

COMMISSION DECISION**of 29 April 2004****implementing Council Directive 91/67/EEC as regards measures against certain diseases
in aquaculture animals***(notified under document number C(2004) 1679)***(Text with EEA relevance)**

(2004/453/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 products³, and in particular Article 12(2), the second subparagraph of Article 13(1) and Article 13(2) thereof,

Having regard 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 market⁴, and in particular Article 10 thereof,

Whereas:

- (1) A Member State that considers its territory or part of territory free from one or more of the diseases listed in Annex A, column I, list III to Directive 91/67/EEC, may under Article 13 of that Directive submit the evidence supporting the claim of freedom of diseases to the Commission for the purpose of being granted disease-free status. Denmark, Finland, Ireland, Sweden and the United Kingdom have submitted such claims to the Commission.
- (2) A Member State that draws up a programme to control with a view to eradicating one or more of the diseases listed in Annex A, column I, list III to Directive 91/67/EEC, may under Article 12 of that Directive submit the programme to the Commission for approval. Finland, Ireland, Sweden and the United Kingdom have submitted such programmes to the Commission.
- (3) Council Regulation (EEC) No 706/73 of 12 March 1973 concerning the Community arrangements applicable to the Channel Islands and the Isle of Man for trade in

³ OJ L 46, 19.2.1991, p. 1. Directive as last amended by Regulation 806/2003 (OJ L 122, 16.5.2003 p. 1).

⁴ OJ L 224, 18.8.1990, p. 24. 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).

agricultural products⁵, lays down that veterinary legislation is to apply to those islands under the same conditions as in the United Kingdom for the products imported into those islands or exported from them to the Community.

- (4) It is necessary to establish the requirements to be fulfilled for Member States to be declared disease-free and the criteria the Member States are to apply under the control and eradication programmes. It is also necessary to define the additional guarantees which are required for the introduction of certain fish species into the disease-free zones and the zones concerned by the control and eradication programmes. For those purposes the recommendations of the World Organisation of Animal Health (OIE) should be taken into account.
- (5) Denmark has submitted evidence of freedom from spring viraemia of carp (SVC), and should therefore be considered free from that disease.
- (6) Finland has submitted evidence of freedom from SVC for its entire territory, and of freedom from *Gyrodactylus salaris* and infectious pancreatic necrosis (IPN) for parts of its territory. The territories concerned should therefore be considered free from those diseases. Finland has also submitted a programme for the control and eradication of bacterial kidney disease (BKD) which will apply to the continental parts of its territory. That programme should be approved with a view to eradicating the disease and achieving disease free status.
- (7) Ireland has submitted evidence of freedom from SVC, BKD and *Gyrodactylus salaris* for its entire territory, and should therefore be considered free from those diseases.
- (8) Sweden has submitted evidence of freedom from SVC and IPN for its entire territory, and should therefore be considered free from those diseases. Sweden has also submitted a programme for the control and eradication of BKD which will apply to the continental parts of its territory. That programme should be approved with a view to eradicating the disease and achieving disease free status.
- (9) The United Kingdom has submitted evidence of freedom from *Gyrodactylus salaris* for its entire territory and of freedom from IPN, BKD and SVC for parts of its territory. The territories concerned should therefore be considered free from those diseases. The United Kingdom has also submitted programmes for the control and eradication of SVC and BKD applicable to other parts of its territory. Those programmes should be approved with a view to eradicating the diseases and achieving disease free status.
- (10) The additional guarantees provided for by this Decision should be reconsidered after three years, taking into account the experience gained in relation to control and eradication of the diseases and the development of alternative control measures such as vaccines.
- (11) Additional guarantees as regards SVC have been defined for certain fish species for consignment to Great Britain, Northern Ireland, the Isle of Man and Guernsey by

⁵ OJ L 68, 15.3.1973, p. 1. Regulation as amended by Regulation (EEC) No 1274/86 (OJ L 107, 24.4.1986, p. 1).

Commission Decision 93/44/EC⁶. That Decision should be repealed and replaced by this Decision.

- (12) Commission Decision 2003/513/EC⁷ is a safeguard decision protecting certain regions of the Community against introduction of *Gyrodactylus salaris*. Those measures have been in force since 1996, and are by their very nature additional guarantees and not safeguard measures. Decision 2003/513/EC should therefore also be repealed and replaced by this Decision.
- (13) The guarantees laid down in Decisions 93/44/EC and 2003/513/EC should be updated to take into account the present scientific knowledge and current recommendations of the World Organisation of Animal Health (OIE).
- (14) The measures provided for in this Decision are in accordance with the opinion of the Scientific Committee for the Food Chain and Animal Health.

HAS ADOPTED THIS DECISION:

Article 1

Requirements for territory being considered disease free disease

The requirements to be fulfilled in order for territory to be considered free of one or more of the diseases listed in Column I, List III of Annex A to Directive 91/67/EEC, are laid down in Annex I, Chapter I to this Decision.

Article 2

Territories considered disease-free

The territories listed in Annex I, Chapter II to this Decision are considered to be free from the diseases listed in Column I, List III of Annex A to Directive 91/67/EEC.

Article 3

Criteria for control and eradication programmes

The criteria a Member States shall apply under a control and eradication programme for one or more of the diseases referred to in Column I, List III of Annex A to Directive 91/67/EEC, are laid down in Annex II, Chapter I to this Decision.

Article 4

Approval of control and eradication programmes

The control and eradication programmes for the territories listed in Annex II, Chapter II to this Decision are approved.

⁶ OJ L 16, 25.1.1993, p. 53. Decision amended by Decision 94/865/EC (OJ L 352, 31.12.1994, p. 75).

⁷ OJ L 177, 16.7.2003, p. 22.

Article 5
Additional guarantees

1. Live aquaculture fish, eggs and gametes which are introduced into the territories listed in Annex I, Chapter II or Annex II, Chapter II, shall comply with the guarantees, including those for packaging and labelling and the appropriate specific additional requirements, as laid down in the health certificate, drawn up in conformity with model health certificate in Annex III, taking into account the explanatory notes in Annex IV.
2. The requirements laid down in paragraph 1 shall not apply when eggs are introduced into the territories listed in Annex I, Chapter II or Annex II, Chapter II, for the purpose of human consumption.
3. The additional guarantees should be maintained when the requirements laid down in Annex V are fulfilled.

Article 6
Transport

Live aquaculture fish, eggs and gametes introduced into the territories listed in Annex I Chapter II, or Annex II Chapter II, shall be transported under conditions not altering their health status and not jeopardising the health status at the place of destination.

Article 7
Repeal

Decisions 93/44/EC and 2003/513/EC are repealed.

Article 8
Review

The Commission shall review the additional guarantees laid down by this Decision by 30 April 2007 at the latest. The review shall take account of the experience gained in relation to control and eradication of the diseases and the development of alternative control measures such as vaccines.

Article 9
Addressees

This Decision is addressed to the Member States

Done at Brussels, 29 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

Disease-free status

Chapter I

Requirements for disease-free status

A. Disease-free country

A Member State shall be considered free of a disease if none of the susceptible species are present or if it meets the conditions in point 1) or 2) below.

If a Member State shares a water catchment area with one or more other Member States, it can only be declared a disease free country if all the shared water catchment areas are declared disease-free zones in both Member States.

1. A Member State where there has not been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression may be considered disease-free if
 - 1.1. basic disease security conditions have been in place continuously for at least the previous 10 years. The basic disease security conditions should as a minimum consist of:
 - (a) the disease is compulsorily notifiable to the Competent Authority, including notification of suspicion;
 - (b) an early detection system ensuring the rapid recognition of signs suspicious of a disease, or an emerging disease situation, or unexplained mortality, in aquatic animals in an aquaculture establishment or in the wild, and the rapid communication of the event to the Competent Authority, with the aim to activate diagnostic investigation with minimal delay, is in place within the country enabling the Competent Authority to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and training of veterinarians or fish health specialists in detecting and reporting unusual disease occurrence. Such an early detection system must at least include the following:
 - (i) broad awareness, e.g. among the personnel employed at aquaculture establishments or involved in processing, of the characteristic signs of the listed diseases;
 - (ii) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
 - (iii) ability of the Competent Authority to undertake rapid and effective disease investigation;

- (iv) access by the Competent Authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases;
- 1.2. infection is not known to be established in wild populations;
 - 1.3. conditions applied to trade and imports to prevent the introduction of the disease into the Member State are in place.
2. A Member State where the last known clinical occurrence was within the past 25 years 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 from the disease if:
- 2.1. it meets basic disease security conditions as described in point 1.1; and
 - 2.2. targeted surveillance has been in place for at least the past 2 years in aquaculture establishments holding any of the susceptible species without detection of the disease agent. If there are areas of the country in which surveillance in aquaculture establishments only, does not give sufficient epidemiological data (where the number of aquaculture establishments are limited), but in which there are wild populations of any of the susceptible species, those wild populations must be included in the targeted surveillance. The sampling methods and sample sizes should be at least equivalent to those laid down in Commission Decision 2001/183/EC or in the relevant chapters of the OIE International Aquatic Animal Health Code and OIE Manual of Diagnostic Tests for Aquatic Animals. The diagnostic methods should be at least equivalent to those laid down in the relevant chapters of the OIE Manual for diagnostic tests in aquatic animals.

B. Disease-free zone

A disease-free zone may be established within the territory of one Member State of infected or unknown status for a disease, if none of the susceptible species are present in the zone, or if the zone meets the conditions referred to in point 1 or 2 below.

Such disease-free zones must comprise: one or more entire water-catchment area(s) from the sources of the waterways to the sea, or part of a catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of fish from lower stretches of the waterway. Such zones must be clearly delineated on a map of the territory of the country concerned by the Competent Authority.

If a water-catchment area extends over more than one Member State, it can only be declared a disease free zone if the conditions outlined below apply to all areas of the zone. Both Member States concerned should apply for approval of the zone.

- 1. A zone where there has not been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression may be considered free if:

- 1.1. basic disease security conditions have been in place continuously for at least the previous 10 years. The basic disease security conditions should as a minimum consist of:
 - (a) the disease is compulsorily notifiable to the Competent Authority, including notification of suspicion;
 - (b) an early detection system ensuring the rapid recognition of signs suspicious of a disease, or an emerging disease situation, or unexplained mortality, in aquatic animals in an aquaculture establishment or in the wild, and the rapid communication of the event to the Competent Authority, with the aim to activate diagnostic investigation with minimal delay, is in place within the country enabling the Competent Authority to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and training of veterinarians or fish health specialists in detecting and reporting unusual disease occurrence. Such an early detection system must at least include the following:
 - (i) broad awareness, e.g. among the personnel employed at aquaculture establishments or involved in processing, of the characteristic signs of the listed diseases;
 - (ii) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
 - (iii) ability of the Competent Authority to undertake rapid and effective disease investigation;
 - (iv) access by the Competent Authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases;
 - 1.2. infection is not known to be established in wild populations;
 - 1.3. conditions applied to trade and imports to prevent the introduction of the disease into the zone are in place.
2. A zone where the last known clinical occurrence was within the past 25 years 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 from the disease if:
 - 2.1. it meets basic disease security conditions as described in point 1.1;

- 2.2. targeted surveillance has been in place for at least the past 2 years in aquaculture establishments holding any of the susceptible species without detection of the disease agent. If surveillance in aquaculture establishments only, does not give sufficient epidemiological data (where the number of aquaculture establishments are limited), but in which there are wild populations of any of the susceptible species, those wild populations must be included in the targeted surveillance. The sampling methods and sample sizes should be at least equivalent to those laid down in Commission Decision 2001/183/EC or in the relevant chapters of the OIE International Aquatic Animal Health Code and OIE Manual of Diagnostic Tests for Aquatic Animals. The diagnostic methods should be at least equivalent to those laid down in the relevant chapters of the OIE Manual for diagnostic tests in aquatic animals.

Chapter II
Territories with approved freedom of certain diseases referred to in Column 1, List III
of Annex A to Council Directive 91/67/EEC

Disease	Member State	Territory or parts of territory
Spring viraemia of carp (SVC)	Denmark	Whole territory
	Finland	Whole territory; the water catchment area of River Vuoksi should be considered as buffer zone.
	Ireland	Whole territory
	Sweden	Whole territory
	United Kingdom	The territories of Northern Ireland, The Isle of Man, Jersey, and Guernsey
Bacterial kidney disease (BKD)	Ireland	Whole territory
	United Kingdom	The territories of Northern Ireland, The Isle of Man, and Jersey
Infectious pancreatic necrosis virus (IPN)	Finland	The continental parts of the territory; the water catchment areas of River Vuoksi and River Kemijoki should be considered as buffer zones.
	Sweden	Whole territory
	United Kingdom	The territory of The Isle of Man
Infection with <i>Gyrodactylus salaris</i>	Finland	The water catchment areas of Tenojoki and Näätamönjoki; the water catchment areas of Paatsjoki, Luttojoki, and Uutuanjoki are considered as buffer zones.
	Ireland	The whole territory
	United Kingdom	The territories of Great Britain, Northern Ireland, The Isle of Man, Jersey and Guernsey.

ANNEX II**Control and eradication programmes****Chapter I****Minimum criteria to be applied in a programme aimed at control and eradication of certain diseases referred to in Column 1, List III of Annex A to Council Directive 91/67/EEC**

- A. The minimum criteria to be applied by the Member State under an approved control and eradication programme are**
1. The disease must be compulsorily notifiable to the Competent Authority, including notification of suspicion.
 2. An early detection system ensuring the rapid recognition of signs suspicious of the disease in question, in aquatic animals in an aquaculture establishment or in the wild, and the rapid communication of the event to the Competent Authority, with the aim to activate diagnostic investigation with minimal delay must be in place enabling the Competent Authority to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and training of veterinarians or fish health specialists in detecting and reporting unusual disease occurrence. Such an early detection system must at least include the following:
 - 2.1. broad awareness, e.g. among the personnel employed at aquaculture establishments or involved in processing, of the characteristic signs of the listed diseases;
 - 2.2. veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
 - 2.3. ability of the Competent Authority to undertake rapid and effective disease investigation;
 - 2.4. access by the Competent Authority to laboratories with the facilities for diagnosing and differentiating the disease in question.
 3. Conditions to trade and imports to prevent the introduction of the disease into the Member State must be in place.

4. Targeted surveillance must be in place in aquaculture establishments holding any of the susceptible species. If there are areas of the country in which surveillance in aquaculture establishments only, does not give sufficient epidemiological data (where the number of aquaculture establishments are limited), but in which there are wild populations of any of the susceptible species, those wild populations must be included in the targeted surveillance. The sampling methods and sample sizes should be at least equivalent to those laid down in Commission Decision 2001/183/EC or in the relevant chapters of the OIE International Aquatic Animal Health Code and OIE Manual of Diagnostic Tests for Aquatic Animals. The diagnostic methods should be at least equivalent to those laid down in the relevant chapters of the OIE Manual for diagnostic tests in aquatic animals.
5. The control and eradication programme should continue until the requirements in Annex I have been fulfilled, and the Member State or parts thereof could be considered free of the disease.
6. Before 1 May each year submit a report to the Commission giving information on the number of suspicions, the number of confirmations, the number of farms and sites under restrictions, the number of restrictions lifted and the result of any active surveillance performed the previous calendar year according to the following table

Member State and disease	
Number of suspicions	
Number of confirmations	
Number of farms and sites under restrictions	
The number of restrictions lifted	
How many farms and fish/pools of fish have been sampled	
How many wild fish/pools of fish have been sampled from which water catchment areas	
Result of sampling	

B. In the case of suspicion of a disease the official service in the Member States shall ensure that:

1. Appropriate samples are taken for examinations with a view of establish the presence of the pathogen in question.

2. Pending the result of the examination referred to in point 1, the competent authority shall place the farm under official surveillance and relevant control measures must be implemented and no fish should leave the affected farm, unless authorised by the official service.
3. If the examination referred to in point 1 show the presence of a pathogen or clinical signs, an epizootic investigation must be carried out by the official service in order to determine the possible means of contamination and to investigate whether fish have left the farm, during the relevant period preceding observation of the suspicion.
4. If the epizootic investigation shows that the disease has been introduced into one or more farms or unenclosed waters the provisions of point 1 shall apply in these areas and;
 - 4.1. all of the farms situated in the same water catchment area or coastal area be placed under official surveillance,
 - 4.2. no fish, eggs or gametes leave these farms without the authorisation of the official service.
5. In the case of extensive water catchment areas or coastal areas, the official service may decide to limit this measure to a less extensive area close to the farm suspected of being infected, if it considers that this area affords maximum guarantees for the prevention of the spread of the disease.

C. In case of confirmation of the disease, the Member States shall ensure that

1. The farm or site containing the infected fish is immediately placed under restrictions and no live fish is moved into the premises, and no fish is moved out of the farm unless authorised by the official services in the Member State.
2. The restrictions shall be maintained until eradication has been achieved either through the requirements in 2.1 or 2.2 below:
 - 2.1. Immediate withdrawal of all stock by
 - (a) Slaughter of all live fish under the supervision of the official service or, in the case of fish which have reached commercial size and show no clinical sign of disease, slaughter under the supervision of the official service for marketing or processing for human consumption. In the latter case, the official service shall ensure that the fish are immediately slaughtered and gutted, that these operations are carried out in conditions such as to prevent the spread of pathogens. The Member State may on a case by case basis, taking into consideration the risk of spreading the disease to other farms or to the wild population, allow fish which have not yet reached commercial size to be kept at the farm until market size is reached; and

- (b) Fallowing of the farm or site (and where appropriate disinfection) for an appropriate period following withdrawal, taking into consideration Section 1.7 of the most current edition of the OIE International Aquatic Animal Health Code.
- 2.2. Progressive measures to clear infection by careful management of infected farms or sites by
- (a) Removal and destruction of dead fish and fish displaying clinical signs of disease, harvesting fish not displaying clinical signs of disease, until each epidemiological unit affected by disease within the site is emptied of fish and disinfected; or
- (b) Removal and destruction of dead fish and fish displaying clinical signs of disease, in the case of sites where withdrawal and/or disinfection may not be possible because of the nature of the site (e.g. a river system or extensive lake).
3. To facilitate a swift and rapid eradication of the disease from infected premises, the competent authority of the Member State may allow fish not displaying clinical signs of disease to be transported – under the supervision of the competent authority – to other farms or areas within the Member State in question that is not covered by disease free status or an approved control and eradication programme.
4. Fish removed and disposed of as a consequence of the action in paragraphs 2.1 and 2.2 must be disposed of in accordance with Regulation 1774/2002.
5. Fish used to re-stock sites must originate from certified disease free sources.
6. Member States shall take the necessary measures to prevent the spreading of the disease to other farmed fish or wild stocks.

Chapter II

Territories with approved control and eradication programmes of certain diseases referred to in Column 1, List III of Annex A to Council Directive 91/67/EEC

Disease	Member State	Territory or parts of territory
Spring viraemia of carp	United Kingdom	The territories of Great Britain
Bacterial kidney disease	Finland	The continental parts of the territory.
	Sweden	The continental parts of the territory.
	United Kingdom	The territories of Great Britain

ANNEX III

**MODEL ANIMAL HEALTH CERTIFICATE FOR THE PLACING ON THE MARKET OF ⁽¹⁾[LIVE FISH]
⁽¹⁾[AND] ⁽¹⁾[EGGS] ⁽¹⁾[AND] ⁽¹⁾[GAMETES], BELONGING TO THE SPECIES SUSCEPTIBLE TO ⁽¹⁾[SPRING
VIRAEMIA OF CARP] ⁽¹⁾[AND] ⁽¹⁾[INFECTIOUS PANCREATIC NECROSIS] ⁽¹⁾[AND] ⁽¹⁾[BACTERIAL KIDNEY
DISEASE], ⁽¹⁾[AND] ⁽¹⁾[GYRODACTYLUS SALARIS], FOR FARMING OR BREEDING IN TERRITORIES WITH
COMMUNITY APPROVED FREEDOM OR CONTROL AND ERADICATION PROGRAMMES FOR ONE OR
MORE OF THOSE DISEASES**

Reference Code No

ORIGINAL

<p>1. Place of origin of the consignment</p> <p>1.1. Member state of origin:</p> <p>1.2. Farm of origin, name:</p> <p>1.3. Address of location of farm:</p> <p>⁽²⁾[1.4. Place of harvest:]</p> <p>1.5. Name, address and phone number of the Consignor:</p>	<p>2. Destination of the consignment</p> <p>2.1. Member State:.....</p> <p>2.2. Zone or part of the Member State:</p> <p>2.3. Farm of destination, name:.....</p> <p>2.4. Address of location of farm:</p> <p>⁽³⁾[2.5. Place of destination:.....]</p> <p>2.6. Name, address and phone number of the Consignee:</p>												
<p>3. Means of transport and consignment identification⁽⁴⁾</p> <p>3.1. Means of transport: ⁽¹⁾[Lorry] ⁽¹⁾[Rail-wagon] ⁽¹⁾[Ship] ⁽¹⁾[Aircraft]</p> <p>3.2. ⁽¹⁾[Registration number(s)] ⁽¹⁾[Ship name] ⁽¹⁾[Flight number]:.....</p> <p>3.3. Consignment identification details:</p>													
<p>4. Description of the consignment</p> <p><input type="checkbox"/> Farmed stocks <input type="checkbox"/> Wild stocks <input type="checkbox"/> Gametes <input type="checkbox"/> Fertilised eggs <input type="checkbox"/> Unfertilised eggs <input type="checkbox"/> Larvae/fry</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Species</th> <th rowspan="2">Total weight of consignment ⁽¹⁾[Number of fish]</th> <th rowspan="2">Volume of ⁽¹⁾[eggs] ⁽¹⁾[gametes]</th> <th rowspan="2">Age of live animals</th> </tr> <tr> <th>Scientific name:</th> <th>Common name:</th> </tr> </thead> <tbody> <tr> <td style="height: 100px;"></td> <td></td> <td></td> <td></td> <td> <input type="checkbox"/> >24 months <input type="checkbox"/> 12-24 months <input type="checkbox"/> 0-12 months; <input type="checkbox"/> unknown </td> </tr> </tbody> </table>		Species		Total weight of consignment ⁽¹⁾ [Number of fish]	Volume of ⁽¹⁾ [eggs] ⁽¹⁾ [gametes]	Age of live animals	Scientific name:	Common name:					<input type="checkbox"/> >24 months <input type="checkbox"/> 12-24 months <input type="checkbox"/> 0-12 months; <input type="checkbox"/> unknown
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Scientific name:	Common name:												
				<input type="checkbox"/> >24 months <input type="checkbox"/> 12-24 months <input type="checkbox"/> 0-12 months; <input type="checkbox"/> unknown									
<p>5. Health attestation</p> <p>I, the undersigned, hereby certify that the ⁽¹⁾[fish] ⁽¹⁾[and] ⁽¹⁾[eggs] ⁽¹⁾[and] ⁽¹⁾[gametes] forming the present consignment belonging to the species susceptible⁽⁵⁾ to ⁽¹⁾[Spring viraemia of carp] ⁽¹⁾[and] ⁽¹⁾[Infectious pancreatic necrosis] ⁽¹⁾[and] ⁽¹⁾[Bacterial kidney disease] ⁽¹⁾[and] ⁽¹⁾[<i>Gyrodactylus salaris</i>] referred to in point 4 of this certificate fulfils the following requirements:</p> <p>5.1</p> <p><i>either</i> ⁽¹⁾[they originate from the following territory:....., which is considered free from ⁽¹⁾[SVC] ⁽¹⁾[and] ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD] ⁽¹⁾[and] ⁽¹⁾[<i>G. salaris</i>] in accordance with Annex I to Decision 2004/xxxx/EC⁽⁶⁾, and where all farms raising species susceptible⁽⁵⁾ to ⁽¹⁾[SVC] ⁽¹⁾[and] ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD] ⁽¹⁾[and] ⁽¹⁾[<i>G. salaris</i>] are under the supervision of the competent authority, and]</p> <p><i>OR</i> ⁽¹⁾[they originate from the following farm:.....⁽⁷⁾, which is under the supervision of the competent authority, and 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 authority, with sampling at least equivalent to those sampling programmes laid down in Commission Decision 2001/183/EC⁽⁸⁾ or surveillance methods as described in the OIE 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 test giving negative results, and]</p>													

Reference Code No

ORIGINAL

or ⁽⁹⁾[they originate from the following continental farm:.....⁽⁷⁾, which is under the supervision of the competent authority, and 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 Commission Decision 2001/183/EC⁽⁸⁾ or surveillance methods as described in the OIE Manual of diagnostic tests for aquatic animals, Chapter 1.1.4 and the relevant disease chapters; and as laboratory tests have been carried out accordance with the relevant chapters in the most current edition of the OIE Manual of diagnostic tests for aquatic animals, with all test giving negative results, and]

or ⁽¹⁰⁾[they originate from the following continental farm:.....⁽⁷⁾, which is under the supervision of the competent authority, and which at the time of the year *G. salaris* is expected to manifest itself has been submitted for at least two years to inspections by the competent authority, with sample size at least equivalent to those sampling programmes laid down in Commission Decision 2001/183/EC⁽⁸⁾ and sampling and 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 test giving negative results; and the farm is either situated in a part⁽¹¹⁾ of water catchment area declared free⁽¹²⁾ from *G. salaris*, or situated in a water catchment area declared free⁽¹²⁾ from *G. salaris*, and all other water catchment areas draining into the same estuary are declared free^(12,13) from *G. salaris*, and]

or ⁽¹⁰⁾[they originate from the following coastal farm:.....⁽⁷⁾, which is under the supervision of the competent authority, which is situated in a coastal zone with a salinity below 25 parts per thousand, and where all water catchment areas draining into the estuary are declared free^(12,13) of *G. salaris*, and]

or ⁽¹⁰⁾[they originate from the following coastal farm:.....⁽⁷⁾, which is under the supervision of the competent authority, and 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⁽⁵⁾ have been introduced during the previous 14 days, and]

or ⁽¹⁴⁾[they originate from the following farm:.....⁽⁷⁾, which is under the supervision of the competent authority, and 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 of parasites belonging to the species *G. salaris*, and]

- where ⁽¹⁾[SVC] ⁽¹⁾[and] ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD] ⁽¹⁾[and] ⁽¹⁾[*G. salaris*] is notifiable to the competent authority, and reports of suspicion of infections must be immediately investigated by the official services, and
- in which all introduction of species susceptible⁽⁵⁾ to ⁽¹⁾[SVC] ⁽¹⁾[and] ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD] ⁽¹⁾[and] ⁽¹⁾[*G. salaris*] has come from a zone or farm certified free of ⁽¹⁾[SVC] ⁽¹⁾[and] ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD] ⁽¹⁾[and] ⁽¹⁾[*G. salaris*], and
- ⁽¹⁵⁾[- in which the fish has not been vaccinated against ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD], and]

5.2. fulfil the following requirements:

- (a) they have not, since the time they were ⁽¹⁾[harvested] ⁽¹⁾[caught], been in contact with other live aquatic animals, eggs or gametes of a lower health status ,
- (b) they are not intended for destruction or slaughter for the eradication of diseases listed in Annex A, column 1, of Directive 91/67/EEC,
- (c) they do not originate from a farm subject to any prohibitions for animal health reasons,
- (d) they do not show any clinical signs of disease on the day of loading,
- (e) they have been subject to a visual check of a randomly selected representative part of the consignment, including each part having a different origin, and no species other than those specified in point 4 of this certificate were detected
- (f) they are placed in [water]¹ [on ice]¹ of a quality that does not alter their health status, and
- (g) they have been placed in ⁽¹⁾[sealed watertight clean containers which were 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 beforehand using an authorised disinfectant, carrying a manifest] with the relevant¹⁶ information referred to at point 1 and 2 of this certificate and the following statement:

"⁽¹⁾[Live fish] ⁽¹⁾[and] ⁽¹⁾[Eggs] ⁽¹⁾[and] ⁽¹⁾[Gametes] belonging to the species susceptible to ⁽¹⁾[SVC] ⁽¹⁾[and] ⁽¹⁾[IPN] ⁽¹⁾[and] ⁽¹⁾[BKD] ⁽¹⁾[and] ⁽¹⁾[*Gyrodactylus salaris*], authorised for placing on the market in Community zones with approved status or control and eradication programme, with regard to ⁽¹⁾[Spring viraemia of carp] ⁽¹⁾[and] ⁽¹⁾[Infectious pancreatic necrosis] ⁽¹⁾[and] ⁽¹⁾[Bacterial kidney disease] ⁽¹⁾[and] ⁽¹⁾[*G. salaris*]

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

Indicative notes

- (1) Retain as appropriate.
- (2) If different from place of origin, retain as appropriate.
- (3) If different from farm of destination, retain as appropriate.
- (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 3.3.
- (5) Known susceptible species (see table)

Disease	Susceptible species*
Spring viraemia of carp (SVC)	common carp and koi carp (<i>Cyprinus carpio</i>), grass carp (<i>Ctenopharyngodon idellus</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), bighead carp (<i>Aristichthys nobilis</i>), crucian carp (<i>Carassius carassius</i>), goldfish (<i>C. auratus</i>), roach (<i>Rutilus rutilus</i>), ide (<i>Leuciscus idus</i>), tench (<i>Tinca tinca</i>) and sheatfish (<i>Silurus glanis</i>)
Infectious pancreatic necrosis (IPN)	rainbow trout (<i>Oncorhynchus mykiss</i>), brook trout (<i>Salvelinus fontinalis</i>), brown trout (<i>Salmo trutta</i>), Atlantic salmon (<i>Salmo salar</i>), and several Pacific salmon species (<i>Oncorhynchus spp.</i>)
Bacterial kidney disease (BKD)	fish belonging to the family Salmonidae
Gyrodactylus salaris	Atlantic salmon (<i>Salmo salar</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), Arctic char (<i>Salvelinus alpinus</i>), North American brook trout (<i>S. fontinalis</i>), grayling (<i>Thymallus thymallus</i>), North American lake trout (<i>Salvelinus namaycush</i>) and brown trout (<i>Salmo trutta</i>). 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 as *susceptible* in the most current edition of the OIE International aquatic animal health code and/or the OIE Manual of diagnostic tests for aquatic animals

- (6) This Decision (SANCO/xxxx/2004/EC).
- (7) Name and address of the farm.
- (8) Commission Decision 2001/183/EC laying down EC-Model A – at least four years documented freedom including two year active targeted surveillance, or EC Model B – at least six years documented freedom including two year active targeted surveillance, or surveillance methods as described in the OIE Manual of diagnostic tests for aquatic animals, Chapter 1.1.4 and the relevant disease chapters.
- (9) 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.
- (10) Applicable to areas with additional guarantees for *Gyrodactylus salaris* only. Retain as applicable
- (11) 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.
- (12) The competent authority of the Member State can declare a water catchment area free of *Gyrodactylus salaris* provided compliance with the requirements in Annex I, Chapter 1.B of This Decision (SANCO/2004/xxxx/EC). Any such declaration of freedom shall be communicated to the Commission and other Member States and shall be open to scrutiny on request.
- (13) 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.
- (14) Applicable to areas with additional guarantees for *Gyrodactylus salaris* only and in relation to trade in eggs, retain as applicable.

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| (15) | 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. |
| (16) | Member state and zone (as applicable) and of destination, name and telephone number of the consignor and consignee. |

ANNEX IV*Explanatory notes for the movement document and labelling*

<p>(a) The movement documents shall be produced by the competent authorities of the Member State of origin, based on the model appearing in Annex I to this Decision taking into account the species of the consignment and the status of the place of destination.</p> <p>(b) The original of each movement document 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.</p> <p>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 movement document shall be numbered - <i>(page number)</i> of <i>(total number of pages)</i>.</p> <p>(c) The original of the movement document and the labels referred to in the model movement document shall be drawn up in at least one official language of the Member State of destination. However, Member States may allow other languages, if necessary, accompanied by an official translation.</p> <p>(d) The original of the movement document must be completed, on the day of loading of the consignment, with an official stamp and signed by an official inspector designated by the competent authority. In doing so, the competent authority of the Member State of origin shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.</p> <p>The stamp, unless embossed, and the signature shall be in a colour different to that of the printing.</p>	<p>(e) If for reasons of identification of the items of the consignment, additional pages are attached to the movement document, these pages shall be considered as forming part of the original and be signed and stamped by the certifying official inspector on each page.</p> <p>(f) The original of the movement document must accompany the consignment until it reaches the place of destination.</p> <p>(g) The movement document 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.</p> <p>(h) The aquatic animals, their eggs and gametes, shall not be transported together with other aquatic animals or their eggs and gametes that are of a lower health status. Furthermore, they must not be transported under any other conditions that alter their health status or could jeopardise the health status at the place of destination.</p>
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ANNEX V

Minimum criteria to be applied to maintain additional guarantees for certain diseases referred to in Column 1, List III of Annex A to Council Directive 91/67/EEC, according to Articles 12 and 13 of Council Directive 91/67/EEC

- A. In order to maintain additional guarantees granted, the Member States must as a minimum comply with the following criteria:**
1. The disease must be compulsorily notifiable to the Competent Authority, including notification of suspicion.
 2. All farms having species susceptible to the disease, to which the Member State has been granted free status, must be under the supervision of the competent authority.
 3. An early detection system ensuring the rapid recognition of signs suspicious of the disease in question, in aquatic animals in an aquaculture establishment or in the wild, and the rapid communication of the event to the Competent Authority, with the aim to activate diagnostic investigation with minimal delay must be in place enabling the Competent Authority to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and training of veterinarians or fish health specialists in detecting and reporting unusual disease occurrence. Such an early detection system must at least include the following:
 - 3.1. broad awareness, e.g. among the personnel employed at aquaculture establishments or involved in processing, of the characteristic signs of the listed diseases;
 - 3.2. veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
 - 3.3. ability of the Competent Authority to undertake rapid and effective disease investigation;
 - 3.4. access by the Competent Authority to laboratories with the facilities for diagnosing and differentiating the disease in question.
 4. Conditions to trade and imports as well as management of wild fish stocks of the susceptible species, to prevent the introduction of the disease in question into the Member State or parts thereof covered by this Decision must be in place. Fish originating in coastal zones should not be introduced into continental zones, unless authorised by the competent authority of the Member State of destination.
 5. In Member States where only parts of territory is declared free according to Annex I, Chapter II (not whole territory is declared free), targeted surveillance must be maintained in accordance with the provisions of Annex II, Chapter I.4 in the areas declared free.
 6. Live aquaculture fish, eggs and gametes introduced into the territories listed in Annex I Chapter II, or Annex II Chapter II, shall be transported under

conditions not altering their health status and not jeopardising the health status at the place of destination. The transport shall take place in water considered free from the disease in question as it is taken from the water source of the farm or site of origin, and that water exchange during transport is done only at places authorised by the competent authority of the Member State of destination, where appropriate in collaboration with the competent authority of the Member State of origin.

7. Vaccination against the disease in question shall not take place.
8. Before 1 May each year submit a report to the Commission giving information on the number of suspicions, the number confirmations, the number of farms and sites under restrictions, the number of restrictions lifted and the result of any active surveillance performed the previous calendar year according to the following table.

Member State and disease	
Number of suspicions	
Number of suspicions	
Number of farms and sites under restrictions	
The number of restrictions lifted	
How many farms and fish/pools of fish have been sampled	
How many wild fish/pools of fish have been sampled from which water catchment areas	
Result of sampling	

B. In the case of suspicion of a disease the official service in the Member States shall ensure that:

1. Appropriate samples are taken for examinations with a view of establish the presence of the pathogen in question.
2. Pending the result of the examination referred to in point 1, the competent authority shall place the farm under official surveillance and relevant control measures must be implemented and no fish should leave the affected farm, unless authorised by the official service.
3. If the examination referred to in point 1 show the presence of a pathogen or clinical signs, an epizootic investigation must be carried out by the official service in order to determine the possible means of contamination and to investigate whether fish have left the farm, during the relevant period preceding observation of the suspicion.
4. If the epizootic investigation shows that the disease has been introduced into one or more farms or unenclosed waters the provisions of point 1 shall apply in these areas and;
 - 4.1. all of the farms situated in the same water catchment area or coastal area be placed under official surveillance,
 - 4.2. no fish, eggs or gametes leave these farms without the authorisation of the official service.
5. In the case of extensive water catchment areas or coastal areas, the official service may decide to limit this measure to a less extensive area close to the farm suspected of being infected, if it considers that this area affords maximum guarantees for the prevention of the spread of the disease.

C. In case of confirmation of the disease, the Member States shall ensure that

1. The farm or site containing the infected fish is immediately placed under restrictions and no live fish is moved into the premises, and no fish is moved out of the farm unless authorised by the official services in the Member State.
2. The restrictions shall be maintained until eradication has been achieved either through the requirements in 2.1 or 2.2 below:
 - 2.1. Immediate withdrawal of all stock from a farm by
 - (a) Slaughter of all live fish under the supervision of the official service or, in the case of fish which have reached commercial size and show no clinical sign of disease, slaughter under the supervision of the official service for marketing or processing for human consumption. In the latter case, the official service shall ensure that the fish are immediately slaughtered and gutted, that these operations are carried out in conditions such as to prevent the spread of pathogens. The Member State may on a case by case basis, taking into consideration the risk of spreading the disease to other farms or to the wild population, allow fish which have not yet reached commercial size to be kept at the farm until market size is reached; and
 - (b) Fallowing, and where appropriate disinfection, of the farm or site for an appropriate period following withdrawal, taking into consideration Section 1.7 of the most current edition of the OIE International Aquatic Animal Health Code.
 - 2.2. Progressive measures to clear infection by careful management of infected farms or waters by
 - (a) Removal and destruction of dead fish and fish displaying clinical signs of disease, harvesting fish not displaying clinical signs of disease, until each epidemiological unit affected by disease within the site is emptied of fish and disinfected; or
 - (b) Removal and destruction of dead fish and fish displaying clinical signs of disease, in the case of sites where withdrawal and/or disinfection may not be possible because of the nature of the site (e.g. a river system or extensive lake).
3. To facilitate a swift and rapid eradication of the disease from infected premises, the competent authority of the Member State may allow fish not displaying clinical signs of disease to be transported – under the supervision of the competent authority – to other farms or areas within the Member State in question that is not covered by disease free status or an approved control and eradication programme.

4. Fish removed and disposed of as a consequence of the action in paragraphs 2.1 and 2.2 must be disposed of in accordance with Regulation 1774/2002.
5. Fish used to re-stock sites must originate from certified disease free sources.
6. Member States shall take the necessary measures to prevent the spreading of the disease to other farmed fish or wild stocks.
7. When the Member State has eradicated the disease from a continental farm according to Point C 2.1 of this Annex, and the epizootic investigations required in Point B 3 of this Annex concludes that the disease has not spread to other farms or into the wild, disease free status is reinstated immediately. Otherwise, the disease free status could only be reinstated after compliance with Annex I.