. Compartments comprising one or more individual farms where the health status regarding a specific disease is independent of the health status regarding that disease of the surrounding natural waters.

3.1. A compartment may comprise:

- (a) an individual farm which may be considered a single epidemiological unit, as it is not influenced by the animal health status in the surrounding waters;

or

- (b) more than one farm where each farm in the compartment complies with the criteria laid down in point 3.1(a) and points 3.2 to 3.6, but, due to extensive movement of animals between farms, shall be considered as a single epidemiological unit, provided that all farms are under a common biosecurity system.

3.2. A compartment shall be supplied with water:

- (a) through a water treatment plant inactivating the relevant pathogen in order to reduce the risk of the introduction of the disease to an acceptable level;

or

- (b) directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water shall be supplied directly to the farm, and be channelled through a pipe.

3.3. There shall be natural or artificial barriers that prevent aquatic animals from entering each farm in a compartment from the surrounding watercourses.

3.4. The compartment shall, where appropriate, be protected against flooding and infiltration of water from the surrounding watercourses.

3.5. The compartment shall comply, *mutatis mutandis*, with the requirements laid down in Part I.2.

- 3.6. A compartment shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.
  - 3.7. Implementing measures concerning point 3.2(a) shall be laid down in accordance with the procedure referred to in Article 62(2).
  4. Special provisions for individual farms which commence or recommence their activities
    - 4.1. A new farm, which meets the requirements referred to in points 3.1(a) and 3.2 to 3.6, but which commences its activities with aquaculture animals from a compartment declared disease-free may be considered disease-free without undergoing the sampling required for approval.
    - 4.2. A farm which recommences its activities after a break with aquaculture animals from a compartment declared disease-free, and meets the requirements referred to in points 3.1(a) and 3.2 to 3.6, may be considered disease-free without undergoing the sampling required for approval, provided that:
      - (a) the health history of the farm over the last four years of its operation is known to the competent authority; however, if the farm concerned has been in operation for less than four years, the actual period in which it has been in operation will be taken into account;
      - (b) the farm has not been subject to animal-health measures in respect of the diseases listed in Part II of Annex IV and there have been no antecedents of those diseases on the farm;
      - (c) prior to the introduction of the aquaculture animals, eggs or gametes, the farm is cleaned and disinfected, followed, as necessary, by a period of fallowing.
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## ANNEX VI

**Functions and duties of laboratories****PART I****Community reference laboratories**

1. In order to be designated as a Community reference laboratory in accordance with Article 55, laboratories shall fulfil the following requirements. They must:
  - (a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence, including trained personnel available for emergency situations occurring within the Community;
  - (b) possess the equipment and products needed to carry out the tasks assigned to them;
  - (c) have an appropriate administrative infrastructure;
  - (d) ensure that their staff respect the confidential nature of certain subjects, results or communications;
  - (e) have sufficient knowledge of international standards and practices;
  - (f) have available, as appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;
  - (g) take account of research activities at national and Community level.
2. However, the Commission may designate only laboratories that operate and are assessed and accredited in accordance with the following European Standards, account being taken of the criteria for different testing methods laid down in this Directive:
  - (a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
  - (b) EN 45002 on 'General criteria for the assessment of testing laboratories';
  - (c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.
3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.
4. For one or more of the diseases under their responsibility, the Community reference laboratories may take advantage of the skills and capacity of laboratories in other Member States or EFTA Member States, provided that the laboratories concerned comply with the requirements laid down in points 1, 2 and 3 of this Annex. Any intention to take advantage of such cooperation shall be part of the information provided as a basis for the designation in accordance with Article 55(1). However, the Community reference laboratory shall remain the contact point for the National reference laboratories in the Member States, and for the Commission.
5. The Community reference laboratories shall:
  - (a) coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
    - (i) typing, storing and, where appropriate, supplying strains of the pathogen of the relevant disease to facilitate the diagnostic service in the Community,
    - (ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in each Member State, where serological tests are required,

- (iii) organising periodic comparative tests (ring tests) of diagnostic procedures at Community level with the national reference laboratories designated by the Member States, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Community;
- (iv) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;
- (b) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;
- (c) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Community;
- (d) collaborate, as regards methods of diagnosing animal diseases falling within their areas of competence, with the competent laboratories in third countries where those diseases are prevalent;
- (e) collaborate with the relevant OIE reference laboratories with regard to exotic diseases listed in Part II of Annex IV under their responsibility;
- (f) collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture.

## PART II

### National reference laboratories

1. The national reference laboratories designated pursuant to Article 56 shall be responsible for coordinating the diagnostic standards and methods within their field of responsibility in the Member State concerned. These national reference laboratories shall:
  - (a) undertake to notify, without delay, the competent authority whenever the laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;
  - (b) coordinate, in consultation with the relevant Community reference laboratory, the methods employed in Member States for diagnosing the diseases concerned under their responsibility;
  - (c) assist actively in the diagnosis of outbreaks of the relevant disease by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;
  - (d) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Member State;
  - (e) ensure confirmation of positive results of all outbreaks of exotic diseases listed in Part II of Annex IV, and of primary outbreaks of non-exotic diseases listed in that Annex;
  - (f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in accordance with Article 57, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Member State;
  - (g) cooperate with the Community reference laboratory referred to in Article 55 and participate in the comparative tests organised by the Community reference laboratories;
  - (h) ensure a regular and open dialogue with their national competent authorities;
  - (i) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:
    - (i) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
    - (ii) EN 45002 on 'General criteria for the assessment of testing laboratories';
    - (iii) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.



2. The accreditation and assessment of testing laboratories referred to in point 1(i) may relate to individual tests or groups of tests.
3. The Member States may designate national reference laboratories which do not comply with the requirements referred to in point 1(i)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided the laboratory operates under quality assurance in line with the guidelines in ISO 9001.
4. Member States may authorise a national reference laboratory situated on their territory to take advantage of the skills and capacity of other laboratories designated pursuant to Article 57, for one or more of the diseases under their responsibility, provided that these laboratories comply with the relevant requirements of this Part. However, the national reference laboratory shall remain the contact point for the central competent authority of the Member State, and for the Community reference laboratory.

### PART III

#### Designated laboratories in Member States

1. The competent authority of a Member State shall designate only laboratories for diagnostic services pursuant to Article 57 that fulfil the following requirements. They must:
    - (a) undertake to notify, without delay, the competent authority whenever a laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;
    - (b) undertake to participate in comparative tests (ring-tests) of diagnostic procedures arranged by the national reference laboratory;
    - (c) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:
      - (i) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
      - (ii) EN 45002 on 'General criteria for the assessment of testing laboratories';
      - (iii) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.
  2. The accreditation and assessment of testing laboratories referred to in paragraph 1(c) may relate to individual tests or groups of tests.
  3. The Member States may designate laboratories which do not comply with the requirements referred to in point 1(c)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided that the laboratory operates under quality assurance in line with the guidelines in ISO 9001.
  4. The competent authority shall cancel the designation where the conditions referred to in this Annex are no longer fulfilled.
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## ANNEX VII

**CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS**

Member States shall ensure that contingency plans meet at least the following requirements:

1. Provision must be made to ensure the legal powers needed to implement contingency plans and put into effect a rapid and successful eradication campaign;
  2. Provision must be made to ensure access to emergency funds, budgetary means and financial resources in order to cover all aspects of the fight against exotic diseases listed in Part II of Annex IV;
  3. A chain of command must be established to guarantee a rapid and effective decision-making process for dealing with exotic diseases listed in Annex IV or emerging diseases. A central decision-making unit must be in charge of the overall direction of control strategies;
  4. Detailed plans must be available for Member States to be prepared for the immediate establishment of local disease control centres in the event of an outbreak of exotic diseases listed in Part II of Annex IV or emerging diseases and to implement disease control and environment protection measures at a local level;
  5. Member States must ensure cooperation between the competent authorities and competent environmental authorities and bodies in order to ensure that actions on veterinary and environmental safety issues are properly coordinated;
  6. Provision must be made for adequate resources to ensure a rapid and effective campaign, including personnel, equipment and laboratory capacity;
  7. An up-to-date operations manual must be available, with a detailed, comprehensive and practical description of all the actions, procedures, instructions and control measures to be employed in handling exotic diseases listed in Part II of Annex IV or emerging diseases;
  8. Detailed plans must be available for emergency vaccination, where appropriate;
  9. Staff must be regularly involved in training in clinical signs, epidemiological enquiry and control of epizootic diseases, in real-time alert exercises, and in training in communication skills to provide ongoing disease awareness campaigns for authorities, farmers and veterinarians;
  10. Contingency plans must be prepared that take into account the resources needed to control a large number of outbreaks occurring within a short period of time;
  11. Without prejudice to the veterinary requirements laid down in Regulation (EC) No 1774/2002, contingency plans must be prepared to ensure that, in the event of an outbreak of diseases, any mass disposal of aquatic animal carcasses and aquatic animal waste is done without endangering animal and human health, using processes or methods which prevent damage to the environment and in particular:
    - (i) with minimum risk to soil, air, surface and groundwater, and to plants and animals;
    - (ii) with minimum nuisance caused by noise or odours;
    - (iii) with minimum adverse effects on the nature or places of special interest;
  12. Such plans must include the identification of appropriate sites and undertakings for the treatment or disposal of animal carcasses and animal waste in the event of an outbreak in accordance with Regulation (EC) No 1774/2002.
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## ANNEX VIII

## CORRELATION TABLE

This Directive	Repealed Directives		
	91/67/EEC	93/53/EEC	95/70/EC
Article 1(1)(a)	Article 1, first subparagraph	—	—
Article 1(1)(b)	—	—	—
Article 1(1)(c)	—	Article 1	Article 1
Article 1(2)	—	Article 20(2)	Article 12(2)
Article 2(1)	—	—	—
Article 2(2)	—	—	—
Article 2(3)	Article 1, second subparagraph	—	—
Article 3	Article 2	Article 2	Article 2
Article 4	—	—	—
Article 5	—	—	—
Article 6	—	—	—
Article 7	—	—	—
Article 8(1)	—	Article 3(2)	Article 3(2)
Article 8(2)	—	—	—
Article 8(3)	—	—	—
Article 8(4)	—	—	—
Article 9	—	—	—
Article 10	—	—	Article 4
Article 11	—	—	—
Article 12	—	—	—
Article 13(1)	Article 4, first paragraph	—	—
Article 13(2)	Article 4, second paragraph	—	—
Article 14(1)(a)	Article 7(1),  Article 8(1)	—	—
Article 14(1)(b)	—	—	—
Article 14(2)	Article 16(1)	—	—
Article 14(3)	Article 16(1),	—	—
Article 14(4)	—	—	—
Article 15(1)	Article 3(1)(a) and (2)	—	—
Article 15(2)	—	—	—
Article 15(3)	Article 3(1)(b) and (2)	—	—
Article 15(4)	—	—	—

This Directive	Repealed Directives		
	91/67/EEC	93/53/EEC	95/70/EC
Article 16(1)	Article 7(1)(a), first sentence Article 7(1)(b) Article 8(1)(a) Article 8(1)(b)	—	—
Article 16(2)	—	—	—
Article 17	—	—	—
Article 18(1)	Article 9	—	—
Article 18(2)	—	—	—
Article 19(1)	—	—	—
Article 19(2)	Article 9(2)	—	—
Article 20	Article 14(3)	—	—
Article 21	—	—	—
Article 22	Article 19(1)	—	—
Article 23(1)	—	—	—
Article 23(2)	Article 22	—	—
Article 23(3)	Article 19(2)	—	—
Article 23(4)	Article 19(3)	—	—
Article 23(5)	—	—	—
Article 24	Article 21	—	—
Article 25(a)	Article 20	—	—
Article 25(b)	—	—	—
Article 25(c)	—	—	—
Article 25(d)	Article 21(2)	—	—
Article 25(e)	—	—	—
Article 26	—	Article 4	Article 5(1)
Article 27	—	—	Article 5(5)
Article 28(a)	—	Article 5(1) Article 10(1)(a)	Article 5(2)(a)
Article 28(b)	—	Article 5(2)(b) Article 10(1)(c)	Article 5(2)(b)
Article 29(1)	—	Article 5 (2)(h) Article 6(a), seventh indent Article 8(1) Article 9(1), first sentence Article 10(1)b	Article 4(1), third subparagraph, third indent Article 5(4), first and fourth subparagraph

This Directive	Repealed Directives		
	91/67/EEC	93/53/EEC	95/70/EC
Article 29(2)	—	Article 5(2)(i)	Article 5(4), second and fourth subparagraph
Article 29(3)	—	Article 6(b) Article 6(d) Article 8(2) Article 8(3) Article 9(2)	—
Article 29(4)	—	Article 5(2)(i), second indent	—
Article 30	—	Article 5(4)	Article 5(3)
Article 31	—	—	—
Article 32	—	Article 5(2), Article 6	Article 4(1), third subparagraph, second indent, Article 5(2)(b), Article 5(4), third and fourth subparagraph
Article 33(1)	Article 3(3)	Article 6(a) fourth indent	—
Article 33(2)	—	Article 6(a), fourth indent	—
Article 33(3)	—	—	—
Article 33(4)	—	—	—
Article 34(1)	—	Article 5(2)(c) Article 6(a), first and third indent	—
Article 34(2)	—	Article 6(a), fourth indent	—
Article 35	—	Article 6(a), second, fifth and sixth indent	—
Article 36	—	—	—
Article 37(a)	—	—	—
Article 37(b)	—	—	Article 5(3)
Article 38(1)	—	Article 9(1), second sentence	—
Article 38(2)	—	Article 9(3)	—
Article 38(3)	—	—	—
Article 39(a)	—	Article 10(1)(c)	Article 4(1), third paragraph, first indent
Article 39(b)	—	—	—
Article 39(c)	—	Article 10(1)(c)	—
Article 39(d)	—	—	—
Article 40	—	Article 7	—



This Directive	Repealed Directives		
	91/67/EEC	93/53/EEC	95/70/EC
Article 41	—	—	—
Article 42	—	—	—
Article 43	—	—	—
Article 44(1)	Article 10	Article 10(2)	—
Article 44(2)	Article 10	Article 10(2)	—
Article 45	Article 10(1)	—	—
Article 46	—	—	—
Article 47	—	Article 6(a), first indent Article 15	—
Article 48(1)	—	Article 14(1)	—
Article 48(2)	—	Article 14(1)	—
Article 48(3)	—	—	—
Article 48(4)	—	—	—
Article 49(1)	Article 5(1)	—	—
Article 49(2)	—	—	—
Article 49(3)	Article 15	—	—
Article 50(1)	Article 5(1) Article 6(1)	—	—
Article 50(2)	—	—	—
Article 50(3)	Article 5(1)	—	—
Article 50(4)	Article 15	—	—
Article 51(1)	—	—	—
Article 51(2)	Article 5(2)	—	—
Article 52	—	—	—
Article 53(1)	—	—	—
Article 53(2)	—	—	—
Article 53(3)	—	Article 9(1), second sentence	—
Article 54(1)	—	—	—
Article 54(2)	—	Article 6(d) Article 8(3)	—
Article 54(3)	—	—	—
Article 55(1)	—	Article 13(1)	Article 7(1)
Article 55(2)	—	Article 13(2)	Article 7(2)
Article 55(3)	—	—	—
Article 56(1)	—	Article 12(1) Article 12(4)	Article 6(2) Article 6(3)
Article 56(2)	—	—	—
Article 56(3)	—	Article 12(6)	Article 6(5)
Article 56(4)	—	—	—
Article 56(5)	—	Article 12(1) Article 12(3)	Article 6(2)

This Directive	Repealed Directives		
	91/67/EEC	93/53/EEC	95/70/EC
Article 57(a)	—	Article 11(2)	—
Article 57(b)	—	Article 11(1)	Article 6(1)
Article 57(c)	—	—	—
Article 58(1)	Article 17	Article 16	Article 8
Article 58(2)	Article 22	—	—
Article 58(3)	Article 17	—	—
Article 59	—	—	—
Article 60	—	—	—
Article 61(1)	—	—	—
Article 61(2)	Article 25	Article 18	Article 9
Article 61(3)	Article 9(3) Article 17(2)	Article 18a	Article 4(2) Article 5(4), fourth sub-paragraph Article 8(4)
Article 62	Article 26 Article 27	Article 19	Article 10
Article 63	—	—	—
Article 64	—	—	—
Article 65	Article 29	Article 20	Article 12
Article 66	—	—	Article 13
Article 67	Article 30	Article 21	Article 14

## II

(Acts whose publication is not obligatory)

## COUNCIL

## COUNCIL DECISION

of 24 October 2006

amending Decision 90/424/EEC on expenditure in the veterinary field

(2006/782/EC)

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 <sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee <sup>(2)</sup>,

Whereas:

- (1) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field <sup>(3)</sup> provides for the possibility of the Community's making a financial contribution to the Member States for the eradication of certain animal diseases. Currently, that Decision also provides for the possibility of a financial contribution from the Community for the eradication of infectious salmon anaemia (ISA) and infectious haematopoietic necrosis (IHN), both of which diseases affect salmonides.
- (2) Disease control actions for ISA and IHN are eligible for Community financial contribution only under Council Regulation (EC) No 2792/1999 of 17 December 1999 laying down the detailed rules and arrangements regarding Community structural assistance in the fisheries sector <sup>(4)</sup>.
- (3) In the light of the adoption of 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 <sup>(5)</sup>, it is appropriate to amend Decision 90/424/EEC so that Community financial contributions can also be granted for eradication measures carried out by the Member States to combat other diseases in aquaculture animals, subject to Community control provisions.

- (4) Member States can receive financial contributions to support their national fisheries and aquaculture sector under Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund <sup>(6)</sup>. Article 32 of that Regulation authorises Member States to allocate funds for the eradication of diseases in aquaculture under the terms of Decision 90/424/EEC.
- (5) The funds for the eradication of diseases in aquaculture animals should be allocated within the operational programmes set up under Regulation (EC) No 1198/2006, the budget for which is fixed at the beginning of the programming period.
- (6) Financial contributions from the Community for disease control purposes in aquaculture animals should be subject to scrutiny regarding compliance with the control provisions laid down in Directive 2006/88/EC, in accordance with the same procedures as those that apply for such scrutiny and control for certain terrestrial animal diseases.
- (7) It is therefore appropriate to apply the procedures for financial contribution laid down in Decision 90/424/EEC also to the use of financial contribution for the control of diseases in aquaculture animals under Regulation (EC) No 1198/2006.
- (8) It is appropriate for this Decision to become applicable at the same time as Directive 2006/88/EC.

<sup>(1)</sup> Opinion of 27 April 2006 (not yet published in the Official Journal).

<sup>(2)</sup> OJ C 88, 11.4.2006, p. 13. Opinion delivered following non-compulsory consultation.

<sup>(3)</sup> OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 2006/53/EC (OJ L 29, 2.2.2006, p. 37).

<sup>(4)</sup> OJ L 337, 30.12.1999, p. 10. Regulation as last amended by Regulation (EC) No 485/2005 (OJ L 81, 30.3.2005, p. 1).

<sup>(5)</sup> See page 14 of this Official Journal.

<sup>(6)</sup> OJ L 223, 15.8.2006, p. 1.

- (9) Decision 90/424/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

#### *Article 1*

Decision 90/424/EEC is hereby amended as follows:

- (1) in Article 3(1), the following indents shall be added:

- ‘epizootic haematopoietic necrosis in fish (EHN),
- epizootic ulcerative syndrome in fish (EUS),
- infection with *Bonamia exitiosa*,
- infection with *Perkinsus marinus*,
- infection with *Microcytos mackini*,
- Taura syndrome in crustaceans,
- yellowhead disease in crustaceans.’;

- (2) the following Article shall be inserted:

#### *‘Article 3b*

Member States may allocate funds within the operational programmes drawn up in accordance with Article 17 of Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund (\*) for the eradication of the exotic diseases in aquaculture animals referred to in Article 3(1) of this Decision, under the procedures laid down in Article 3(3), (4) and (5) of this Decision, provided that the minimum control and eradication measures laid down in Section 3 of Chapter V of 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 (\*\*) are complied with.

(\*) OJ L 223, 15.8.2006, p. 1.

(\*\*) OJ L 328, 24.11.2006, p. 14.’;

- (3) Article 5(2) shall be replaced by the following:

‘2. In accordance with the procedure laid down in Article 41, the list in Article 3(1) may be supplemented in line with developments in the situation, to include diseases which must be notified in accordance with Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (\*) and diseases which can be transmitted to aquaculture animals. The list may also be amended or shortened to take account of

progress made with the measures decided at Community level to control certain diseases.

(\*) OJ L 378, 31.12.1982, p. 58. Directive as last amended by Commission Decision 2004/216/EC (OJ L 67, 5.3.2004, p. 27).’;

- (4) The following paragraph shall be added to Article 24:

‘13. Member States may allocate funds within the operational programmes drawn up in accordance with Article 17 of Regulation (EC) No 1198/2006 for the eradication of the diseases in aquaculture animals referred to in the Annex.

The funds shall be allocated in accordance with the procedures laid down in this Article, with the following adjustments:

- (a) the rate of aid shall be in accordance with the rate laid down in Regulation (EC) No 1198/2006;
- (b) paragraphs 8 and 9 of this Article shall not apply.

The eradication shall be carried out in accordance with Article 38(1) of Directive 2006/88/EC, or under an eradication programme drawn up, approved and carried out in accordance with Article 44(2) of that Directive.’;

- (5) the following indents shall be added to the Annex, Group I:

- ‘Spring viraemia of carp (SVC),
- Viral haemorrhagic septicaemia (VHS),
- Koi herpes virus infection (KHV),
- Infection with *Bonamia ostreae*,
- Infection with *Marteilia refringens*,
- White spot disease in crustaceans.’

#### *Article 2*

This Decision shall apply from 1 August 2008.

#### *Article 3*

This Decision is addressed to the Member States.

Done at Luxembourg, 24 October 2006.

*For the Council*  
*The President*  
J. KORKEAOJA

(Acts adopted under Title VI of the Treaty on European Union)

**COUNCIL FRAMEWORK DECISION 2006/783/JHA**

**of 6 October 2006**

**on the application of the principle of mutual recognition to confiscation orders**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 31(1)(a) and 34(2)(b) thereof,

Having regard to the initiative of the Kingdom of Denmark <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Whereas:

- (1) The European Council, meeting in Tampere on 15 and 16 October 1999, stressed that the principle of mutual recognition should become the cornerstone of judicial cooperation in both civil and criminal matters within the Union.
- (2) According to paragraph 51 of the conclusions of the Tampere European Council, money laundering is at the very heart of organised crime, and should be rooted out wherever it occurs; the European Council is determined to ensure that concrete steps are taken to trace, freeze, seize and confiscate the proceeds of crime. In that connection, in paragraph 55 of the conclusions, the European Council calls for the approximation of criminal law and procedures on money laundering (e.g. tracing, freezing and confiscating funds).
- (3) All Member States have ratified the Council of Europe Convention of 8 November 1990 on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (the 1990 Convention). The Convention obliges signatories to recognise and enforce a confiscation order made by another party, or to submit a request to its competent authorities for the purpose of obtaining an order of confiscation and, if such order is granted, enforce it. The

Parties may refuse requests for confiscation *inter alia* if the offence to which the request relates would not be an offence under the law of the requested Party, or if under the law of the requested Party confiscation is not provided for in respect of the type of offence to which the request relates.

- (4) On 30 November 2000 the Council adopted a programme of measures to implement the principle of mutual recognition of decisions in criminal matters, giving first priority (measures 6 and 7) to the adoption of an instrument applying the principle of mutual recognition to the freezing of evidence and property. Moreover, pursuant to paragraph 3.3 of the programme, the aim is to improve, in accordance with the principle of mutual recognition, execution in one Member State of a confiscation order issued in another Member State, *inter alia* for the purpose of restitution to a victim of a criminal offence, taking into account the existence of the 1990 Convention. With a view to achieving this aim, this Framework Decision, within its field of application, reduces the grounds for refusal of enforcement and suppresses, among Member States, any system of conversion of the confiscation order into a national one.
- (5) Council Framework Decision 2001/500/JHA <sup>(3)</sup> lays down provisions on money laundering, the identification, tracing, freezing, seizing and confiscation of instrumentalities and the proceeds from crime. Under that Framework Decision, Member States are also obliged not to make or uphold reservations in respect of Article 2 of the 1990 Convention, in so far as the offence is punishable by deprivation of liberty or a detention order for a maximum of more than one year.
- (6) Finally, on 22 July 2003 the Council adopted Framework Decision 2003/577/JHA on the execution in the European Union of orders freezing property or evidence <sup>(4)</sup>.

<sup>(1)</sup> OJ C 184, 2.8.2002, p. 8.

<sup>(2)</sup> Opinion delivered on 20 November 2002 (OJ C 25 E, 29.1.2004, p. 205).

<sup>(3)</sup> OJ L 182, 5.7.2001, p. 1.

<sup>(4)</sup> OJ L 196, 2.8.2003, p. 45.

- (7) The main motive for organised crime is financial gain. In order to be effective, therefore, any attempt to prevent and combat such crime must focus on tracing, freezing, seizing and confiscating the proceeds from crime. It is not enough merely to ensure mutual recognition within the European Union of temporary legal measures such as freezing and seizure; effective control of economic crime also requires the mutual recognition of orders to confiscate the proceeds from crime.
- (8) The purpose of this Framework Decision is to facilitate cooperation between Member States as regards the mutual recognition and execution of orders to confiscate property so as to oblige a Member State to recognise and execute in its territory confiscation orders issued by a court competent in criminal matters of another Member State. This Framework Decision is linked to Council Framework Decision 2005/212/JHA of 24 February 2005 on Confiscation of Crime-Related Proceeds, Instrumentalities and Property <sup>(1)</sup>. The purpose of that Framework Decision is to ensure that all Member States have effective rules governing the confiscation of proceeds from crime, *inter alia* in relation to the onus of proof regarding the source of assets held by a person convicted of an offence related to organised crime.
- (9) Cooperation between Member States, based on the principle of mutual recognition and immediate execution of judicial decisions, presupposes confidence that the decisions to be recognised and executed will always be taken in compliance with the principles of legality, subsidiarity and proportionality. It also presupposes that the rights granted to the parties or bona fide interested third parties will be preserved. In this context, due consideration should be given to preventing successful dishonest claims by legal or natural persons.
- (10) The proper practical operation of this Framework Decision presupposes close liaison between the competent national authorities involved, in particular in cases of simultaneous execution of a confiscation order in more than one Member State.
- (11) The terms 'proceeds' and 'instrumentalities' used in this Framework Decision are sufficiently broadly defined to include objects of offences whenever necessary.
- (12) Where there are doubts with regard to the location of property which is the subject of a confiscation order, Member States should use all available means in order to identify the correct location of that property, including the use of all available information systems.
- (13) This Framework Decision respects fundamental rights and observes the principles recognised by Article 6 of the Treaty on European Union and reflected by the Charter of Fundamental Rights of the European Union, in particular Chapter VI thereof. Nothing in this Framework Decision may be interpreted as prohibiting refusal to confiscate property for which a confiscation order has been issued when objective grounds exist for believing that the confiscation order was issued for the purpose of prosecuting or punishing a person on account of his or her sex, race, religion, ethnic origin, nationality, language, political opinion or sexual orientation, or that that person's position may be prejudiced for any of these reasons.
- (14) This Framework Decision does not prevent any Member State from applying its constitutional rules relating to due process, freedom of association, freedom of the press and freedom of expression in other media.
- (15) This Framework Decision does not address the restitution of property to its rightful owner.
- (16) This Framework Decision does not prejudice the end to which the Member States apply the amounts obtained as a consequence of its application.
- (17) This Framework Decision does not affect the exercise of the responsibilities incumbent upon Member States with regard to the maintenance of law and order and the safeguarding of internal security in accordance with Article 33 of the Treaty on European Union,
- HAS ADOPTED THIS FRAMEWORK DECISION:

#### Article 1

#### Objective

1. The purpose of this Framework Decision is to establish the rules under which a Member State shall recognise and execute in its territory a confiscation order issued by a court competent in criminal matters of another Member State.

2. This Framework Decision shall not have the effect of modifying the obligation to respect fundamental rights and fundamental legal principles as enshrined in Article 6 of the Treaty on European Union, and any obligations incumbent on judicial authorities in this respect shall remain unaffected.

<sup>(1)</sup> OJ L 68, 15.3.2005, p. 49.



## Article 2

**Definitions**

For the purpose of this Framework Decision,

- (a) 'issuing State' shall mean the Member State in which a court has issued a confiscation order within the framework of criminal proceedings;
- (b) 'executing State' shall mean the Member State to which a confiscation order has been transmitted for the purpose of execution;
- (c) 'confiscation order' shall mean a final penalty or measure imposed by a court following proceedings in relation to a criminal offence or offences, resulting in the definitive deprivation of property;
- (d) 'property' shall mean property of any description, whether corporeal or incorporeal, movable or immovable, and legal documents and instruments evidencing title to or interest in such property, which the court in the issuing State has decided:
  - (i) is the proceeds of an offence, or equivalent to either the full value or part of the value of such proceeds,
  - or
  - (ii) constitutes the instrumentalities of such an offence,
  - or
  - (iii) is liable to confiscation resulting from the application in the issuing State of any of the extended powers of confiscation specified in Article 3(1) and (2) of Framework Decision 2005/212/JHA,
  - or
  - (iv) is liable to confiscation under any other provisions relating to extended powers of confiscation under the law of the issuing State;
- (e) 'proceeds' shall mean any economic advantage derived from criminal offences. It may consist of any form of property;
- (f) 'instrumentalities' shall mean any property used or intended to be used, in any manner, wholly or in part, to commit a criminal offence or criminal offences;
- (g) 'cultural objects forming part of the national cultural heritage' shall be defined in accordance with Article 1(1) of Council Directive 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State <sup>(1)</sup>;

<sup>(1)</sup> OJ L 74, 27.3.1993, p. 74. Directive as last amended by Directive 2001/38/EC of the European Parliament and of the Council (OJ L 187, 10.7.2001, p. 43).

- (h) where the criminal proceedings leading to a confiscation order involve a predicate offence as well as money laundering, a 'criminal offence' mentioned in Article 8(2)(f) shall mean a predicate offence.

## Article 3

**Determination of the competent authorities**

1. Each Member State shall inform the General Secretariat of the Council which authority or authorities, under its law, are competent according to this Framework Decision when that Member State is:

— the issuing State,

or

— the executing State.

2. Notwithstanding Articles 4(1) and (2), each Member State may designate, if it is necessary as a result of the organisation of its internal system, one or more central authorities responsible for the administrative transmission and reception of the confiscation orders and to assist the competent authorities.

3. The General Secretariat of the Council shall make the information received available to all Member States and the Commission.

## Article 4

**Transmission of confiscation orders**

1. A confiscation order, together with the certificate provided for in paragraph 2, the standard form for which is given in the Annex, may, in the case of a confiscation order concerning an amount of money, be transmitted to the competent authority of a Member State in which the competent authority of the issuing State has reasonable grounds to believe that the natural or legal person against whom the confiscation order has been issued has property or income.

In the case of a confiscation order concerning specific items of property, the confiscation order and the certificate may be transmitted to the competent authority of a Member State in which the competent authority of the issuing State has reasonable grounds to believe that property covered by the confiscation order is located.

If there are no reasonable grounds which would allow the issuing State to determine the Member State to which the confiscation order may be transmitted, the confiscation order may be transmitted to the competent authority of the Member State where the natural or legal person against whom the confiscation order has been issued is normally resident or has its registered seat respectively.

2. The confiscation order or a certified copy thereof, together with the certificate, shall be transmitted by the competent authority of the issuing State directly to the authority of the executing State which is competent to execute it, by any means capable of producing a written record, under conditions allowing the executing State to establish authenticity. The original of the confiscation order, or a certified copy thereof, and the original of the certificate shall be transmitted to the executing State if it so requires. All official communications shall be made directly between the said competent authorities.

3. The certificate, shall be signed, and its contents certified as accurate, by the competent authority of the issuing State.

4. If the authority competent to execute the confiscation order is not known to the competent authority of the issuing State, the latter shall make all necessary enquiries, including via the contact points of the European judicial network, in order to obtain information from the executing State.

5. Where the authority of the executing State which receives a confiscation order has no jurisdiction to recognise it and take the necessary measures for its execution, it shall, *ex officio*, transmit the order to the authority competent to execute it, and shall inform the competent authority of the issuing State accordingly.

#### Article 5

##### Transmission of a confiscation order to one or more executing States

1. Subject to paragraphs 2 and 3, a confiscation order may only be transmitted pursuant to Article 4 to one executing State at any one time.

2. A confiscation order concerning specific items of property may be transmitted to more than one executing State at the same time in cases where:

- the competent authority of the issuing State has reasonable grounds to believe that different items of property covered by the confiscation order are located in different executing States,
- the confiscation of a specific item of property covered by the confiscation order involves action in more than one executing State,

or

- the competent authority of the issuing State has reasonable grounds to believe that a specific item of property covered by the confiscation order is located in one of two or more specified executing States.

3. A confiscation order concerning an amount of money may be transmitted to more than one executing State at the same time, where the competent authority of the issuing State deems there is a specific need to do so, for example where:

- the property concerned has not been frozen under Council Framework Decision 2003/577/JHA of,

or

- the value of the property which may be confiscated in the issuing State and any one executing State is not likely to be sufficient for the execution of the full amount covered by the confiscation order.

#### Article 6

##### Offences

1. If the acts giving rise to the confiscation order constitute one or more of the following offences, as defined by the law of the issuing State, and are punishable in the issuing State by a custodial sentence of a maximum of at least three years, the confiscation order shall give rise to execution without verification of the double criminality of the acts:

- participation in a criminal organisation,
- terrorism,
- trafficking in human beings,
- sexual exploitation of children and child pornography,
- illicit trafficking in narcotic drugs and psychotropic substances,
- illicit trafficking in weapons, munitions and explosives,
- corruption,
- fraud, including that affecting the financial interests of the European Communities within the meaning of the Convention of 26 July 1995 on the protection of the European Communities' financial interests,
- laundering of the proceeds of crime,
- counterfeiting currency, including of the euro,
- computer-related crime,
- environmental crime, including illicit trafficking in endangered animal species and in endangered plant species and varieties,
- facilitation of unauthorised entry and residence,
- murder, grievous bodily injury,
- illicit trade in human organs and tissue,

- kidnapping, illegal restraint and hostage-taking,
- racism and xenophobia,
- organised or armed robbery,
- illicit trafficking in cultural goods, including antiques and works of art,
- swindling,
- racketeering and extortion,
- counterfeiting and piracy of products,
- forgery of administrative documents and trafficking therein,
- forgery of means of payment,
- illicit trafficking in hormonal substances and other growth promoters,
- illicit trafficking in nuclear or radioactive materials,
- trafficking in stolen vehicles,
- rape,
- arson,
- crimes within the jurisdiction of the International Criminal Court,
- unlawful seizure of aircraft/ships,
- sabotage.

2. The Council may decide to add other categories of offences to the list contained in paragraph 1 at any time, acting unanimously after consultation of the European Parliament under the conditions laid down in Article 39(1) of the TEU. The Council shall consider, in the light of the report submitted by the Commission pursuant to Article 22, whether the list should be extended or amended.

3. For offences other than those covered by paragraph 1, the executing State may make the recognition and execution of a confiscation order subject to the condition that the acts giving rise to the confiscation order constitute an offence which permits confiscation under the law of the executing State, whatever its constituent elements or however it is described under the law of the issuing State.

#### Article 7

##### Recognition and execution

1. The competent authorities in the executing State shall without further formality recognise a confiscation order which has been transmitted in accordance with Articles 4 and 5, and shall forthwith take all the necessary measures for its execution, unless the competent authorities decide to invoke one of the grounds for non-recognition or non-execution provided for in Article 8,

or one of the grounds for postponement of execution provided for in Article 10.

2. If a request for confiscation concerns a specific item of property, the competent authorities of the issuing and the executing States may, if provided for under the law of those States, agree that confiscation in the executing State may take the form of a requirement to pay a sum of money corresponding to the value of the property.

3. If a confiscation order concerns an amount of money, the competent authorities of the executing State shall, if payment is not obtained, execute the confiscation order in accordance with paragraph 1 on any item of property available for that purpose.

4. If a confiscation order concerns an amount of money, the competent authorities of the executing State shall, if necessary, convert the amount to be confiscated into the currency of the executing State at the rate of exchange obtaining at the time when the confiscation order was issued.

5. Each Member State may state in a declaration deposited with the General Secretariat of the Council that its competent authorities will not recognise and execute confiscation orders under circumstances where confiscation of the property was ordered under the extended powers of confiscation referred to in Article 2(d)(iv). Any such declaration may be withdrawn at any time.

#### Article 8

##### Reasons for non-recognition or non-execution

1. The competent authority of the executing State may refuse to recognise and execute the confiscation order if the certificate provided for in Article 4 is not produced, is incomplete, or manifestly does not correspond to the order.

2. The competent judicial authority of the executing State, as defined in the law of that State, may also refuse to recognise and execute the confiscation order if it is established that:

- (a) execution of the confiscation order would be contrary to the principle of *ne bis in idem*;
- (b) in one of the cases referred to in Article 6(3), the confiscation order relates to acts which do not constitute an offence which permits confiscation under the law of the executing State; however, in relation to taxes, duties, customs duties and exchange activities, execution of a confiscation order may not be refused on the ground that the law of the executing State does not impose the same kind of tax or duty or does not contain the same types of rules concerning taxes, duties, customs duties and exchange activities as the law of the issuing State;

- (c) there is immunity or privilege under the law of the executing State which would prevent the execution of a domestic confiscation order on the property concerned;
  - (d) the rights of any interested party, including bona fide third parties, under the law of the executing State make it impossible to execute the confiscation order, including where this is a consequence of the application of legal remedies in accordance with Article 9;
  - (e) according to the certificate provided for in Article 4(2), the person concerned did not appear personally and was not represented by a legal counsellor in the proceedings resulting in the confiscation order, unless the certificate states that the person was informed personally, or via his representative competent according to national law, of the proceedings in accordance with the law of the issuing State, or that the person has indicated that he or she does not contest the confiscation order;
  - (f) the confiscation order is based on criminal proceedings in respect of criminal offences which:
    - under the law of the executing State, are regarded as having been committed wholly or partly within its territory, or in a place equivalent to its territory,
    - or
    - were committed outside the territory of the issuing State, and the law of the executing State does not permit legal proceedings to be taken in respect of such offences where they are committed outside that State's territory;
  - (g) the confiscation order, in the view of that authority, was issued in circumstances where confiscation of the property was ordered under the extended powers of confiscation referred to in Article 2(d)(iv);
  - (h) the execution of a confiscation order is barred by statutory time limitations in the executing State, provided that the acts fall within the jurisdiction of that State under its own criminal law.
3. If it appears to the competent authority of the executing State that:
- the confiscation order was issued in circumstances where confiscation of the property was ordered under the extended powers of confiscation referred to in Article 2(d)(iii),
  - and
  - the confiscation order falls outside the scope of the option adopted by the executing State under Article 3(2) of Framework Decision 2005/212/JHA,
- it shall execute the confiscation order at least to the extent provided for in similar domestic cases under national law.
4. The competent authorities of the executing State shall give specific consideration to consulting, by any appropriate means, the competent authorities of the issuing State before deciding not to recognise and execute a confiscation order pursuant to paragraph 2, or to limit the execution thereof pursuant to paragraph 3. Consultation is obligatory where the decision is likely to be based on:
- paragraph 1,
  - paragraph 2(a), (e), (f) or (g),
  - paragraph 2(d) and information is not being provided under Article 9(3),
  - or
  - paragraph 3.
5. Where it is impossible to execute the confiscation order for the reason that the property to be confiscated has already been confiscated, has disappeared, has been destroyed, cannot be found in the location indicated in the certificate or the location of the property has not been indicated in a sufficiently precise manner, even after consultation with the issuing State, the competent authority of the issuing State shall be notified forthwith.

#### Article 9

#### Legal remedies in the executing State against recognition and execution

1. Each Member State shall put in place the necessary arrangements to ensure that any interested party, including bona fide third parties, has legal remedies against the recognition and execution of a confiscation order pursuant to Article 7, in order to preserve his or her rights. The action shall be brought before a court in the executing State in accordance with the law of that State. The action may have suspensive effect under the law of the executing State.
2. The substantial reasons for issuing the confiscation order cannot be challenged before a court in the executing State.
3. If action is brought before a court in the executing State, the competent authority of the issuing State shall be informed thereof.

*Article 10***Postponement of execution**

1. The competent authority of the executing State may postpone the execution of a confiscation order transmitted in accordance with Articles 4 and 5:

- (a) if, in the case of a confiscation order concerning an amount of money, it considers that there is a risk that the total value derived from its execution may exceed the amount specified in the confiscation order because of simultaneous execution of the confiscation order in more than one Member State;
- (b) in the cases of legal remedies referred to in Article 9;
- (c) where the execution of the confiscation order might damage an ongoing criminal investigation or proceedings, until such time as it deems reasonable;
- (d) where it is considered necessary to have the confiscation order or parts thereof translated at the expense of the executing State, for the time necessary to obtain its translation,

or

- (e) where the property is already the subject of confiscation proceedings in the executing State.

2. The competent authority of the executing State shall, for the duration of postponement, take all the measures it would take in a similar domestic case to prevent the property from no longer being available for the purpose of execution of the confiscation order.

3. In the case of postponement pursuant to paragraph 1(a), the competent authority of the executing State shall inform the competent authority of the issuing State thereof immediately by any means capable of producing a written record, and the competent authority of the issuing State shall comply with the obligations referred to in Article 14(3).

4. In the cases referred to in paragraph 1(b), (c), (d) and (e), a report on the postponement, including the grounds for the postponement and, if possible, the expected duration of the postponement, shall be made forthwith by the competent authority of the executing State to the competent authority of the issuing State by any means capable of producing a written record.

As soon as the ground for postponement has ceased to exist, the competent authority of the executing State shall forthwith take the necessary measures for the execution of the confiscation order and inform the competent authority of the issuing State thereof by any means capable of producing a written record.

*Article 11***Multiple confiscation orders**

If the competent authorities of the executing State are processing:

- two or more confiscation orders concerning an amount of money, which have been issued against the same natural or

legal person, and the person concerned does not have sufficient means in the executing State to enable all the orders to be executed,

or

- two or more confiscation orders concerning the same specific item of property,

the decision on which of the confiscation orders is or are to be executed shall be taken by the competent authority of the executing State according to the law of the executing State, with due consideration of all the circumstances, which may include the involvement of frozen assets, the relative seriousness and the place of the offence, the dates of the respective orders and the dates of transmission of the respective orders.

*Article 12***Law governing execution**

1. Without prejudice to paragraph 3, the execution of the confiscation order shall be governed by the law of the executing State and its authorities alone shall be competent to decide on the procedures for execution and to determine all the measures relating thereto.

2. In the case where the person concerned is able to furnish proof of confiscation, totally or in part, in any State, the competent authority of the executing State shall consult the competent authority of the issuing State by any appropriate means. Any part of the amount, in the case of confiscation of proceeds, that is recovered pursuant to the confiscation order in any State other than the executing State shall be deducted in full from the amount to be confiscated in the executing State.

3. A confiscation order issued against a legal person shall be executed even if the executing State does not recognise the principle of criminal liability of legal persons.

4. The executing State may not impose measures as an alternative to the confiscation order, including custodial sanctions or any other measure limiting a person's freedom, as a result of a transmission pursuant to Articles 4 and 5, unless the issuing State has given its consent.

*Article 13***Amnesty, pardon, review of confiscation order**

1. Amnesty and pardon may be granted by the issuing State and also by the executing State.

2. Only the issuing State may determine any application for review of the confiscation order.



*Article 14***Consequences of transmission of confiscation orders**

1. The transmission of a confiscation order to one or more executing States in accordance with Articles 4 and 5 does not restrict the right of the issuing State to execute the confiscation order itself.

2. In the case of transmission of a confiscation order concerning an amount of money to one or more executing States, the total value derived from its execution may not exceed the maximum amount specified in the confiscation order.

3. The competent authority of the issuing State shall immediately inform the competent authority of any executing State concerned by any means capable of producing a written record:

- (a) if it considers that there is a risk that execution beyond the maximum amount may occur, for example on the basis of information notified to it by an executing State pursuant to Article 10(3). In the event of the application of Article 10(1)(a), the competent authority of the issuing State shall as soon as possible inform the competent authority of the executing State whether the risk referred to has ceased to exist;
- (b) if all or a part of the confiscation order has been executed in the issuing State or in another executing State. The amount for which the confiscation order has not yet been executed shall be specified;
- (c) if, after transmission of a confiscation order in accordance with Articles 4 and 5, an authority of the issuing State receives any sum of money which the person concerned has paid voluntarily in respect of the confiscation order. Article 12(2) shall apply.

*Article 15***Termination of execution**

The competent authority of the issuing State shall forthwith inform the competent authority of the executing State by any means capable of reducing a written record of any decision or measure as a result of which the order ceases to be enforceable or shall be withdrawn from the executing State for any other reason. The executing State shall terminate execution of the order as soon as it is informed by the competent authority of the issuing State of that decision or measure.

*Article 16***Disposal of confiscated property**

1. Money which has been obtained from the execution of the confiscation order shall be disposed of by the executing State as follows:

- (a) if the amount obtained from the execution of the confiscation order is below EUR 10 000, or the equivalent to that amount, the amount shall accrue to the executing State;

- (b) in all other cases, 50 % of the amount which has been obtained from the execution of the confiscation order shall be transferred by the executing State to the issuing State.

2. Property other than money, which has been obtained from the execution of the confiscation order, shall be disposed of in one of the following ways, to be decided by the executing State:

- (a) the property may be sold. In that case, the proceeds of the sale shall be disposed of in accordance with paragraph 1;
- (b) the property may be transferred to the issuing State. If the confiscation order covers an amount of money, the property may only be transferred to the issuing State when that State has given its consent;
- (c) when it is not possible to apply (a) or (b), the property may be disposed of in another way in accordance with the law of the executing State.

3. Notwithstanding paragraph 2, the executing State shall not be required to sell or return specific items covered by the confiscation order which constitute cultural objects forming part of the national heritage of that State.

4. Paragraphs 1, 2 and 3 apply unless otherwise agreed between the issuing State and the executing State.

*Article 17***Information on the result of the execution**

The competent authority of the executing State shall without delay inform the competent authority of the issuing State by any means capable of producing a written record:

- (a) of the transmission of the confiscation order to the competent authority, according to Article 4(5);
- (b) of any decision not to recognise the confiscation order, together with the reasons for the decision;
- (c) of the total or partial non-execution of the order for the reasons referred to in Article 11, Article 12(1) and (2) or Article 13(1);
- (d) as soon as the execution of the order has been completed;
- (e) of the application of alternative measures, according to Article 12(4).

*Article 18***Reimbursement**

1. Without prejudice to Article 9(2), where the executing State under its law is responsible for injury caused to one of the interested parties mentioned in Article 9 by the execution of a confiscation order transmitted to it pursuant to Articles 4 and 5, the issuing State shall reimburse to the executing State any sums paid in damages by virtue of that responsibility to the said party except if, and to the extent that, the injury or any part of it is exclusively due to the conduct of the executing State.

2. Paragraph 1 is without prejudice to the law of the Member States on claims by natural or legal persons for compensation of damage.

*Article 19***Languages**

1. The certificate shall be translated into the official language or one of the official languages of the executing State.

2. Any Member State may, when this Framework Decision is adopted or at a later date, state in a declaration deposited with the General Secretariat of the Council that it will accept a translation in one or more other official languages of the Institutions of the European Communities.

*Article 20***Costs**

1. Without prejudice to Article 16, Member States may not claim from each other the refund of costs resulting from application of this Framework Decision.

2. Where the executing State has had costs which it considers large or exceptional, it may propose to the issuing State that the costs be shared. The issuing State shall take into account any such proposal on the basis of detailed specifications given by the executing State.

*Article 21***Relationship with other agreements and arrangements**

This Framework Decision shall not affect the application of bilateral or multilateral agreements or arrangements between Member States in so far as such agreements or arrangements help to

further simplify or facilitate the procedures for the execution of confiscation orders.

*Article 22***Implementation**

1. Member States shall take the necessary measures to comply with this Framework Decision by 24 November 2008.

2. Member States shall communicate to the General Secretariat of the Council and to the Commission the text of the provisions transposing into their national law the obligations resulting from this Framework Decision. On the basis of a report established on the basis of this information by the Commission, the Council shall, by 24 November 2009, assess the extent to which Member States have taken the necessary measures to comply with this Framework Decision.

3. The General Secretariat of the Council shall notify the Member States and the Commission of the declarations made pursuant to Articles 7(5) and 19(2).

4. A Member State which has experienced repeated difficulties or lack of activity by another Member State in the mutual recognition and execution of confiscation orders, which have not been resolved through bilateral consultations, may inform the Council with a view to evaluating the implementation of this Framework Decision at Member State level.

5. The Member States, acting as executing States, shall inform the Council and the Commission, at the beginning of the calendar year, of the number of cases in which Article 17(b) has been applied and a summary of reasons for this.

By 24 November 2013, the Commission shall establish a report on the basis of the information received, accompanied by any initiatives it may deem appropriate.

*Article 23***Entry into force**

This Framework Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Luxembourg, 6 October 2006.

*For the Council*  
*The President*  
K. RAJAMÄKI



## ANNEX

## CERTIFICATE

referred to in Article 4 of Council Framework Decision 2006/783/JHA on the application of the principle of mutual recognition to confiscation orders

(a) Issuing and executing States:

Issuing State: .....

Executing State: .....

(b) Court which issued the confiscation order:

Official name: .....

Address: .....

.....

File reference: .....

Tel. (country code) (area/city code): .....

Fax (country code) (area/city code): .....

E mail (when available): .....

Languages in which it is possible to communicate with the Court: .....

.....

Contact details for person(s) to contact in order to obtain additional information for the purpose of the execution of the confiscation order, or, where applicable, for the purpose of coordination of the execution of a confiscation order transmitted to two or more executing States, or for the purpose of the transfer to the issuing State of monies or properties obtained from the execution (name, title/grade, tel., fax, and, when available, e mail):

.....

.....

.....

- (c) Authority competent for the execution of the confiscation order in the issuing State (if the authority is different from the Court under point (b)):

Official name: .....

.....

Address: .....

.....

Tel. (country code) (area/city code): .....

Fax (country code) (area/city code): .....

E mail (when available): .....

.....

Languages in which it is possible to communicate with the authority competent for the execution: .....

.....

.....

Contact details for person(s) to contact in order to obtain additional information for the purpose of the execution of the confiscation order or, where applicable, for the purpose of coordination of the execution of a confiscation order transmitted to two or more executing States, or for the purpose of the transfer to the issuing State of monies or properties obtained from the execution, (name, title/grade, tel., fax, and, when available, e mail): .....

.....

.....

- (d) Where a central authority has been made responsible for the administrative transmission and reception of confiscation orders in the issuing State:

Name of the central authority: .....

.....

.....

Contact person, if applicable (title/grade and name): .....

.....

Address: .....

.....

File reference: .....

Tel. (country code) (area/city code): .....

Fax (country code) (area/city code): .....

E mail (when available): .....

(e) Authority or authorities which may be contacted (if point (c) and/or (d) has(have) been completed):

☐ Authority mentioned under point (b)

Can be contacted for questions concerning: .....

☐ Authority mentioned under point (c)

Can be contacted for questions concerning: .....

☐ Authority mentioned under point (d)

Can be contacted for questions concerning: .....

(f) Where the confiscation order is a follow up to a freezing order transmitted to the executing State pursuant to Council Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence <sup>(1)</sup>, provide relevant information to identify the freezing order (the dates of issue and transmission of the freezing order, the authority to which it was transmitted, reference number, if available): .....

.....

.....

(g) Where the confiscation order has been transmitted to more than one executing State, provide the following information:

1. The confiscation order has been transmitted to the following other executing State(s) (country and authority): .....

.....

.....

2. The confiscation order has been transmitted to more than one executing State for the following reason (tick the relevant box):

2.1. Where the confiscation order concerns one or more specific items of property:

☐ Different specific items of property covered by the confiscation order are believed to be located in different executing States.

☐ The confiscation of a specific item of property involves action in more than one executing State.

☐ A specific item of property covered by the confiscation order is believed to be located in one of two or more specified executing States.

2.2. Where the confiscation order concerns an amount of money:

☐ The property concerned has not been frozen under Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence.

☐ The value of the property which may be confiscated in the issuing State and any one executing State is not likely to be sufficient for the execution of the full amount covered by the confiscation order.

☐ Other reason(s) (to be specified): .....

.....

.....

<sup>(1)</sup> OJ L 196, 2.8.2003, p. 45.

(h) Information regarding the natural or legal person against whom the confiscation order has been issued:

1. **In the case of a natural person:**

Name: .....

Forename(s): .....

Maiden name, (where applicable): .....

Aliases, (where applicable): .....

Sex: .....

Nationality: .....

Identity number or social security number (when possible): .....

Date of birth: .....

Place of birth: .....

Last known address: .....

.....

Language(s) which the person understands (if known): .....

.....

1.1. If the confiscation order concerns an amount of money:

The confiscation order is transmitted to the executing State because (tick the relevant box):

- ☐ (a) the issuing State has reasonable grounds to believe that the person against whom the confiscation order has been issued has property or income in the executing State. Add the following information:

Grounds for believing that the person has property/income: .....

.....

Description of the property of the person/source of income: .....

.....

Location of the property of the person/source of income (if not known, the last known location): .....

.....

- ☐ (b) there are no reasonable grounds, as referred to under (a), which would allow the issuing State to determine the Member State to which the confiscation order may be sent, but the person against whom the confiscation order has been issued is normally resident in the executing State. Add the following information:

Normal residence in the executing State: .....

.....

.....

1.2. If the confiscation order concerns specific item(s) of property:

The confiscation order is transmitted to the executing State because (tick the relevant box):

- ☐ (a) the specific item(s) of property is(are) located in the executing State. (See point (i))
- ☐ (b) the issuing State has reasonable grounds to believe that all or part of the specific item(s) of property covered by the confiscation order is (are) located in the executing State. Add the following information:

Grounds for believing that the specific item(s) of property is located in the executing State: .....

.....

- ☐ (c) there are no reasonable grounds, as referred to in (b), which would allow the issuing State to determine the Member State to which the confiscation order may be transmitted, but the person against whom the confiscation order has been issued is normally resident in the executing State. Add the following information:

Normal residence in the executing State: .....

.....

.....

2. In the case of a legal person:

Name: .....

Form of legal person: .....

Registration number (if available) <sup>(1)</sup>: .....

Registered seat (if available) <sup>(1)</sup>: .....

Address of the legal person: .....

2.1. If the confiscation order concerns an amount of money:

The confiscation order is transmitted to the executing State because (tick the relevant box):

- ☐ (a) the issuing State has reasonable grounds to believe that the legal person against whom the confiscation order has been issued has property or income in the executing State. Add the following information:

Grounds for believing that the person has property/income: .....

.....

Description of the property of the person/source of income: .....

.....

Location of the property of the person/source of income (if not known, the last known location): .....

.....

<sup>(1)</sup> Where a confiscation order is transmitted to the executing State because the legal person against whom the confiscation order has been issued has its registered seat in that State, Registration number and Registered seat must be completed.

- ☐ (b) there are no reasonable grounds, as referred to in (a), which would allow the issuing State to determine the Member State to which the confiscation order may be sent but the legal person against whom the confiscation order has been issued has its registered seat in the executing State. Add the following information:

Registered Seat in the executing State: .....

.....

.....

2.2. If the confiscation order concerns specific item(s) of property:

The confiscation order is transmitted to the executing State because (tick the relevant box):

- ☐ (a) the specific item(s) of property is (are) located in the executing State. (See point (i)).
- ☐ (b) the issuing State has reasonable grounds to believe that all or part of the specific item(s) of property covered by the confiscation order is (are) located in the executing State. Add the following information:

Grounds for believing that the specific item(s) of property is (are) located in the executing State: .....

.....

.....

- ☐ (c) there are no reasonable grounds, as referred to in (b), which would allow the issuing State to determine the Member State to which the confiscation order may be transmitted but the legal person against whom the confiscation order has been issued has its registered seat in the executing State. Add the following information:

Registered seat in the executing State: .....

.....

.....

(i) The confiscation order

The confiscation order was issued on (date): .....

.....

The confiscation order became final on (date): .....

Reference number of the confiscation order (if available): .....

1. Information on the nature of the confiscation order

1.1. Indicate (by ticking in the relevant box(es)) if the confiscation order concerns:

☐ an amount of money

The amount for execution in the executing State with indication of currency (in figures and words): .....

.....

The total amount covered by the confiscation order with indication of currency (in figures and words): .....

.....

☐ specific item(s) of property

Description of the specific item(s) of property: .....

.....

Location of the specific item(s) of property (if not known, the last known location): .....

.....

.....

Where the confiscation of the specific item(s) of property involves action in more than one executing State, description of the action to be taken: .....

.....

1.2. The Court has decided that the property (tick the relevant box(es)):

☐ (i) is the proceeds of an offence, or is equivalent to either the full value or part of the value of such proceeds,

☐ (ii) constitutes the instrumentalities of such an offence,

☐ (iii) is liable to confiscation resulting from the application in the issuing State of extended powers of confiscation as specified in (a), (b) and (c). The basis for the decision is that the Court, based on specific facts, is fully convinced that the property in question has been derived from:

☐ (a) criminal activities of the convicted person during a period prior to conviction for the offence concerned which is deemed to be reasonable by the Court in the circumstances of the particular case,

☐ (b) similar criminal activities of the convicted person during a period prior to conviction for the offence concerned which is deemed to be reasonable by the Court in the circumstances of the particular case, or

☐ (c) the criminal activity of the convicted person, and it has been established that the value of the property is disproportionate to the lawful income of that person.



- ☐ (iv) is liable to confiscation under any other provision relating to extended powers of confiscation under the law of the issuing State.

If two or more categories of confiscation are involved, provide details on which property is confiscated in relation to which category: .....

.....

2. Information on the offence(s) resulting in the confiscation order

2.1. A summary of facts and a description of the circumstances in which the offence(s) resulting in the confiscation order has(have) been committed, including time and place:

.....  
.....  
.....  
.....  
.....

2.2. Nature and legal classification of the offence(s) resulting in the confiscation order and the applicable statutory provision/code on basis of which the decision was made:

.....  
.....  
.....  
.....  
.....  
.....

2.3. If applicable, indicate one or more of the following offences to which the offence(s) identified under point 2.2 relate(s), if the offence(s) are punishable in the issuing State by a custodial sentence of a maximum of at least 3 years (tick the relevant box(es)):

- ☐ participation in a criminal organisation;
- ☐ terrorism;
- ☐ trafficking in human beings;
- ☐ sexual exploitation of children and child pornography;
- ☐ illicit trafficking in narcotic drugs and psychotropic substances;
- ☐ illicit trafficking in weapons, munitions and explosives;
- ☐ corruption;
- ☐ fraud, including that affecting the financial interests of the European Communities within the meaning of the Convention of 26 July 1995 on the protection of the European Communities' financial interests;

- ☐ laundering of the proceeds of crime;
- ☐ counterfeiting currency, including of the euro;
- ☐ computer related crime;
- ☐ environmental crime, including illicit trafficking in endangered animal species and in endangered plant species and varieties;
- ☐ facilitation of unauthorised entry and residence;
- ☐ murder, grievous bodily injury;
- ☐ illicit trade in human organs and tissue;
- ☐ kidnapping, illegal restraint and hostage taking;
- ☐ racism and xenophobia;
- ☐ organised or armed robbery;
- ☐ illicit trafficking in cultural goods, including antiques and works of art;
- ☐ swindling;
- ☐ racketeering and extortion;
- ☐ counterfeiting and piracy of products;
- ☐ forgery of administrative documents and trafficking therein;
- ☐ forgery of means of payment;
- ☐ illicit trafficking in hormonal substances and other growth promoters;
- ☐ illicit trafficking in nuclear or radioactive materials;
- ☐ trafficking in stolen vehicles;
- ☐ rape;
- ☐ arson;
- ☐ crimes within the jurisdiction of the International Criminal Court;
- ☐ unlawful seizure of aircraft/ships;
- ☐ sabotage.

2.4. To the extent that the offence(s) resulting in the confiscation order identified under point 2.2 is (are) not covered by point 2.3, give a full description of the offence(s) concerned (this should cover the actual criminal activity involved as opposed for instance to legal classifications): .....

.....

.....

.....

.....

.....

.....

(j) Proceedings resulting in the confiscation order

Indicate the following concerning the proceedings resulting in the confiscation order (tick the relevant box(es)):

- ☐ (a) The person concerned appeared personally in the proceedings.
- ☐ (b) The person concerned did not appear personally in the proceedings, but was represented by a legal counsellor.
- ☐ (c) The person concerned did not appear in the proceedings and was not represented by a legal counsellor. It is confirmed that:
- ☐ the person was informed personally, or via a representative competent according to national law, of the proceedings in accordance with the law of the issuing State, or
- ☐ the person has indicated that he or she does not contest the confiscation order.

(k) Conversion and transfer of property

1. If the confiscation order concerns a specific item of property, state whether the issuing State allows for the confiscation in the executing State to take the form of a requirement to pay a sum of money corresponding to the value of the property.

☐ yes

☐ no

2. If the confiscation order concerns an amount of money, state whether property, other than money obtained from the execution of the confiscation order, may be transferred to the issuing State:

☐ yes

☐ no

(l) Alternative measures, including custodial sanctions

1. State whether the issuing State allows for the application by the executing State of alternative measures where it is not possible to execute the confiscation order, either totally or in part:

☐ yes

☐ no

2. If yes, state which sanctions may be applied (nature and maximum level of the sanctions):

☐ Custody ( maximum period): .....

☐ Community service (or equivalent) ( maximum period): .....

☐ Other sanctions (description): .....  
.....

(m) Other circumstances relevant to the case (optional information): .....  
.....  
.....

(n) The confiscation order is attached to the certificate.

Signature of the authority issuing the certificate and/or its representative certifying the content of the certificate as accurate: .....  
.....

Name: .....

Post held (title/grade): .....

Date: .....

Official stamp (if available):