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COMMISSION DECISION

of 21 November 2003

laying down the animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption

(notified under document number C(2003) 4219)

(Text with EEA relevance)

(2003/858/EC)

(OJ L 324, 11.12.2003, p. 37)

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<u>▶</u>B

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		No	page	date
► <u>M1</u>	Commission Decision 2004/454/EC of 29 April 2004	L 202	20	7.6.2004
► <u>M2</u>	Commission Decision 2004/914/EC of 16 December 2004	L 385	60	29.12.2004
► <u>M3</u>	Commission Decision 2005/742/EC of 19 October 2005	L 279	71	22.10.2005
► <u>M4</u>	Commission Decision 2006/680/EC of 6 October 2006	L 279	24	11.10.2006
► <u>M5</u>	Commission Decision 2006/767/EC of 6 November 2006	L 320	58	18.11.2006
► <u>M6</u>	Commission Regulation (EC) No 1792/2006 of 23 October 2006	L 362	1	20.12.2006
►M7	Commission Decision 2007/158/EC of 7 March 2007	L 68	10	8.3.2007

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(Text with EEA relevance)

(2003/858/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 (1), as last amended by Council Regulation (EC) No 806/2003 (2), and in particular Article 19 (1), Article 20(1) and Article 21(2) thereof,

Whereas:

- (1) A list of third countries or parts thereof, from which Member States are authorised to import live fish, their eggs and gametes for farming in the Community, should be established.
- It is necessary to lay down specific animal health conditions and model certificates for those third countries, taking into account the animal health situation of the third country concerned and of the fish, eggs or gametes to be imported, in order to prevent the introduction of disease agents that could cause significant impact to the fish stock in the Community.
- Attention should be paid to emerging diseases and diseases which (3) are exotic to the Community and which could have serious impact on the fish stocks in the Community. Furthermore, the vaccination policy and the disease situation as regards epizootic haematopoietic necrosis (EHN) and the fish diseases referred to in Annex A to Directive 91/67/EEC, at the place or production and where appropriate at the place of destination should be taken into account.
- It is necessary that countries or parts thereof from which Member States are authorised to import live fish, their eggs and gametes for farming, must apply conditions for disease control, and monitoring at least equivalent to Community standards as laid down in Directive 91/67/EEC and in Council Directive 93/53/EC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases (3), as last amended by Commission Decision 2001/288/EC (4). The sampling and testing methods used should be at least equivalent to Commission Decision 2001/183/EC (5) of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC, and Commission Decision 2003/466/EC (6) of 13

⁽¹⁾ OJ L 46, 19.2.1991, p. 1.

⁽²⁾ OJ L 122, 16.5.2003, p. 1.

⁽³⁾ OJ L 175, 19.7.1993, p. 23.

⁽⁴⁾ OJ L 99, 10.4.2001, p. 11.

⁽⁵⁾ OJ L 67, 9.3.2001, p. 65.

⁽⁶⁾ OJ L 156, 25.6.2003, p. 61.

- June 2003 establishing criteria for zoning and official surveillance following suspicion or confirmation of the presence of Infectious salmon anaemia (ISA). In cases where sampling and testing methods are not laid down in the Community legislation, the sampling and testing methods used should be in accordance with those laid down in the International Office of Epizootics (OIE) Manual of Diagnostic Tests for Aquatic Animals.
- (5) It is necessary that the responsible competent authorities of these third countries undertake to notify by fax, telegram or electronic mail, the Commission and the Member States within 24 hours, of any occurrence of epizootic haematopoietic necrosis (EHN), or diseases referred to in Annex A to Directive 91/67/EEC, as well as any other disease outbreaks causing a significant impact to the fish stock within their territory or parts thereof from which imports covered by this Decision are authorised. In such event, the responsible competent authorities of those third countries must take measures to prevent the disease spreading into the Community. Furthermore and as applicable, the Commission and the Member States should be notified of any alteration in the vaccination policy against such diseases.
- (6) In addition, when importing live fish of aquaculture origin and products thereof for human consumption, it is necessary to prevent the introduction into the Community of serious diseases affecting aquaculture animals.
- (7) Therefore, it is necessary to supplement the certification requirements relating to the importation of live fish of aquaculture origin and products thereof under Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products (1), as last amended by Regulation (EC) No 806/2003, with the animal health certification requirements.
- (8) It would reduce the possibility to control and eradicate diseases which are exotic to the Community and which could have serious impact on the fish stocks in the Community, if fish that could carry the disease are released into unenclosed waters in the Community. Live fish, eggs and gametes of aquaculture origin, should therefore be imported into the Community only if they are introduced into a farm.
- (9) This Decision should not apply to the importation of tropical ornamental fish kept permanently in aquariums.
- (10) This Decision should apply without prejudice to the public health conditions established under Directive 91/493/EEC.
- (11) This Decision should apply without prejudice to Community or national provision on the conservation of species.
- (12) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (2) lays down standards of certification. The rules and principles applied by third-country certifying officers should provide guarantees, which are equivalent to those laid down in that Directive.
- (13) The principles laid down in Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (3), in particular Article 3 of that Directive should be taken into account.
- (14) A transitional period of time should be provided for the implementation of the new import certification requirements.

⁽¹⁾ OJ L 268, 24.9.1991, p. 15.

⁽²⁾ OJ L 13, 16.1.1997, p. 28.

⁽³⁾ OJ L 18, 23.1.2003, p. 11.

- (15) The list of approved countries referred to in Annex I to this Decision should be reviewed no later than 12 months after the date of application.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Scope

- 1. This Decision establishes harmonised animal health rules for the importation of:
- (a) live fish, their eggs and gametes, intended for farming in the Community;
- (b) live fish of aquaculture origin intended for restocking of put-and take fisheries in the Community;
- (c) live fish of aquaculture origin and products thereof, intended for immediate human consumption or further processing before human consumption.
- 2. This Decision shall not to apply to the importation of tropical ornamental fish kept permanently in aquariums.

Article 2

Definitions

- 1. For the purpose of this Decision, the definitions in Article 2 of Directives 91/67/EEC and 93/53/EEC shall apply.
- 2. The following definitions shall also apply:
- (a) 'aquaculture origin' means fish originating from a farm;
- (b) 'approved import centre' means any establishment in the Community where special bio-security measures have been put in place, approved by the competent authority of the Member State concerned, for further processing of imported live fish of aquaculture origin and products thereof;
- (c) 'coastal zone' means a zone consisting of a part of the coast or sea water or an estuary:
 - which has a precise geographical delimitation and consists of a homogeneous hydrological system or a series of such systems, or
 - (ii) which is situated between the mouths of two watercourses, or
 - (iii) where there are one or more farms and all farms are surrounded by appropriate buffer zones on both sides of the farm or farms;
- (d) 'continental zone' means a zone consisting of either:
 - (i) a part of the territory comprising an entire catchment area from the sources of the waterways to the estuary or more than one catchment area in which fish is reared, kept or caught, as necessary surrounded by a buffer zone in which a monitoring program is carried out without the necessity of obtaining the status of an approved zone, or
 - (ii) a part of a catchment area from the sources of the waterways to a natural or artificial barrier preventing fish migrating from

downstream of that barrier, as necessary surrounded by a buffer zone in which a monitoring program is carried out without the necessity of obtaining the status of an approved zone.

The size and the geographical situation of the continental zone must be such that the possibilities for recontamination e.g. by migrating fish are reduced to a minimum;

- (e) 'designated farm' means either:
 - (i) a coastal farm in a third country subject to all necessary measures to prevent the introduction of diseases and to which the water is supplied by means of a system which ensures the complete inactivation of the following pathogens: infectious salmon anaemia (ISA), viral heamorrhagic septicaemia (VHS) and infectious haemorrhagic necrosis (IHN), or
 - (ii) an inland farm in a third country subject to all necessary measures to prevent the introduction of diseases. The farm is, if necessary, protected against flooding and infiltration of water, and there is a natural or artificial barrier situated down stream, which prevents fish from entering the farm. The water is supplied directly to the farm from a borehole, spring, or well, channelled through a pipe, open channel or a natural conduit, which does not constitute a source of infection for the farm and does not allow the introduction of wild fish. The water channel is under the control of the farm or of the competent authorities;
- (f) 'establishment' means: any premises approved according to Directive 91/493/EEC, where fishery products are prepared, processed, chilled, frozen, packaged or stored, but excluding auction and wholesale markets in which only display and sale by wholesale takes place;

▼M2

(g) 'farming' means the keeping of aquatic animals on a farm;

▼B

- (h) 'fish products of aquaculture origin' means any products intended for human consumption derived from fish of aquaculture origin, including whole fish (un-eviscerated), eviscerated fish, and filets, and any products thereof;
- (i) 'further processing' means preparation and processing before human consumption by any kind of measures and techniques, that produces waste or byproducts which could cause a risk of spreading diseases, including: operations affecting the anatomical wholeness such as bleeding, gutting/evisceration, heading, slicing, filleting;
- (j) 'immediate human consumption' means that the fish imported for the purpose of human consumption do not undergo any further processing within the Community before being placed on the retail market for human consumption;
- (k) 'put and take fisheries' means ponds, lakes or unenclosed waters that are sustained by the introduction of fish primarily for recreational fishing rather than for conservation or improvement of natural population;
- 'territory' means either a whole country, a coastal zone, a continental zone or a designated farm, which is authorised by the central competent authority of the third country concerned for exportation to the Community.

Article 3

Conditions for importation of live fish, their eggs and gametes intended for farming, and of live fish of aquaculture origin for restocking of put-and take fisheries, within the European Community

- 1. Member States shall authorise the importation into their territory live fish, their eggs and gametes for farming only if:
- (a) the fish originate in a territory listed in Annex I;
- (b) the consignment complies with the guarantees, including those for packaging and labelling and the appropriate specific additional requirements, as laid down in the animal health certificate, drawn up in conformity with the model in Annex II, taking into account the explanatory notes in Annex III;
- (c) the fish have been transported under conditions not altering their health status.
- 2. Member States shall authorise the importation into their territory live fish of aquaculture origin, their eggs and gametes intended for direct restocking of put-and take fisheries only if:
- (a) the consignment comply with the rules laid down in paragraph 1;
- (b) the put and take fishery do not represent lakes or unenclosed waters.
- 3. Member States shall ensure that imported fish of aquaculture origin, their eggs and gametes intended for farming or restocking of put-and take fisheries in Community waters, only are introduced into farms or put-and take fisheries representing ponds, and not introduced into unenclosed waters.
- 4. Member States shall ensure that imported live fish or aquaculture origin, their eggs and gametes are transported directly to the farm or pond of destination, as stated on the animal health certificate.

▼<u>M2</u>

Article 4

Conditions related to importation of live fish of aquaculture origin for human consumption

Member States shall authorise the importation into their territory of live fish of aquaculture origin intended for immediate human consumption or for further processing before human consumption, only if:

- (a) the fish originate in third countries authorised under Article 11 of Directive 91/493/EEC, and comply with the public health certification requirements laid down under that Directive; and
- (b) the consignment complies with the conditions laid down in Article 3 (1); or
- (c) the fish is sent directly to an approved import centre to be slaughtered and eviscerated.

▼M5

Article 5

Conditions for the importation of fish products of aquaculture origin for human consumption

1. Member States shall authorise the importation into their territory of fish products of aquaculture origin intended for human consumption, only if:

▼M7

(a) the third country of dispatch appears either on the list established by Commission Decision 2006/766/EC (¹) or, during the transitional period referred to in Commission Regulation (EC) No 2076/2005 (²), on the list established by that Regulation;

▼ M<u>5</u>

- (b) the consignment is accompanied by a joint public and animal health certificate drawn up in conformity with the model laid down in Commission Regulation (EC) No 2074/2005;
- (c) the consignment comply with the provisions for packaging and labelling provided for in Regulation (EC) No 853/2004.

▼M2

- 2. Member States shall ensure that the processing of fish products of aquaculture origin from species susceptible to EHN, ISA, VHS and IHN takes place in approved import centres unless:
- (a) the fish have been eviscerated before dispatch to the European Community; or
- (b) the place of origin in the third country has a health status as regards EHN, ISA, VHS and IHN, equivalent to the place where they are to be processed.

▼<u>M5</u>

Article 6

Additional conditions for the importation of certain fish products of aquaculture origin for human consumption

- 1. Consignments of fish species susceptible to ISA and/or EHN must, in addition to the requirements set out in Article 5, also comply with the following:
- (a) the source must be recognised free from diseases in question in accordance with Community legislation or the relevant OIE (World Organisation for Animal Health) Standard by the competent authority of the third country of origin, or
- (b) the fish must be eviscerated before dispatch, or
- (c) the consignment must be sent directly to an approved import centre where the fish are further processed.
- 2. Consignments of fish species susceptible to VHS and/or IHN, imported into Member States or zones being declared free or under programme for achieving such status in accordance with Articles 5 or 10 of Directive 91/67/EEC, must comply with the following, in addition to the requirements set out in Article 5:
- (a) the source must be recognised free from the relevant disease in accordance with Community legislation or the relevant OIE Standard by the competent authority of the third country of origin, or
- (b) the fish must be eviscerated before dispatch, or
- (c) the consignment must be sent directly to an approved import centre where the fish are further processed.

⁽¹⁾ OJ L 320, 18.11.2006, p. 53.

⁽²⁾ OJ L 338, 22.12.2005, p. 83.

Article 7

Control procedures

- 1. Live fish, their eggs and gametes imported for the purpose of farming, and live fish of aquaculture origin imported for the purposes of restocking of put and take fisheries shall be subject to veterinary checks at the border inspection post in the Member State of arrival according to Article 8 of Directive 91/496/EEC, and the common veterinary entry document provided for in Regulation (EC) No 282/2004 shall be completed accordingly.
- 2. Live fish of aquaculture origin and products thereof imported for immediate human consumption or for further processing before human consumption, shall be subject to veterinary checks at the border inspection post in the Member State of arrival according to Article 8 of Directive 97/78/EC, and the common veterinary entry document provided for in Regulation (EC) No 136/2004 shall be completed accordingly.

Article 8

Preventing contamination of natural waters

- 1. Member States shall ensure that imported live fish of aquaculture origin intended for human consumption are not released into natural waters within their territory.
- 2. Member States shall ensure that imported products of aquaculture origin intended for human consumption do not contaminate any natural waters within their territory.
- 3. Members States shall ensure that transport water from imported consignments does not lead to contamination of natural waters within their territory.

▼<u>B</u>

Article 9

Approval of import centres

- 1. The competent authority of the Member States shall approve an establishment as an approved import centre provided that it satisfies the minimum animal health conditions of Annex VII to this Decision.
- 2. The competent authority of the Member State shall draw up a list of approved import centres, each of which shall be given an official number.
- 3. The list of approved import centres, and any subsequent amendments thereto, shall be communicated by the competent authority of each Member State to the Commission and to the other Member States.

Article 10

Date of application

This Decision shall apply from 1 May 2004.

Article 11

This Decision is addressed to the Member States.

▼<u>M4</u>

▼<u>M6</u>

▼M4

ZA

South Africa

 ${\it ANNEX~I}$ Territories from which importation of certain species of live fish, their eggs, and gametes intended for farming in the European Community (EC) is authorised

Country			Territory		
ISO Code	Name	Code	Description	Comments (1)	
AU	Australia				
BR	Brazil			Cyprinidae only	
CA	Canada				
CG	Congo			Cyprinidae only	
CL	Chile				
CN	China			Cyprinidae only	
СО	Colombia			Cyprinidae only	
HR	Croatia				
ID	Indonesia				
IL	Israel				
JM	Jamaica			Cyprinidae only	
JP	Japan			Cyprinidae only	
LK	Sri Lanka			Cyprinidae only	
MK (²)	former Yugoslav Republic of Macedonia			Cyprinidae only	
MY	Malaysia (Peninsula, Western Malaysia only)			Cyprinidae only	
NZ	New Zealand				
RU	Russia				
SG	Singapore			Cyprinidae only	
TH	Thailand			Cyprinidae only	
TR	Turkey				
TW	Taiwan			Cyprinidae only	
US	United States				

⁽¹⁾ No limitations if left blank. If a country or territory is allowed to expert certain species, and/or eggs or gametes, the species must be specified and/or a comment, for example, 'eggs only' must be inserted in this

⁽²⁾ Provisional code that does not affect the definitive denomination of the country to be attributed after the conclusion of the negotiations currently taking place in the United Nations.

ANNEX II

Model animal health certificate for the importation of (1) [live fish, eggs and gametes for farming] (1) [live fish of aquaculture origin for the purpose of (1) [human consumption] (1) [restocking of put and take fisheries]] into the European Community (EC)

Reference code No ORIGINAL
Reference code No of
public health certificate (where appropriate)

Note for the importer: This certificate is only for veterinary purposes and has — in its original — to accompany the consignment until it reaches the border inspection post.

Where the live fish, eggs or gametes are intended for farming or restocking of put and take fisheries in the Community, the consignment should be subjected to veterinary controls according to Council Directive 91/496/EEC, at a border inspection post approved for live animals.

Where the live fish are intended human consumption in the Community, the consignment should be subjected to veterinary controls according to Council Directive 97/78/EC, at a border inspection post approved for animal products. In the last case, this certificate must be attached to the certificate issued pursuant to Council Directive 91/493/EEC.

3. Destination of the consignment
3.1. Member State:
(¹)[3.2. Zone or part (³) of the Member State:
]
(1)[3.3. Farm, name:
]
3.4. Address:
3.5. Name, address and phone number of the consignee:
4. Means of transport and consignment identification (4)
4.1. Means of transport: (¹) [Lorry] (¹) [Rail-wagon] (¹) [Ship] (¹) [Aircraft]
4.2. (¹) [Registration number(s)] (¹) [Ship name] (¹) [Flight
in the state of th
4.3. Consignment identification details:

▼<u>M2</u>

5.	Description of the consignment				
☐ Farmed stocks ☐ Wild stocks ☐ Live fish ☐ Gametes ☐ Fertilised eggs ☐ Unfertilised eggs ☐ Larvae/fry					
Fish species Scientific name: Common name:		Total weight of fish (kg) (¹)[Number of fish]	(¹)[Volume of eggs] (¹)[Volume of gametes]	Age of live fish	
Scier	шис паше.	Common name:	(*)[Number of listi]	gametesj	□ >24 months □ 12-24 months □ 0-11 months □ unknown
6.	Animal health attestation for importation of $\binom{1}{2}$ [$\binom{1}{2}$ [live fish] $\binom{1}{2}$ [and] $\binom{1}{2}$ [gametes] for farming] $\binom{1}{2}$ [live fish of aquaculture origin intended for $\binom{1}{2}$ [human consumption] $\binom{1}{2}$ [for farming or restocking of put and take fisheries]]				
	I, the undersigned official inspector, hereby certify that the (¹)[live fish] (¹)[and] (¹)[eggs] (¹)[and] (¹)[gametes], referred to at point 5 of this certificate fulfils the following requirements:				
6.1.	either:				
	(⁵)[They originate from the territory (²) with the code:				
	are officially registered by the competent authority,				
	 keep an updated record of live fish, eggs and gametes entering and leaving the farm and all information relating to their delivery and dispatch, their number or weight, their size, their source, their suppliers and observed mortality (⁷), 				
	 have to notify as soon as possible to the competent authority any suspicion of the following diseases: ISA, EHN, VHS and IHN, and any clinical signs giving reason to suspect the presence of a disease capable of causing significant impact on the fish stock, 				
	— are subject to appropriate disease control measures as necessary at least equivalent to those required in Council Directives 91/67/EEC and 93/53/EEC including prohibition as regards vaccination against ISA, and as regards sampling and testing also Commission Decisions 2001/183/EC and 2003/466/EC; in cases where sampling and testing methods are not established in the Community legislation, the methods are those laid down in the relevant chapters of the OIE (8) Manual of Diagnostic Tests for Aquatic Animals, fourth edition, 2003,				
	 have had no disease, that has caused significant impact to the stock during the last six months prior to dispatch, and during the last two years, no cases of the diseases ISA and EHN, 				
	 have, during the last two years prior to dispatch, not introduced live fish, eggs or gametes with a lower health status, 				
	 there are, on the day of loading, no clinical signs of disease and there is no suspicion of the presence of any of the following diseases: ISA, EHN, VHS and IHN.] 				
	or				
	(5)[They originate from the territory (2) with the code:				
	— is a designated farm, or a farm that is not connected with a watercourse, or with coastal or estuarial waters, and that does not contain fish of the species considered as susceptible (6) to the diseases: infectious salmon anaemia (ISA), epizootic haematopoietic necrosis (EHN), viral haemorrhagic septicaemia (VHS), and infectious haematopoietic necrosis (IHN),				
	 keep an updated record of live fish, eggs and gametes entering and leaving the farm and all information relating to their delivery and dispatch, their number or weight, their size, their source, their suppliers and observed mortality (7).] 				
	or				
	(9)[They origin	(2) (They originate from the territory (2) with the code:(2) in which:			
	susceptible necrosis (E	— there are no farms rearing or keeping live fish, their eggs or gametes, of any species considered as susceptible (⁶) to the following diseases: infectious salmon anaemia (ISA), epizootic haematopoietic necrosis (EHN), viral haemorrhagic septicaemia (VHS), and infectious haematopoietic necrosis (IHN), and such species are not present in the natural waters,			
	 there has be dispatch.]. 	peen no disease that has	caused significant impa	ct on the stock during th	e last six months prior to

6.2. They:

- have not, since the time of collection, been in contact with live fish, eggs or gametes of a lower health status than referred to in point 6.1. of this certificate,
- are not intended for destruction or slaughter for the eradication of the following diseases: ISA, VHS, IHN, EHN, spring viraemia of carp (SVC), infectious pancreatic necrosis (IPN), bacterial kidney disease (BKD, Renibacterium salmoninarum), furunculosis (Aeromonas salmonicida), enteric redmouth disease (ERM, Yersinia ruckeri), Gyrodactylus salaris, or due to diseases caused by any other pathogen,
- are not subject to any prohibitions for animal health reasons,
- showed no clinical signs of disease on the day of loading,
- (10)[were subject to a visual check of a randomly selected representative part of the consignment, including each part having a different origin, and no fish species other than those specified in point 5 of this certificate were detected], and
- (11)[have been disinfected in accordance with OIE (8) International Aquatic Animal Health Code, edition 2003, Appendix 5.2.1.].

(12) [7. Specific animal health requirements as regards VHS, IHN, SVC, IPN, BKD and Gyrodactylus salaris

(13) [7.1. I, the undersigned official inspector, hereby certify that the (1) [live fish] (1) [and] (1) [eggs] (1) [and] (1) [gametes], referred to at point 5 of this certificate, originate from a territory (2) that, in addition to the guarantees given in point 6 of this certificate, is approved by the competent authority as having an equivalent health status to those farms and zones within the Community, with approved status as regards (1) [VHS] (1) [and] (1) [IHN], as they:

Either

- (1)[either (1)[originate from a coastal zone in which all farms are under the supervision of the competent authority, and the fish]
- or (1) [originate from a continental zone in which all farms are under the supervision of the competent authority, and the fish]
- or (1) [originate from a designated farm which is under the supervision of the competent authority, and the fish]
- or (1) [originate from a farm which is under the supervision of the competent authority, and where the water is supplied by means of a system which ensures the complete inactivation of (1)[VHS] (1) [and] (1) [IHN], and the fish]
- or (1) [originate from a coastal zone in which there are no farms, and the wild fish:]
- or (1) [originate from a continental zone in which there are no farms, and the wild fish:]
 - have been subject to health inspections, carried out at intervals adapted to the development of (¹) [VHS] (¹) [and] (¹) [IHN] and samples are taken and examined for these pathogens with a negative result by an officially authorised laboratory and the sampling and testing methods are at least equivalent to those laid down in Directives 91/67/EEC, 93/53/EEC and Decision 2001/183/EC as the following surveillance scheme has been used:
 - (14) ['EC Model A' at least four years documented freedom, including a two-year surveillance program] (14) ['EC Model B' at least six years documented freedom, including a two-year surveillance program with reduced sample size] (15) ['EC Special provisions' new farms] (15) ['EC Special provisions' farms which recommence their activities] (1) ['OIE' methods as described in the OIE (8) *Manual of Diagnostic Tests for Aquatic Animals*, fourth edition, 2003, Chapters: I.1.4. (General) and (1) [2.1.5. (VHS)] (1) [and] (1) [2.1.2. (IHN)]],
 - since at least two years have been free of clinical and other signs of (1)[VHS] (1)[and] (1)[IHN],
 - originate from a territory (2) where all necessary measures (16) are taken to prevent the introduction of diseases.]

Or

(¹) [originate from a farm that is not connected with a watercourse, or with coastal or estuarial waters and
does not contain any fish of the species considered as susceptible (⁶) to (¹) [VHS] (¹) [and] (¹) [IHN].]

Or

— (¹) [originate from a farm that is connected with a watercourse, or with coastal or estuarial waters but where the competent authority has recognised that neither the farm, nor the watercourse, or coastal or estuarial waters contain any fish of the species considered as susceptible (6) to (¹) [VHS] (¹) [and] (¹) [IHN].]].

- (17) [7.2. I, the undersigned official inspector, hereby certify that the (1) [live fish] (1) [and] (1) [eggs] (1) [and] (1) [gametes], referred to at point 5 of this certificate, which is considered susceptible (6) to (1) [spring viraemia of carp] (1) [and] (1) [infectious pancreatic necrosis] (1) [and] (1) [bacterial kidney disease], originate from a territory (2)
 - where (¹) [SVC] (¹) [and] (¹) [IPN] (¹) [and] (¹) [BKD] is notifiable to the competent authority, and reports of suspicion of infections must be immediately investigated by the official services,
 - in which all introduction of species susceptible (6) to (1) [SVC] (1) [and] (1) [IPN] (1) [and] (1) [BKD] has come from a zone or farm having the same health status with respect to (1) [SVC] (1) [and] (1) [IPN] (1) [and] (1) [BKD].
 - (18)[in which the fish has not been vaccinated against (1)[SVC] (1)[and] (1)[IPN] (1)[and] (1)[BKD]],
 - where all farms raising species susceptible (⁶) to (¹) [SVC] (¹) [and] (¹) [IPN] (¹) [and] (¹) [BKD] are under the supervision of the competent authority,
 - where all necessary measures (16) are taken to prevent the introduction of diseases,
 - that, in addition to the guarantees given in point 6 of this certificate, is approved by the competent authority as having an equivalent health status to zones within the Community, having additional guarantees with regard to (¹) [SVC] (¹) [and] (¹) [IPN] (¹) [and] (¹) [BKD] as they:
 - either (1) [originate from the following territory (2):, which is considered free from (1) [SVC] (1) [and] (1) [IPN] (1) [and] (1) [BKD] in accordance with Annex I to Decision 2003/858/EC.]
 - or (¹)[originate from the following farm:, which at the time of the year (¹)[SVC] (¹)[and] (¹)[IPN] (¹)[and] (¹)[BKD] is expected to manifest itself, have been submitted for at least two years to inspections by the competent authorities, with sampling at least equivalent to those sampling programmes laid down by Decision 2001/183/EC(¹⁴) or surveillance methods as described in the OIE(8) Manual of diagnostic tests for aquatic animals, Chapter 1.1.4. and the relevant disease chapters, and as laboratory tests have been carried out in accordance with the relevant chapters in the most current edition of the OIE(8) Manual of diagnostic tests for aquatic animals, with all tests giving negative results.¹
 - or (19) [originate from the following continental farm:, where (1) [SVC] (1) [and] (1) [IPN] (1) [and] (1) [BKD] have occurred within in the previous two years, but where the whole fish population has been withdrawn, and all ponds, tanks or other installations and equipment disinfected under the supervision of the competent authority, and where restocking has taken place with fish from a source certified free by the competent authority after sampling at least equivalent to those sampling programmes laid down in Decision 2001/183/EC (12) (13) or surveillance methods as described in the OIE (8) Manual of diagnostic tests for aquatic animals, Chapter 1.1.4. and the relevant disease chapters and as laboratory tests have been carried out in accordance with the relevant chapters in the most current edition of the OIE Manual of diagnostic tests for aquatic animals, with all tests giving negative results.].
- (20) [7.3. I, the undersigned official inspector, hereby certify that the (1) [live fish] (1) [and] (1) [eggs] (1) [and] (1) [gametes] referred to at point 5 of this certificate, which is considered susceptible (6) to *Gyrodactylus salaris*, originate from a territory (2)
 - where G. salaris is notifiable to the competent authority, and reports of suspicion of infections must be immediately investigated by the official services,
 - in which all introduction of species susceptible (6) to G. salaris has come from a zone or farm declared free
 from G. salaris,
 - where all farms raising species susceptible (6) to G. salaris are under the supervision of the competent authority,
 - where all necessary measures (16) are taken to prevent the introduction of diseases,
 - that, in addition to the guarantees given in point 6 of this certificate, is approved by the competent authority as having an equivalent health status to those zones within the Community, having additional guarantees with regard to Gyrodactylus salaris, as they:

either (1) [originate from the following territory (2):, which is considered free from Gyrodactylus salaris in accordance with Annex I to Decision 2003/858/EC.]

- or (1) [originate from the following continental farm:, which at the time of the year Gyrodactylus salaris is expected to manifest itself, has been submitted for at least two years to inspections by the competent authorities, with sample size at least equivalent to those sampling programmes laid down in Decision 2001/183/EC(14) and sampling and laboratory tests have been carried out in accordance with the relevant chapters in the most current edition of the OIE(8) Manual of diagnostic tests for aquatic animals, with all tests giving negative results; and the farm is either situated in a part(21) of a water catchment area declared free(22) from G. salaris and all other water catchment areas draining into the same estuary are declared free(22) from G. salaris, and]
- or (1) [originate from the following coastal farm:, which is situated in an coastal zone with a salinity below 25 parts per thousand, and where all water catchment areas draining into the estuary are declared free $(^{22})(^{23})$ of G. salaris, and]
- or (1) [originate from the following coastal farm:, which is situated in a coastal zone where the seawater has a salinity of more than 25 parts per thousand and no live fish of the susceptible species (6) have been introduced during the previous 14 days, and]
- or (11) [originate from the following farm:, where the eggs have been disinfected according to the OIE International Aquatic Animal Health Code, sixth edition, 2003, Appendix 5.2.1., ensuring the elimination G. salaris.].]

8. Transport requirements

Furthermore, they:

- are placed under conditions that do not alter their health status, and
- have been placed in (¹) [sealed watertight containers or boxes suitable for the purpose, which are new or have been cleaned and disinfected beforehand using an authorised disinfectant and which bear on the exterior a legible label] (¹) [a well boat where the well and its pipe and pump systems were free of fish, cleaned and disinfected using an authorised disinfectant, and inspected before loading, carrying a manifest] with the relevant (²⁴) information referred to in points 1, 2 and 3 of this certificate and with the following statement:

either

o['(¹)Live fish] (¹)[and] (¹)[Eggs] (¹)[and] (¹)[Gametes] intended for farming in European Community zones and farms except those with a Community approved programme or status, and additional guarantees with regard to: viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN), spring viraemia of carp (SVC), infectious pancreatic necrosis (IPN), bacterial kidney disease (BKD) and *Gyrodactylus salaris.*']

or

['Live fish of aquaculture origin intended for (¹) [restocking of put-and take fisheries] (¹) [human consumption] in European Community zones and farms except those with a Community approved programme or status, additional guarantees or protective measures with regard to: viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN), spring viraemia of carp (SVC), infectious pancreatic necrosis (IPN), bacterial kidney disease (BKD) and *Gyrodactylus salaris.*']

or

['(¹) [Live fish] (¹) [and] (¹) [Eggs] (¹) [and] (¹) [Gametes] intended for farming in European Community zones and farms including those with a Community approved programme or status, additional guarantees or protective measures with regard to: (¹) [viral haemorrhagic septicaemia (VHS)] (¹) [and] (¹) [infectious haematopoietic necrosis (IHN)] (¹) [and] (¹) [spring viraemia of carp] (¹) [and] (¹) [infectious pancreatic necrosis] (¹) [and] (¹) [bacterial kidney disease] (¹) [and] (¹) [Gyrodactylus salaris].']

or

['Live fish of aquaculture origin intended for (1) [restocking of put and take fisheries] (1) [human consumption] in European Community zones and farms including those with a Community approved programme or status, additional guarantees or protective measures with regard to: (1) [viral haemorrhagic septicaemia (VHS)] (1) [and] (1) [infectious haematopoietic necrosis (IHN)] (1) [and] (1) [spring viraemia of carp] (1) [and] (1) [infectious pancreatic necrosis] (1) [and] (1) [bacterial kidney disease] (1) [and] (1) [Gyrodactylus salaris]']

or

['Live fish of aquaculture origin intended for further processing in approved import centres before human consumption'].

Done at	,	on
	(Place)	(Date)
Official stamp		(Signature of official inspector) (Name in capital letters, qualifications and title)

Indicative notes

- (1) Retain as appropriate.
- (2) Territory (a whole country, or a zone or a farm) and code of territory as appearing in Annex I to Commission Decision 2003/858/EC.
- (3) Specify as applicable: zone, farm, or in case of live fish for human consumption, establishment. If the zone is specified under point 3.2., then the name of the farm, or in case of live fish for human consumption, establishment, must be specified under point 3.3.
- (4) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft shall be specified.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, shall be indicated under point 4.3.

- (5) Retain where the third country keep species susceptible to EHN, ISA, VHS and/or IHN in fish farms, or if any of such species are present in the natural waters of the country.
- (6) Known susceptible species, see table below.

Disease	Susceptible host species (*)			
ISA	Atlantic salmon (Salmo salar), rainbow trout (Oncorhynchus mykiss), brown trout (Salmo trutta)			
EHN	Redfin perch (<i>Perca fluviatilis</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), Macquarie perch (<i>Macquaria australasica</i>), silver perch (<i>Bidyanus bidyanus</i>), mountain galaxias (<i>Galaxias olidus</i>), sheatfish (<i>Silurus glanis</i>), catfish (<i>Ictalurus melas</i>) and mosquito fish (<i>Gambusa affinis</i>) and other species belonging to the family <i>Poeciliidae</i>			
VHS	Fish belonging to the family Salmonidae, grayling (Thymalius thymalius), white fish (Coregonus spp.), pike (Esox lucius), turbot (Scophthalmus maximus), herring and sprat (Clupea spp.), Pacific salmon (Oncorhynchus spp.), Atlantic cod (Gadus morhua), Pacific cod (G. macrocephalus), haddock (G. aeglefinus) and rockling (Onos mustelus)			
IHN	Fish belonging to the family Salmonidae, pike (Esox lucius)			
svc	Common carp and koi carp (Cyprinus carpio), grass carp (Ctenopharyngodon idellus), silver carp (Hypophthalmichthys molitrix), bighead carp (Aristichthys nobilis), crucian carp (Carassius carassius), goldfish (Carassius auratus), tench (Tinca tinca) and sheatfish (Silurus glanis)			
IPN	Rainbow trout (Oncorhynchus mykiss), brook trout (Salvelinus fontinalis), brown trout (Salmo trutta), Atlantic salmon (Salmo salar), and several Pacific salmon species (Oncorhynchus spp.)			
BKD	Fish belonging to the family Salmonidae			
Gyrodactylus salaris	Atlantic salmon (Salmo salar), rainbow trout (Oncorhynchus mykiss), Arctic char (Salvelinus alpinus), North American brook trout (S. fontinalis), grayling (Thymallus thymallus), North American lake trout (Salvelinus namaycush) and brown trout (Salmo trutta); other species of fish on sites where any of the above species are present shall also be considered as susceptible species			

^(*) And any other species referred to in the most recent edition of the OIE International Aquatic Animal Health Code and/or the OIE Manual of diagnostic tests for aquatic animals as being susceptible for the pathogen/disease in question.

- (7) As applicable
- (8) World Organisation for Animal Health.
- (9) Retain where the third country do not keep species susceptible to EHN, ISA, VHS and/or IHN in fish farms, and in addition any such species are not present in the natural waters of the country.
- (10) Only applicable for live fish; retain as appropriate.
- (11) Applicable to eggs only; retain as appropriate.
- (12) As laid down in Directive 91/67/EEC, specific animal health requirements are needed in the case of exports to farms or zones within the EC with a Community approved programme, status, or additional guarantees with regard to one or more of the diseases referred to in Lists II and III of Annex A to Directive 91/67/EEC.
- (13) Specific requirements needed in the case of exports to farms or zones within the EC with a Community approved programme or status for viral haemorrhagic septicaemia (VHS) and/or infectious haematopoietic necrosis (IHN) respectively.
- (14) 'Model A or B' as laid down in Decision 2001/183/EC, as well as the requirements in Directives 91/67/EEC and 93/53/EEC, retain as appropriate.
- (15) In accordance with Directives 91/67/EEC and 93/53/EEC, and Decision 2001/183/EC; new farms which commence activity with fish, eggs and gametes that have an equivalent health status according to the central competent authority of the exporting country to those farms and zones approved in the EC with regard to VHS and/or IHN respectively, and otherwise meet the requirements in Annex C, I.A, 6(a) to Directive 91/67/EEC; or farms which recommence their activities after officially supervised cleaning and disinfection and 15 days of fallowing, and which introduce only fish, eggs and gametes that have an equivalent health status according to the central competent authority of the exporting country to those farms and zones approved in the EC with regard to VHS and/or IHN respectively and otherwise meet the requirements in Annex C, I.A, 6(b) to Directive 91/67/EEC. Retain as appropriate.
- (16) Not applicable to coastal or continental zones with no farms. High bio-security level must be maintained. Fish from non-approved farms or zones must not be introduced into approved farms and zones. Ponds with susceptible species should be covered or be located at a safe distance from non-approved farms. Uncontrolled public access should be prevented. The site must not be used for angling purposes unless under conditions authorised and supervised by the local competent authority.
- (17) Specific additional requirements needed in the case of exports to Member States or parts of Member States within the EC with Community approved free status or control and eradication programmes (additional guarantees) as regards spring viraemia of carp (SVC), infectious pancreatic necrosis (IPN), and/or bacterial kidney disease (BKD), according to Commission Decision 2004/453/EC.
- (18) Applicable to species susceptible to SVC, IPN and/or BKD only, introduced into areas with additional guarantees for SVC, IPN and/or BKD. Retain as applicable.
- (19) Applicable only to continental farms where epizootiological investigations have shown that the disease has not spread to other farms or into the wild. Retain as applicable.
- (20) Specific additional requirements needed in the case of exports to Member States or parts of Member States within the EC with Community approved free status (additional guarantees) as regards Gyrodactylus salaris according to Decision 2004/453/EC.
- (21) According to Annex B, I.A to Directive 91/67/EEC a part of a water catchment area can only be declared free from a disease if it consists of the upper part of the catchment area from its sources of the waterways to a natural or artificial barrier preventing fish migrating from downstream of that barrier.
- (22) According to the requirements in Chapter 1.B of Annex I to Decision 2004/453/EC.
- (23) When declaring continental zones free of Gyrodactylus salaris, it must be taken into account that the disease may spread by migrating fish between different continental zones if the salinity between them is low or intermediate (below 25 ppt). Hence one individual continental zone can not be declared free if another continental zone draining into the same coastal zone is infected or has unknown status, unless they are separated by seawater with salinity above 25 ppt.
- (24) Country and territory of origin (code) and of destination; name and telephone number of the consignor and consignee. In case of a transport with well boat, the transport route from the place of loading to the place of destination should be given.

ANNEX III

EXPLANATORY NOTES

- (a) The certificates shall be produced by the competent authorities of the exporting country, based on the appropriate model appearing in Annex II, IV or V to this Decision taking into account the destination and use of the fish or products after the arrival in the European Community (EC).
- (b) Considering the status of the place of destination as regards viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN), spring viraemia of carp (SVC), bacterial kidney disease (BKD), infectious pancreatic necrosis (IPN) and *Gyrodactylus salaris* (*G. salaris*) in the EC Member State, the appropriate specific additional requirements shall be incorporated and completed in the certificate.
- (c) The original of each certificate shall consist of a single page, double-sided, or, where more than one page is required, it shall be in such a form that all pages form part of an integrated whole and are indivisible.
 - It shall, on the right hand side of the top of each page, be marked as 'original' and bear a specific code number issued by the competent authority. All pages of the certificate shall be numbered (page number) of (total number of pages).
- (d) The original of the certificate and the labels referred to in the model certificate shall be drawn up in at least one official language of the EC Member State in which the inspection at the border post shall be carried out and of the EC Member State of destination. However, these Member States may allow other languages, if necessary, accompanied by an official translation.
- (e) The certificate issued for live fish, their eggs and gametes must be completed on the day of loading of the consignment for exportation to the EC. The original of the certificate must be completed with an official stamp and signed by an official inspector designated by the competent authority. In doing so, the competent authority of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.
 - The stamp, unless embossed, and the signature shall be in a colour different to that of the printing.
- (f) If for reasons of identification of the items of the consignment, additional pages are attached to the certificate, these pages shall be considered as forming part of the original and be signed and stamped by the certifying official inspector on each page.
- (g) The original of the certificate must accompany the consignment until it reaches the EC border inspection post.
- (h) The certificate issued for live fish, their eggs and gametes shall be valid for 10 days from the date of issue. In the case of transport by ship, the time of validity is prolonged by the time of journey at sea.
- (i) The live fish, their eggs and gametes shall not be transported together with other fish, eggs or gametes that, either are not destined to EC, or are of a lower health status. Furthermore, they must not be transported under any other conditions that alter their health status.
- (j) The possible presence of pathogens in the water is relevant for considering the health status of live fish, eggs and gametes. The certifying officer should therefore consider the following:
 - the 'Place of origin' should be the localisation of the farm where the fish, eggs or gametes was reared reaching their commercial size relevant for the consignment covered by this certificate.

ANNEX VII

Minimum animal health conditions for the approval of 'approved import centres' for processing of fish of aquaculture origin

A. General provisions

- Member States shall only approve establishments as import centres for further processing of imported live fish of aquaculture origin and products thereof provided that the conditions at the import centre are such that risks of contamination of fish in Community waters, with pathogens capable of causing significant impact to fish stock, via discharges or other waste, or by other means, are avoided.
- Establishments approved as 'approved import centre', must not be allowed to move live fish out of the establishment.
- 3. In addition to the appropriate public health provisions laid down under Directive 91/493/EEC for any establishments, as well as health rules laid down by Community legislation concerning animal by-products not intended for human consumption, the minimum animal health conditions as laid down below, shall apply.

B. Management provisions

- Approved import centres must be open to inspection and control by the competent authority at all times.
- 2. Approved import centres must have an efficient disease control, and monitoring system; in application of Council Directive 93/53/EEC, cases of suspected disease and mortality shall be investigated by the competent authority; the necessary analysis and treatment must be carried out in consultation with and under the control of the competent authority, taking into consideration the requirement in Article 3(1)(a) of Directive 91/67/EEC.
- Approved import centres must apply a management system, approved by the competent authority, including hygiene and disposal routines for transports, transport containers, facilities, and equipment. The guidelines laid down for disinfection of fish farms in the OIE International Aquatic Animal Health Code, Sixth Edition, 2003, Appendix 5.2.2, should be followed. The disinfectants used must be approved for the purpose by the competent authority and appropriate equipment must be available for cleaning and disinfection. Discharges of by-products and other waste materials including dead fish and their products must be carried out in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council (1). The management system at the approved import centre shall be such that risks of contamination of fish in Community waters with pathogens capable of causing significant impact to fish stock, in particular as regards pathogens exotic to the Community and the fish pathogens referred to in list I and II, column 1, of Annex A to Directive 91/67/EEC, are avoided.
- 4. Approved import centres must keep an updated record of: observed mortality; and of all the live fish, eggs and gametes entering the centre and products leaving the centre including their source, their suppliers and their destination. The record should be open to scrutiny by the competent authority at all times.
- Approved import centres must be cleaned and disinfected regularly in accordance with the programme described in point 3 above.
- Only authorised persons may enter approved import centres and must wear protective clothing including appropriate footwear.