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**Guidelines for the interpretation of Decisions 2003/804/EC
(molluscs) and 2003/858/EC (fish) on harmonised certificates
for the import of aquaculture animals from third countries**

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This document has no legally binding force.

Guidelines for the interpretation of harmonised certificates for the import of aquaculture animals from third countries.

1. Purpose

The purpose of these guidelines is to achieve a common understanding in the Member States and in third countries on the functioning of the harmonised certificates applicable under Commission Decisions 2003/804/EC (molluscs) and 2003/858/EC (fish).

2. Background

- 2.1. Since the date of application of Council Directive 91/67/EEC, the animal health certificates which accompanied aquaculture animals imported from third countries were not harmonised. However, in late 2003, new Decisions harmonising the animal health certificates were laid down. These reflect the underlying requirements set out in the Directive.
- 2.2. Each Member State had laid down its own requirements and drawn up its own certificate for such consignments. Over a period of several years the issue of harmonised certificates was discussed between the Commission Services and the Member States. In April 2003, the Commission Services received a favourable opinion (through a technical vote) enabling the European Communities to submit a SPS notification to the WTO/SPS in May 2003. All WTO Members were then notified about the draft for harmonised certificates. By the end of the notification period, the Community had received comments from Australia, Canada, Chile, and China. In addition, New Zealand requested consultations under the equivalence agreement, and USA submitted comments after the expiry of the notification period. Some of the comments received were taken into account and a revised proposal was presented again to the SCFCAH in October 2003. Finally Commission Decisions 2003/804/EC (molluscs) and 2003/858/EC (fish) were adopted in December 2003. The date of application was 1 May 2004.
- 2.3. This revision of the Guidelines takes into account amendments approved by the Standing Committee of the Food Chain and Animal Health between December 2003 and 1 October 2004.

3. Limitations

- 3.1. Council Directive 91/67/EEC applies to aquaculture animals. Article 2.1 of Directive 91/67/EEC defines aquaculture animals as: *“live fish, molluscs or crustaceans coming from a farm, including those from the wild intended for a farm”*. Therefore, none of the Decisions does therefore apply to live animals or products, which are not originating from a farm unless they are intended for a farm (see definitions in Art 2.1). Hence, fish caught or harvested by the fishing fleet and products thereof is not covered by Decision 2003/858/EC, except live fish caught for the purpose of further farming (use as broodstock). However due to disease control rules for molluscs (see point 4.1 below), all mollusc are considered aquaculture animals regardless of their origin.

- 3.2. Decision 2003/804/EC applies to molluscs. It has been drawn up to implement the measures foreseen in Council Directives 91/67/EEC and 95/70/EEC and any implementing Decisions adopted by the Commission, as regards the import of bivalve molluscs (class Bivalva) and gastropods (class Gastropoda). Although taxonomically octopus (class Cephalopoda) is considered as being a mollusc, Decision 2003/804/EC is not applicable for laying down the animal health conditions for import of cephalopods. In these cases, the Member States will have to draw up a certificate, preferable according to the model in Annex II of Decision 2003/804/EC, but pursuant to the provisions of Article 20.3 of Directive 91/67/EEC.
- 3.3. These Decisions do not apply to imports of ornamental molluscs, and to imports of tropical ornamental fish which are kept permanently in aquariums (see Articles 1.2 in Decisions 2003/804/EC and 2003/858/EC respectively). However, Council Directive 91/67/EEC applies to such commodities, but the import certificates that should accompany these commodities are not yet harmonised. It is therefore still the responsibility of the Member States to draw up the necessary certificates with the necessary requirements, to fulfil the requirements of Chapter III of Directive 91/67/EEC (see Article 20.3 of Directive 91/67/EEC). There exists no precise definition of “tropical ornamental fish”. Normally it would mean ornamental fish having their natural habitat in the warm waters of the tropics (i.e. the area between 23.5 degrees south (tropic of Capricorn) and 23.5 degrees north (tropic of Cancer)). Others define “tropical ornamental fish” as warm-water ornamental fish not able to survive in cold waters (below 5-8°C). Taking into variety of the Community waters into account, “tropical ornamental fish” should be understood as ornamental fish having their natural habitat in the warm waters of the tropics and not being able to survive in Community waters. Koi carps are not considered tropical ornamental fish. Tropical ornamental fish are only exempted from Decision 2003/858/EC when they are imported for aquarium purposes, or for the purpose of being held in private garden ponds which has no direct contact with natural Community waters. Ornamental molluscs are exempted when they are imported for aquarium purposes, or for the purpose of being held in private garden ponds which has no direct contact with natural Community waters.
- 3.4. None of the Decisions applies to import of crustaceans. It is therefore still the responsibility of the Member States to draw up the necessary certificates and with the necessary requirements, to fulfil the requirements of Chapter III of Directive 91/67/EEC (see Article 20.3 of Directive 91/67/EEC) for import of crustaceans originating from aquaculture until harmonised certification is laid down. The minimum requirements for farmed crustaceans, is compliance with Article 3 of Directive 91/67/EEC. For farmed crustaceans for human consumption in EU, the requirements should be similar to those in Annex V of Decision 2003/858/EC.

4. Import of molluscs

4.1. Scope

Council Directive 91/67/EEC applies to aquaculture animals. In Chapter III of that Directive (import rules) there is a specific requirement that the Community shall take into account, both the disease status and disease control rules in third countries. A general view is that the Community can request guarantees similar to that applicable for placing on the market in the Community and disease control in the Community. In Council Directive 95/70/EC on minimum measures for the control of certain mollusc diseases, there is a general requirement of monitoring and sampling (art 5), in both mollusc farms, and in harvested natural beds (wild molluscs). As a consequence, all molluscs, including those harvested from the wild, are covered by the Community legislation on placing on the market and disease control.

The same applies to third country import, as all molluscs imported (both those farmed and those harvested from the wild) are considered to be covered by Decision 2003/804/EC, unless they are ornamental molluscs (see point 3.1. “limitations”).

4.2. Non-viable mollusc and mollusc products (Article 5 of Decision 2003/804/EC)

Non-viable molluscs are live molluscs that will not be able to survive if they are reintroduced into the natural habitat. Examples of such molluscs are molluscs where half the shell is taken off, or molluscs completely taken out of their shells. For the purpose of simplicity, as the same risk management applies, mollusc products are included in that term. Non-viable molluscs include therefore, any “half shell” or “shucked mollusc” and any mollusc products (dead molluscs, frozen, cooked, canned, in brine etc). The import of non-viable mollusc poses a relatively low risk to animal health in the community. There are therefore no specific animal health requirements for such commodities. The general requirement of Directive 91/67/EEC, Art 3.1 that aquaculture animals should be free of clinical signs of disease is considered to be covered if the molluscs comply with the requirements in Council Directive 91/493/EEC.

Non-viable molluscs (including processed molluscs) can enter the Community without specific animal health certification. Public health certification required under Directive 91/493/EEC must nevertheless accompany the consignment.

4.3. Live molluscs for human consumption (Article 4 of Decision 2003/804/EC)

Live molluscs can be imported into the Community either *in* full compliance with the animal health guarantees or *without* full compliance.

4.3.1. *In full compliance with animal health guarantees*

Live molluscs imported for human consumption in bulk will in many cases not be shipped directly to the consumer, supermarket or retail salesman. It is

common that after the journey from the third country to the Member State of destination, such molluscs are temporarily re-laid in water at the place of destination for the purpose of “resuscitation” (to drink and to be able to recover after transport). From an animal health risk point of view, this activity poses the same risk as if the molluscs were introduced into Community waters for farming or further growth. In such cases, live molluscs can only be imported into the Community for the purpose of human consumption in full compliance with the animal health guarantees in Annex II of Decision 2003/804/EC (see Article 4.1 a).

4.3.2. Without full compliance with all animal health guarantees

Live molluscs can be imported into the Community for the purpose of human consumption also without full compliance with the animal health guarantees in Annex II of Decision 2003/804/EC.

The general requirement of Directive 91/67/EEC, Art 3.1 that aquaculture animals should be free of clinical signs of disease, is considered to be covered if the molluscs comply with the requirements in Council Directives 91/492/EEC and 91/493/EEC

4.3.2.1. In consumer ready packages

These molluscs may be packed in consumer ready packages, normally in “baskets” (oysters) or under controlled atmosphere (mussels), with a size of 1-3 kg. The molluscs may also be destined for restaurant or catering purposes. In such case, the packages may be larger than those intended for direct consumer size, or the molluscs can arrive in boxes or nets weighing approximately 5-20 kg. As long as these molluscs are not re-immersed in Community water, they pose a relatively low risk to animal health in the community.

There are therefore no specific animal health requirements for such commodities, provided they are clearly labelled “Live molluscs for immediate human consumption. Not to be relayed in Community waters” and are imported in packages of a size suitable for retail sale to restaurants or directly to the consumer. (See Article 4.2. a of Decision 2003/804/EC)

4.3.2.2. In bulk through approved import centres

However, live molluscs in bulk can also be imported into the Community for the purpose of human consumption without having to comply with the animal health guarantees in Annex II of Decision 2003/804/EC.

The consignment can be sent directly to an approved import centre where the molluscs are further processed.

Live molluscs can leave approved import centres only if they are packaged and labelled as described in 4.3.2.1. (see Article 4.2. b) of Decision 2003/804/EC). Otherwise, they must be processed and leave the premises as “non-viable” molluscs (see Article 4.1. b)

4.4. Live molluscs for further growth, fattening or relaying in Community waters

Community legislation (Directives 91/67/EEC and 95/70/EC) lays down the requirements that have been incorporated and implemented via Decision 2003/804/EC. It is a general principle, in Community law, and in the OIE Guidelines, that molluscs introduced into an area free of a certain disease should be accompanied by a certificate certifying the molluscs come from an area with at least the same health status.

4.4.1. Freedom of exotic diseases

The diseases covered by Community legislation are the same as listed by the OIE. The Community considers itself free from those diseases referred to in Annex D to Directive 95/70/EC. Some exemptions exist however (like *Perkinus atlanticus/olseni* in Italy, Spain and France), but strict movement restrictions apply to these areas (see Art 5.4 of Directive 95/70/EC). Thus under the SPS agreement, the Community can request that molluscs introduced into the Community come from areas free of these diseases. Therefore, in order for a third country to export live molluscs to the Community, the third country (or regions in the third countries) must certify that they are free of those diseases. In international trade, this is normally done by complying with the OIE Guidelines for freedom.

It is therefore a requirement that the third countries, or parts of the third countries authorised for export to any parts of the Community are free of the diseases referred to in Annex D to Directive 95/70/EC.

4.4.2. Freedom of “non-exotic” diseases

The same principle of freedom applies to the diseases referred to in list II of Annex A to Directive 91/67/EEC (see Art 8 of that Directive). In order to be introduced into an area in the Community that is approved as free of *Bonamia ostrea* or *Marteilia refringens*, they must originate from an area with the same health status. The areas in the Community free of those diseases are listed in Commission Decision 2002/300/EC (for the time being, parts of UK and Ireland). In addition, France has a programme with a view to achieving approved freedom (Commission Decision 94/722/EC), and the same principle also applies therefore to import into France.

It is therefore a requirement that the third countries, or parts of the third countries authorised for export to those parts of the Community referred to in Decision 2002/300/EC and 94/722/EC are free of the mollusc diseases referred to in list II of Annex A to Directive 91/67/EC (see also below)

4.4.3. Special provisions/derogations

Decision 2003/804/EC provides for three possible options, where the Community applies the principle of risk management with respect to consignments that may be allowed to enter the Community, where the consignment do not comply with all the Community animal health requirements. These are outlined below in 4.3.3.1 and 4.3.3.2

4.4.3.1. Non-carrier species

The rules and principle described in points 4.4.1 and 4.4.2 above applies to species susceptible to the diseases in question. When defining which species are susceptible, the Community considers any species referred to in the OIE Code and/or manual as susceptible species.

A problem which is special for trade in aquatic animals is that many species not considered as susceptible can transmit a disease by passive transmission (vector) if transferred from an area not declared free to an area declared free. This risk is accepted world wide (and included in the OIE Guidelines), due to the nature of the shipment (live aquatic animals are transported in water that might be infected) and the biology of the aquatic animals as such (pathogen may passively be carried in/on the mucus of the animals). This problem is dealt with in Community legislation through Article 14 of Directive 91/67/EEC. Here it is stated that introduction of species other than those considered susceptible to a certain disease should follow the same rules as the susceptible species, unless it is proven that they cannot transmit the disease by passive transmission. The principle is “guilty until proven innocent”. This principle is applied in Commission Decision 2003/390/EC. In Annex III of that Decision, there is a list of species considered “innocent”.

Table 1 List of non-carrier (“innocent”) species (see Decision 2003/390/EC)

Mollusc disease (pathogen)	Mollusc species
Bonamiosis (<i>Bonamia ostreae</i>)	Pacific oyster <i>Crassostrea gigas</i> Mussels <i>Mytilus edulis</i> and <i>M. galloprovincialis</i> European native clam <i>Ruditapes decussatus</i> , Manila clam <i>Ruditapes philippinarum</i>
Marteiliosis (<i>Marteilia refringens</i>)	Pacific oyster <i>Crassostrea gigas</i>

4.4.3.2. Designated farms

Live molluscs may be imported into the Community if they do not originate from a territory declared free (according to the OIE) if

- they come from a coastal farm or an inland farm to which the water is supplied by means of an artificial water system which ensures the complete inactivation of the pathogens referred to in Annex D to Directive 95/70/EC, or
- they come from farm that is not connected with coastal or estuarial waters, and does not contain any molluscs, eggs or gametes thereof, of the species referred to as susceptible to the diseases referred to in Annex D to Directive 95/70/EC.

If the molluscs originate from such farms, the risk connected with the introduction into the Community is considered low.

However, the farms must be registered by the competent authorities in the third country, have record keeping in place, and be covered by the notification obligations similar to those existing in the Community.


4.5. Trade patterns

As a consequence of the above described rules and principles, all consignments of mollusc do not necessarily satisfy the conditions for introduction into the whole EU. Certain consignments can not enter certain parts of the Community. This “trade pattern” is decided by the animal health status at the place of origin and on the place of destination. Tables 2 and 3 give a brief overview of this pattern.

Table 2 Import for further growth, fattening or relaying Article 3 of Decision 2003/804/EC.

Disease status third country	Destination in EU	Remarks
<p>Third country territory¹ is free² of all of the following diseases</p> <ul style="list-style-type: none"> - infection with <i>Bonamia exitiosa</i>; - infection with <i>Mikrocytos roughleyi</i>; - infection with <i>Marteilia sydneyi</i>; - infection with <i>Mikrocytos mackini</i>; - infection with <i>Perkinsus marinus</i>; - infection with <i>P. olseni/atlanticus</i>; - infection with <i>Haplosporidium nelsoni</i>; infection with <i>H. costale</i>; - infection with <i>Candidatus Xenohalictis californiensis</i>; - infection with <i>Bonamia ostreae</i>; - infection with <i>Marteilia refringens</i>. 	<p>Can export for further growth fattening or relaying into the whole EU, including those parts of UK, Ireland and France free of the disease in question or covered by a programme Decision 2002/300/EC Decision 1994/722/EC</p>	<p>Applies to all species of molluscs (bivalva and gastropoda).</p> <p>Consignment accompanied by certificate in Annex II of Decision 2003/804/EC.</p>
<p>Third country territory¹ is free² of all of the following diseases</p> <ul style="list-style-type: none"> - infection with <i>Bonamia exitiosa</i>; - infection with <i>Mikrocytos roughleyi</i>; - infection with <i>Marteilia sydneyi</i>; - infection with <i>Mikrocytos mackini</i>; - infection with <i>Perkinsus marinus</i>; - infection with <i>P. olseni/atlanticus</i>; - infection with <i>Haplosporidium nelsoni</i>; infection with <i>H. costale</i>; - infection with <i>Candidatus Xenohalictis californiensis</i>; <p>but NOT</p> <ul style="list-style-type: none"> - infection with <i>Bonamia ostreae</i>; - infection with <i>Marteilia refringens</i> 	<p>Can export to all EU Member States for <u>further growth fattening or relaying, except</u></p> <ul style="list-style-type: none"> - parts of UK and Ireland, - France 	<p>Applies to all species of molluscs (bivalva and gastropoda). However, if consignment is non-carrier species (see table 1), introduction for further growth fattening or relaying into EU approved zones is allowed also from territories¹ without similar free status.</p> <p>Consignment accompanied by certificate in Annex II of Decision 2003/804/EC.</p>
<p>Third country territory¹ is <u>NOT free²</u> of one or more of</p> <ul style="list-style-type: none"> - bonamiosis (<i>Bonamia exitiosa</i> and <i>Mikrocytos roughleyi</i>); - marteiliosis (<i>Marteilia sydneyi</i>); - mikrocytosis (<i>Mikrocytos mackini</i>); - perkinsosis (<i>Perkinsus marinus</i> and <i>P. olseni/atlanticus</i>); - haplosporidiosis (<i>Haplosporidium nelsoni</i> and <i>H. costale</i>) - withering syndrome (<i>Candidatus Xenohalictis californiensis</i>) 	<p><u>CANNOT</u> export to <u>ANY</u> EU Member States for <u>further growth fattening or relaying</u></p>	<p>Applies to all species of molluscs (bivalva and gastropoda).</p>
<p>¹territory may be a whole country, a coastal zone, a farming area, or a harvested natural bed</p> <p>²demonstration of freedom according to the OIE Code and Manual</p>		

Table 3 Import for human consumption Articles 4 and 5 of Decision 2003/804/EC.

Disease status third country	Destination in EU	Remarks
Live molluscs exported for the purpose of further processing, from a territory ¹ <u>that complies</u> with one of the situations described in Table 2	Establishment as in Community territories described in Table 2	Complies with the animal health guarantees for further growth fattening or relaying according to Article 4.1 a
Live molluscs exported for the purpose of further processing, from a territory ¹ <u>that does not complies</u> with one of the situations described in Table 2 	Can not enter Community waters. Must be sent directly to approved import centre in any EU Member State where they	Where they are packed into consumer ready packages for further distribution on the Community market, and labelled according to Article 4.2.a
	Either Or	No animal health certificate required. Where they are processed and distribution on the Community market as “non-viable molluscs” No animal health certificate required.
Live molluscs exported for the purpose immediate human consumption, from a territory ¹ <u>that does not complies</u> with one of the situations described in Table 2	Can not enter Community waters. Can be sent to any EU Member State for immediate human consumption	Provided they are packed in consumer ready packages and labelled according to Article 4.2.a No animal health certificate required.
Non-viable molluscs exported for the purpose further processing or immediate human consumption	Sent to any EU Member State	No animal health certificate required.
¹ territory may be a whole country, a coastal zone, a farming area, or a harvested natural bed ² demonstration of freedom according to the OIE Code and Manual		

4.6. Requirements in the certificate

The requirements for animal health certification in Annex II of Decision 2003/804/EC are based on the corresponding requirements that are applicable to Member States with respect to placing on the market (Directive 91/67/EEC) and disease control (Directive 95/70/EC).

Points 1 through 6 of the certificate are mainly the description of the consignment.

Points 7 and 8 contain the animal health requirements. The corresponding requirements in Community legislation and/or in international guidelines or agreements are given in table 4.

Table 4 Relationship between animal health requirements and certificate

Point in the Annex II	Requirement	Legislation
7.1 Territory requirements Alternative 1 A	The molluscs originate from a territory where all farms rearing live molluscs, their eggs or gametes are officially registered by the competent authority	Directive 95/70 Art 3.1
B	The molluscs originates from a territory where all farms rearing live molluscs, their eggs or gametes keep an updated record open to scrutiny by the official service at all time of: observed abnormal mortality; and of all the live molluscs, eggs and gametes entering the farm and leaving the farm for introduction into other farms or waters and all information relating to their delivery and dispatch, their number or weight, their size, their origin, their suppliers and their destination	Directive 95/70 Art 3.2
C	The molluscs originates from a territory which during the last two years have been considered free from bonamiosis (<i>Bonamia exitiosa</i> and <i>Mikrocytos roughleyi</i>); marteiliosis (<i>Marteilia sydneyi</i>); mikrocytosis (<i>Mikrocytos mackini</i>); perkinsosis (<i>Perkinsus marinus</i> and <i>P. olseni/atlanticus</i>); haplosporidiosis (<i>Haplosporidium nelsoni</i> and <i>H. costale</i>) and Withering syndrome (<i>Candidatus Xenohaliotis californiensis</i>)	Diseases are referred to in Annex D to Directive 95/70. Movement restrictions apply (see art 5.4 of Directive 95/70) in case of positive findings. Principle is in accordance with OIE Guidelines and SPS agreement.
D	The molluscs originate from a territory which is subject to a risk based health monitoring and sampling programme - put in place, or officially recognised, by the competent authority - carried out in order to detect abnormal mortality and keep track of the health situation of the susceptible stocks, in particular as regards bonamiosis (<i>Bonamia ostreae</i> , <i>B. exitiosa</i> and <i>Mikrocytos roughleyi</i>); marteiliosis (<i>Marteilia refringens</i> and <i>Marteilia sydneyi</i>); mikrocytosis (<i>Mikrocytos mackini</i>); perkinsosis (<i>Perkinsus marinus</i> and <i>P. olseni/atlanticus</i>); haplosporidiosis (<i>Haplosporidium nelsoni</i> and <i>H. costale</i>) and Withering syndrome (<i>Candidatus Xenohaliotis californiensis</i>)	Directive 95/70 Art 4.1
E	The molluscs originates from a territory where all farms rearing live molluscs, their eggs or gametes have to notify as soon as possible to the competent authority any abnormal mortality ⁽⁵⁾ and suspicion of the diseases above,	Directive 95/70 Art 5.5
F	The molluscs originates from a territory subject to appropriate disease control measures as necessary and at least equivalent to those required in Council Directives 91/67/EEC and 95/70/EC, and as regards sampling and testing for monitoring and in case of suspicion of disease, including abnormal mortality Decision 2002/878/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 Manual of Diagnostic Tests for Aquatic Animals, Fourth edition, 2003,	Follows from the SPS agreement that the importing country can request from the exporting country to have a level of protection similar to the importing country
G	The molluscs originates from a territory where all farms rearing live molluscs, their eggs or gametes have had no unexplained abnormal mortality ⁽⁵⁾ or abnormal mortality ⁽⁵⁾ caused by a pathogen during the last two years prior to shipment,	follows from f) and Arts 4 and 5 of Directive 95/70
H	The molluscs originates from a territory where all farms rearing live molluscs, their eggs or gametes have, during the last two years prior to shipment introduced live molluscs, eggs or gametes with a lower health status,	Directive 91/67 Arts 8, 9.2 and 10
I	The molluscs originates from a territory where there are, on the day of loading, no abnormal mortality and no suspicion of the presence of any of the disease listed in point 7.1(d) of the certificate, and	Directive 91/67 Art 3.1
Point 7.1 Alternative 2 A	The molluscs originate from and are harvested in a designated farm, or a farm that is not connected with coastal or estuarial waters, and does not contain any molluscs, eggs or gametes thereof, of the species referred to as susceptible to the following diseases: bonamiosis (<i>Bonamia exitiosa</i> and <i>Mikrocytos roughleyi</i>); marteiliosis (<i>Marteilia sydneyi</i>); mikrocytosis (<i>Mikrocytos mackini</i>); perkinsosis (<i>Perkinsus marinus</i> and <i>P. olseni/atlanticus</i>); haplosporidiosis (<i>Haplosporidium nelsoni</i> and <i>H. costale</i>) and Withering syndrome (<i>Candidatus Xenohaliotis californiensis</i>),	Elaborated from Directive 91/67/EEC Art 8.1.b taking into account the principle of "approved farm in non-approved zone". However, here the concept is further developed, compared to Directive 91/67/EEC
B	The farm is officially registered by the competent authority	Directive 95/70 Art 3.1
C	The farm keeps an updated record open to scrutiny by the official service at all time of: observed abnormal mortality; and of all the live molluscs, eggs	Directive 95/70 Art 3.2

	and gametes entering the farm and leaving the farm for introduction into other farms or waters and all information relating to their delivery and dispatch, their number or weight, their size, their origin, their suppliers and their destination	
D	The farm has to notify as soon as possible to the competent authority any abnormal mortality and suspicion of the diseases above,	Directive 95/70 Art 5.5
Point 7.2 Requirements related to the fish a	The molluscs have not, since the time of harvest, been in contact with other live molluscs, eggs or gametes of a lower health status,	Directive 91/67 Arts 3.1.c and 8.1 b
B	The molluscs are not intended for destruction or slaughter for the eradication of any of the diseases bonamiosis (<i>Bonamia ostreae</i> , <i>B. exitiosa</i> and <i>Mikrocytos roughleyi</i>); marteiliosis (<i>Marteilia refringens</i> and <i>Marteilia sydneyi</i>); mikrocytosis (<i>Mikrocytos mackini</i>); perkinsosis (<i>Perkinsus marinus</i> and <i>P. olseni/atlanticus</i>); haplosporidiosis (<i>Haplosporidium nelsoni</i> and <i>H. costale</i>) and Withering syndrome (<i>Candidatus Xenohalotis californiensis</i>), or due to abnormal mortality caused by any other pathogen,	Directive 91/67 art 3.1.b
C	The molluscs are not subject to any prohibitions for animal health reasons,	Directive 91/67 art 3.1.c
D	The molluscs were examined on the day of loading and showed no clinical signs of disease, including abnormal mortality,	Directive 91/67 art 3.1.a
E	The molluscs were subject to an individual visual check of at least 1,000 molluscs randomly selected from each part of the consignment with a different origin, and no mollusc species other than those specified in point 6 of the certificate were detected	Directive 91/67 Arts 5, 6 and 8
Point 8 Bonamia/Marteilia guarantees	The molluscs originate from a territory that, in addition to the guarantees given in point 7 of this certificate is approved by the central competent authority as having a health status equivalent to the status of those farms and zones with approved status or approved program in the Community or in accordance with the relevant chapters of the most recent edition of the OIE International Aquatic Animal Health Code, with regard to <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i> – as they originate from:	Directive 91/67 Arts 5, 6 and 8
Alternative a	<p>a coastal zone in which all farms and harvested natural beds</p> <ul style="list-style-type: none"> - are under the supervision of the competent authority, - are subject to health inspections, carried out at intervals adapted to the development of <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i> and samples are taken and examined for these pathogens with a negative result by an officially authorised laboratory in accordance with the procedures laid down in the OIE Manual of Diagnostic Tests for Aquatic Animals, Fourth Edition, 2003, Chapters: 1.1.4; 3.1.1; and 3.1.3; and - since at least 2 years have been free of clinical and other signs of <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i> 	<ul style="list-style-type: none"> - Directive 91/67 Annex B III B2 - Directive 91/67 Art 8 + Decision 2002/878/EC - Directive 91/67 Art 8 and Annex B III B 1
Alternative B	<p>a designated farm, where the water is supplied by means of a system which ensures the complete inactivation of <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i>; and</p> <ul style="list-style-type: none"> - is under the supervision of the competent authority, - is subject to health inspections, carried out at intervals adapted to the development of <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i> and samples are taken and examined for these pathogens with a negative result by an officially authorised laboratory in accordance with the procedures laid down in the OIE Manual of Diagnostic Tests for Aquatic Animals, Fourth Edition, 2003, Chapters: 1.1.4; 3.1.1; and 3.1.3; and - since at least 2 years have been free of clinical and other signs of <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i> 	<p>Elaborated from Directive 91/67/EEC Art 8.1.b taking into account the principle of “approved farm in non-approved zone”. However, here the concept is developed further, compared to Directive 91/67/EEC</p> <ul style="list-style-type: none"> - Directive 91/67 Annex B III B2 - Directive 91/67 Art 8 + Decision 2002/878/EC - Directive 91/67 Art 8 and Annex B III B 1
Alternative c	a farm that is not connected with coastal or estuarial waters and does not contain any molluscs of the species referred to as susceptible to <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i>	Directive 91/67 Annex B III B 3

5. Import of fish

5.1. Scope

Council Directive 91/67/EEC applies to aquaculture animals. In Chapter III of that Directive (import rules) there is a specific requirement that the Community shall take into account, both the disease status and disease control rules in third countries. A general view is that the Community can request guarantees similar to that applicable for placing on the market in the Community and disease control in the Community.

As regards fish, the application of Directive 91/67/EEC is limited to fish coming from or intended for a farm (see Art 2.1), hence the use of the term “fish of aquaculture origin”.

5.2. Fish products – not live fish

Imports of fish products of aquaculture origin (dead fish) may pose a risk, although small, to aquatic animal health in the Community. These commodities are covered by Articles 5 or 6 in Decision 2003/858/EC

5.2.1. Fish products for immediate human consumption (Article 6 of Decision 2003/858/EC)

The import of fish products of aquaculture origin for immediate human consumption poses a relatively low risk to animal health in the Community.

Article 6 shall apply to fish products of aquaculture origin, that have been processed, or packed in an establishment in the third country, and is intended for retail sale directly to restaurants or consumers in the Community without undergoing any kind of measures and techniques, that produces waste or by-products which could cause a risk of spreading diseases, including: operations affecting the anatomical wholeness such as bleeding, gutting/evisceration, heading, slicing, filleting. Such products must consequently be packed and labelled according to the provisions of Directive 91/493/EC.

Therefore there are no specific animal health requirements for such commodities (including non-eviscerated fish intended for retail sale), apart from the general requirement of Directive 91/67/EEC, Art 3,1 that aquaculture animals should be free of clinical signs of disease. Annex V of Decision 2003/858/EC is the certificate which must be used for such consignments. The certificate must be attached to the public health certificate issued pursuant to Directive 91/493/EC.

5.2.2. Fish products for further processing before human consumption

The import of fish products of aquaculture origin for further “industrialised” processing may pose a greater risk than if imported for immediate human consumption. It is a well established fact that effluents from establishments processing farmed fish are a major risk factor in spreading diseases of farmed

fish. Consequently, such commodities are treated different than described under 5.2.1. above.

According to Directive 91/67/EEC, Art 9, dead fish of species susceptible to certain diseases (VHS and IHN), must be eviscerated before introduced into a declared disease free area, unless they come from an area with similar health status. The parts of the fish most likely to carry high numbers of pathogens if the fish were infected are taken out by evisceration. It is therefore a requirement in Decision 2003/858/EC that fish products imported for further processing in the Community must be eviscerated before dispatch, unless the place of origin has a disease status at least equivalent to the place where the processing takes place. According to Commission Decisions 2001/872/EC this also applies in cases of ISA.

As a result, fish products of species susceptible to ISA, and EHN imported for further processing in the Community (whole EU) must either come from a territory free of EHN and ISA, be eviscerated before dispatch from the third country, or be channelled to an “approved import centre” in the Community where processing can take place without any risk for spreading diseases.

Fish products of species susceptible to VHS and/or IHN imported for further processing in the Community in an area declared VHS and/or IHN free, or have an approved programme, (Commission Decisions 2002/308/EC and 2003/634/EC lists declared disease free areas and approved programmes in Member States respectively), must either come from a territory free of VHS and/or IHN, be eviscerated before dispatch from the third country, or be channelled to an “approved import centre” in “declared disease free areas” in the Community where processing can take place without any risk for spreading diseases. If imported for further processing in an area in the Community without declared disease free status as regards VHS and/or IHN, there are no requirements for evisceration, even if the origin is not free of these diseases.

Fish products of aquaculture origin imported for the purpose of further “industrialised” processing in the Community must be accompanied by the certificate in Annex IV of Decision 2003/858/EC. The certificate must be attached to the public health certificate issued pursuant to Directive 91/493/EC.

5.3. Live fish

Import of live fish may have two purposes; either for farming, or for human consumption.

Live fish imported for human consumption are in most cases imported for the purpose of “exhibition” in restaurants. From an animal health risk point of view, this activity poses almost the same risk as if the fish were introduced into Community waters for farming. There are many examples that such fish are released into the wild if not consumed within a reasonable time. In addition, most such exhibition aquariums pass effluent directly into Community waters without

any treatment. Consequently, the risk management as regards live fish for human consumption and live fish for farming must be considered the same.

Community legislation (Directives 91/67/EEC and 93/53/EEC) lays down the requirements that have been incorporated and implemented via Decision 2003/858/EC. It is a general principle, in Community law, and through the OIE Guidelines, that fish introduced into an area free of a certain disease should be accompanied by an animal health certificate certifying that the fish come from an area with at least the same animal health status.

5.3.1. Freedom of exotic diseases

The diseases covered by Community legislation are all diseases listed by the OIE. The only disease listed in Community legislation as exotic is Infectious salmon anaemia. Within the framework of the project to redraft the aquatic animal health legislation, the Commission and the Member States have agreed to include EHN as an exotic disease for the purpose of Decision 2003/858/EC, although the disease is not yet listed in Community legislation. However, there is a common understanding that, the disease is a candidate to be listed in the future legislation, the disease is notifiable to the OIE and the only known occurrence in the EU was stamped out by the competent authority of the Member State concerned. Therefore, in order for a third country to export live fish to the Community, third countries (or regions in third countries) must certify that they are free from ISA and EHN. In international trade, this is normally done by complying with the OIE Guidelines for freedom. According to the OIE Guidelines, a territory can only be declared free after two years of targeted active surveillance.

It is therefore a requirement that third countries, or parts of third countries authorised for export to any parts of the Community are free of ISA and EHN.

5.3.2. Freedom of “non-exotic” diseases

The same principle applies to the diseases referred to in list II and III of Annex A to Directive 91/67/EEC (see Art 7, 12 and 13 of that Directive). For live fish to be introduced into an area in the Community that is declared free of VHS, IHN, SVC, IPN, BKD and/or *G salaris*, they must originate from an area with the same health status. The areas in the Community declared free of these diseases are listed in Commission Decisions 2002/308/EC and 2004/453/EC. In addition, several Member States have approved programmes for achieving declared disease free status (Commission Decision 2003/634/EC and 2004/453/EC), and the same principle applies therefore also to importation into these areas.

It is therefore a requirement that third countries, or parts of third countries authorised for export to those parts of the Community referred to in Decision 2002/308/EC and 2004/453/EC are free of relevant diseases VHS, IHN, SVC, IPN, BKD, and/or *G salaris*. (see also below)

5.3.3. Special provisions/derogations

Decision 2003/858/EC provides for three options, where the Community applies the principle of risk management with respect to consignments that

may be allowed entering the Community, although the consignments do not comply with all the Community animal health requirements. These are outlined below in 5.3.3.1 and 5.3.3.2

5.3.3.1. Designated farms

Live fish may be imported into the Community although they do not originate from a territory declared free (according to Community rules of according to the OIE Guidelines) if

- a) they come from a coastal farm or an inland farm to which the water is supplied by means of an artificial water system which ensures the complete inactivation of the pathogens causing ISA, VHS and/or IHN, or
- b) they come from a continental farm supplied by water from a well, spring or a bore hole, and it complies with the requirements of Art 7.1.b of Directive 91/67/EEC.

If the fish originate from such farms, the risk connected with the introduction into the Community is considered low.

However, the farms must be registered by the competent authority of the third country, have record keeping in place, and be covered by the notification obligations similar to those existing in the Community.

5.3.3.2. Approved import centre

Live fish can also be imported into the Community although they do not meet the animal health requirements of Annex II. However, in such cases they must be immediately shipped to an “approved import centre” (see Art 4 b of Decision 2003/858/EC).

Approved import centres are establishments in the Community, approved according to Directives 91/492/EEC or 91/493/EEC 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. The bio-security measures are laid down in Annex VII of Decision 2003/858/EC.

An important issue with respect to the use of these “approved import centres” is that they should not be used as transit places for live fish which do not comply with all Community animal health requirements, as they could be shipped through such approved import centre prior to introduction into farms or release into put and take fisheries in a Member State. It is therefore required that live fish can not leave the approved import centre.

5.4. Trade patterns

As a consequence of the above described rules and principles, all consignments of fish of aquaculture origin and certain products thereof, do not necessarily satisfy the conditions for introduction into the whole EU. Certain consignments can not enter certain parts of the Community. This “trade pattern” is decided by the animal health status at the place of origin and on the place of destination. Tables 5 - 8 give a brief overview of this pattern.

Table 5 Import of live fish for farming purposes Article 3 of Decision 2003/858/EC

Disease status third country	Destination in EU	Remarks
1. Third country territory ¹ <u>is free² of all of the following diseases</u> - EHN - ISA - VHS - IHN - SVC - IPN - BKD - G salaris	Can export live fish for farming to the whole EU for farming <u>including</u> to those parts the Community referred to in - Decision 2002/308/EC - Decision 2003/634/EC - Decision 2004/453/EC	Applies to all species of fish and also to eggs and gametes. 2003/804/EC.
2. Third country territory ¹ <u>is not free² of</u>	Can export live fish for farming to the whole EU, <u>except those</u> parts of the Community referred to in:	Consignment accompanied by certificate in Annex II of Decision Applies to the following species:
- VHS	- Decision 2002/308/EC or	All species (according to Article 14.1 of Directive 91/67)
- IHN	- Decision 2003/634/EC	Species susceptible to SVC ³
- SVC		Species susceptible to IPN ³
- IPN	- Decision 2004/453/EC	Species susceptible to BKD ³
- BKD		Species susceptible to G salaris ^{3,4}
- G salaris		
3. Third territory ¹ is <u>NOT free² of</u> - ISA - EHN	<u>CANNOT</u> export live fish for farming to <u>ANY</u> EU Member States	As regards ISA, territories considered NOT free, according to Decision 2003/466/EC
¹ territory may be a whole country, a coastal or continental zone, or a farm		
² demonstration of freedom according to the OIE Code and Manual		
³ susceptible species according to OIE Code and Decision 2004/453/EC		
⁴ disinfected eggs still allowed		

Table 6 Import of live fish of aquaculture origin or human consumption Article 4 of Decision 2003/858/EC

Disease status third country	Destination in EU	Remarks
1. Live fish or aquaculture origin exported from a territory ¹ <u>that complies</u> with one of the situations described in Table 5, for the purpose of further “industrialised” processing	Establishment as in Community territories described in Table 5	Complies with the animal health guarantees for further farming according to Article 4.a Consignment accompanied by certificate in Annex II of Decision
2. Live fish or aquaculture origin exported from a territory ¹ <u>that do not complies</u> with one of the situations described in Table 5, for the purpose of further “industrialised” processing	Can not enter Community waters, but must be sent directly to an approved import centre in any Member State for further processing	Can not leave the approved import centre as live fish, must be processed Article 4 b Consignment accompanied by certificate in Annex II of Decision
¹ territory may be a whole country, a coastal or continental zone, or a farm		

Table 7 Import of fish products of aquaculture origin for further processing before human consumption Article 5 of Decision 2003/858/EC

1. Fish products of susceptible species ¹ of aquaculture origin exported from a territory ² <u>which is free³ of all of the following diseases (ISA, EHN, VHS and IHN)</u> for the purpose of further “industrialised” processing in the Community	Sent to any Member State	Can be further processed in any Member State Consignment accompanied by certificate in Annex IV of Decision
2. Fish products of susceptible species ¹ of aquaculture origin exported from a territory ² <u>which is not free³ of the following diseases</u> for the purpose of further “industrialised” processing in the Community		Consignment accompanied by certificate in Annex IV of Decision
- EHN and ISA	Sent to any Member State	Must either be processed in approved import centre or be eviscerated before dispatch.
- VHS and/or – IHN	Sent to Member States or parts thereof referred to in - Decision 2002/308/EC or - Decision 2003/634/EC	
3. All types of fish product (round fish, eviscerated fish, processed fish etc) of aquaculture origin of species other than those susceptible to EHN, ISA, VHS and IHN exported from <u>any territory</u> , regardless of disease status at the place of origin, intended for further processing (as defined in Article 2.2.(i)) in the Community	Sent to any Member State	Consignment accompanied by certificate in Annex IV of Decision
¹ susceptible species according to OIE Code ² territory may be a whole country, a coastal or continental zone, or a farm ³ demonstration of freedom according to the OIE Code and Manual		

Table 8 Import of fish products of aquaculture origin for immediate human consumption Article 6 of Decision 2003/858/EC

1. All types of fish products (round fish, eviscerated fish, processed fish etc) of aquaculture origin of <u>any species exported from any territory</u> , regardless of disease status at the place of origin, intended for immediate human consumption	Sent to any Member State	Consignment accompanied by certificate in Annex V of Decision Consignment must consist of fish products suitable for retail sale to restaurants or directly to the consumer without further processing as defined in Article 2.2.(i) of Decision 2003/858/EC; and labelled in accordance with the provisions of Council Directive 91/493/EC. Must not be subject to further processing (defined in Article 2.2.(i)) in any Member State. In that case, the consignment should fall under Article 5, see table 7 above.
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5.5. Requirements in the certificate for import of live fish

The requirements for animal health certification in Annex II of Decision 2003/858/EC are based on the corresponding requirements that are applicable to Member States with respect to placing on the market (Directive 91/67/EEC) and disease control (Directive 93/53/EC).

Points 1 through 5 of the certificate are mainly a description of the consignment.

Points 6 and 7 contain the animal health requirements. The corresponding requirements in Community legislation and/or in international guidelines or agreements are given in table 9.

Table 9 Relationship between animal health requirements and certificate

Point in the Annex II	Requirement	Legislation
Point 6.1 Territory or farm requirements Alternative 1	All farms rearing species susceptible to ISA, EHN, VHS and/or IHN are officially registered by the competent authority	Directive 93/53 Art 3.1
	All farms 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	Directive 93/53 Art 3.2
	All farms 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 to the fish stock,	Directive 93/53 Art 4
	All farms 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 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 Manual of Diagnostic Tests for Aquatic Animals, Fourth edition, 2003,	Follows from the SPS agreement that the importing country can request from the exporting country to have a level of protection similar to the importing country
	All farms 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	Follows from point above, OIE Code Article 1.3.1.3 and Directive 93/53 Arts 5, 6 and 7, as well as Decision 2003/466/EC
	All farms have, during the last two years prior to dispatch not introduced live fish, eggs or gametes with a lower health status,	Directive 91/67 Arts 7, 9.1 and 10.
	Where 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	Directive 91/67 Art 3.1.a
Point 6.1 Alternative 2	They originate from 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 to the diseases: infectious salmon anaemia (ISA); epizootic haematopoietic necrosis (EHN); viral haemorrhagic septicaemia (VHS); and infectious haematopoietic necrosis (IHN)	Elaborated from Directive 91/67/EEC Art 7.1.b taking into account the principle of “approved farm in non-approved zone”. However, here the concept is further developed, compared to Directive 91/67/EEC
	Where the farm keeps 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	Directive 93/53 Art 3.2

Point 6.1 Alternative 3	They originate from the territory in which there are no farms rearing or keeping live fish, their eggs or gametes, of any species considered as susceptible to ISA, EHN, VHS or IHN, and such species are neither present in the natural waters.	A natural and logic consequence of Directive 93/53 Art. 3 which applies to List I and II diseases. Territories without species susceptible to List I and II diseases, do not need to comply with Point 6.1. alternative 1 or 2
	have had no disease, that has caused significant impact to the stock during the last six months prior to dispatch.	Follows from OIE Code Article 1.3.1.3 that the exporting country shall inform the importing country of incidences of epidemiological importance
Point 6.2	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,	Directive 91/67/EEC Art 3.1. b)
	are not subject to any prohibitions for animal health reasons,	Directive 91/67/EEC Art 3.1. c)
	showed no clinical signs of disease day of loading,	Directive 91/67/EEC Art 3.1. a)
	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	Consignment check
	Eggs should have been disinfected in accordance with OIE Code	Risk mitigation procedure
Point 7.1 VHS/IHN guarantees Territory requirements Alternative 1	They originate from a zone in which all farms are under the supervision of the competent authority or from a designated farm which is under the supervision of the competent authority or originate from a zone in which there are no farms and the wild fish	Directive 93/53 Art 3.1 As regards the wild fish; according to Directive 91/67 Annex B I. B 3
	have been subject to health inspections, carried out at intervals adapted to the development of VHS and/or 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: EC Model A" - at least four years documented freedom, including a two-year surveillance program EC Model B" - at least six years documented freedom, including a two-year surveillance program with reduced sample size EC Special provisions" - new farms EC Special provisions"- farms which recommence their activities OIE" - methods as described in the OIE ⁽⁷⁾ Manual of Diagnostic Tests for Aquatic Animals, Fourth edition, 2003, Chapters: 1.1.4 (General) and the relevant disease chapters	Directive 91/67 Annex B Decision 2001/183 Decision 2001/183 Directive 91/67 Annex C 6. Gives the third country the possibility to use OIE Guidelines instead of Community sampling schemes
	since at least 2 years have been free of clinical and other signs of VHS and/or IHN	Directive 91/67 Art 7 and Annex B
	all necessary measures are taken to prevent the introduction of diseases	

Alternative 2	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 to VHS and/or IHN	Not foreseen in Community legislation, but an additional alternative further developed from Directive 91/67 Annex C. Gives a third country an possibility to trade which EU members do not have.
Alternative 3	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 VHS and/or IHN	Not foreseen in Community legislation but a logical consequence of Point 6.1. Alternative 3.
Point 7.2 SVC, IPN, and BKD guarantees Territory requirements	The fish originates from a territory where SVC, IPN and/or BKD is notifiable to the competent authority, and reports of suspicion of infections must be immediately investigated by the official services	Directive 91/67 Arts 12 and 13 Decision 2004/453/EC Annex V A 1
	The fish originates from a territory in which all introduction of species susceptible SVC, IPN and/or BKD has come from a zone or farm having at least the same health status with respect to SVC, IPN and/or BKD	Directive 91/67 Arts 12 and 13 Decision 2004/453/EC Art 5
	The fish originates from a territory in which the fish has not been vaccinated against SVC, IPN and/or BKD	Directive 91/67 Arts 12 and 13 Decision 2004/453/EC Annex V A 7
	The fish originates from a territory where all farms raising species susceptible to SVC, IPN and/or BKD are under the supervision of the competent authority;	Directive 91/67 Arts 12 and 13 Decision 2004/453/EC Annex V A 2
	The fish originates from a territory where all necessary measures are taken to prevent the introduction of diseases,	This is the overall principle of Directives 91/67 and 93/53.
Alternatives for disease freedom Alternative 1	The fish originate from a territory which is considered free from SVC, IPN and/or BKD in accordance with Annex I to Decision 2003/858/EC.	
Alternative 2	The fish originate from a farm which at the time of the year SVC, IPN and/or 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 Commission Decision 2001/183/EC 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.	Directive 91/67 Arts 12 and 13 Decision 2004/453/EC Annex I and Annex III
Alternative 3	The fish originate from a continental farm where SVC, IPN and/or 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 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.	Directive 91/67 Arts 12 and 13 Decision 2004/453/EC Annex I and Annex III

Point 7.3 G salaris guarantees Territory requirements	The fish originate from a territory where <i>G. salaris</i> is notifiable to the competent authority, and reports of suspicion of infections must be immediately investigated by the official services,	Directive 91/67 Art 13 Decision 2004/453/EC Annex V A 1
	The fish originate from a territory in which all introduction of species susceptible to <i>G. salaris</i> has come from a zone or farm declared free from <i>G. salaris</i> ,	Directive 91/67 Art 13 Decision 2004/453/EC Art 5
	The fish originate from a territory where all farms raising species susceptible to <i>G. salaris</i> are under the supervision of the competent authority,	Directive 91/67 Art 13 Decision 2004/453/EC Annex V A 2
	The fish originate from a territory where all necessary measures are taken to prevent the introduction of diseases,	This is the overall principle of Directives 91/67 and 93/53.
Disease free farm Alternative 1	The fish originate from a territory which is considered free from <i>Gyrodactylus salaris</i> in accordance with Annex 1 to Decision 2003/858/EC	
Disease free farm Alternative 2	The fish originate from a continental farm which at the time of the year <i>Gyrodactylus salaris</i> 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 Commission Decision 2001/183/EC 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 of a water catchment area declared free from <i>Gyrodactylus salaris</i> , or situated in a water catchment area declared free from <i>G. salaris</i> and all other water catchment areas draining into the same estuary are declared free from <i>G. salaris</i> ,	Directive 91/67 Art 13 Decision 2004/453/EC Annex I
Disease free farm Alternative 3	The fish originate from a 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 of <i>G. salaris</i>	Directive 91/67 Art 13 Decision 2004/453/EC Annex I
Disease free farm Alternative 4	The fish originate a 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 have been introduced during the previous 14 days	Directive 91/67 Art 13 Decision 2004/453/EC Annex I
Disease free eggs	The eggs have been disinfected according to the OIE International Aquatic Animal Health Code Sixth edition 2003, Appendix 5.2.1, ensuring the elimination <i>G. salaris</i> .	Directive 91/67 Art 13 Decision 2004/453/EC Annex III Risk mitigation procedure

5.6. Requirements in the certificate for import of fish products (slaughtered fish)

The requirements for animal health certification in Annexes IV and V of Decision 2003/858/EC are based on the corresponding requirements that are applicable to Member States with respect to placing on the market (Directive 91/67/EEC) of products of aquaculture origin

Fish products of aquaculture origin must be accompanied by a public health certificate drawn up according to the provisions laid down in Council Directive 91/493/EC. In order not to have unnecessary duplication of information, the animal health certificates as laid down in Decision 2003/858/EC shall be attached to the public health certificates. All necessary information about the consignments shall be on the public health certificate. In addition, the corresponding animal health requirements in Community legislation and/or in international guidelines or agreements are given in tables 10 and 11.

Table 10 Relationship between animal health requirements and certificate as regards fish products which will be subject for further processing in the Community before placed on the market for human consumption

Point in the Annex II	Requirement	Legislation
Point 1 General requirement	the fish products of aquaculture originate from fish which showed no clinical signs of disease at the time of collection, slaughter or loading	Directive 91/67/ Art 3.3
Point 1 Requirement for species susceptible to ISA and/or EHN Alternative 1	originate from fish harvested from a farm or a zone which is approved by the central competent authority as being free from infectious salmon anaemia (ISA) or epizootic haematopoietic necrosis (EHN), and	Follows from the principles of Directive 91/67 Art 9.1 and Decision 2003/71, as well as OIE Code
Alternative 2	have been slaughtered and eviscerated	Follows from the principles of Directive 91/67 Art 9.1 and Decision 2003/71, as well as OIE Code
Point 1 Requirement for species susceptible to VHS and/or IHN Alternative 1	originate from a designated farm	Not foreseen in Community legislation, but an additional alternative further developed from Directive 91/67 Article 9.1 .
Alternative 2	originate from fish harvested from a farm or a zone which is approved by the central competent authority as having an equivalent health status to those farms and zones with Community approved programmes or status as regards VHS/IHN	Directive 91/67 Art 9.1 as well as OIE Code
Alternative 3	have been slaughtered and eviscerated	Directive 91/67 Art 9.1 as well as OIE Code

Table 11 Relationship between animal health requirements and certificate as regards fish products which will NOT be subject for further processing in the Community before placed on the market for human consumption

Point in the Annex II	Requirement	Legislation
Point 1 General requirement	the fish products of aquaculture originate from fish which showed no clinical signs of disease at the time of collection, slaughter or loading	Directive 91/67/ Art 3.3

6. Control procedures

6.1. Molluscs

Consignments of live molluscs entering the Community for the purpose of further growth, fattening or relaying must be accompanied by an animal health certificate drawn up according to the model laid down in Annex II to Decision 2003/804/EC.

Consignments of live molluscs entering the Community for the purpose of human consumption must be accompanied by the public health certificate drawn up pursuant to Directives 91/492/EEC, 91/493/EEC, or special certificates drawn up pursuant to equivalence agreements with third countries where such exists. In addition the consignment must either

- (a) be accompanied by an animal health certificate drawn up according to the model laid down in Annex II to Decision 2003/804/EC;
or
- (b) the consignment must be packed in packages of a size suitable for retail sale to restaurants or directly to the consumer; and the packages clearly labelled with the following text "*Live molluscs for immediate human consumption. Not to be relayed in Community waters.*";
or
- (c) the consignment must be sent directly to an approved import centre where the molluscs are further processed.

However, viable molluscs can be sent to approved import centres for repacking and can thereafter be placed on the market in the Community provided they are packaged and labelled as required in (b) above.

Live bivalve molluscs imported from third countries 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 (channelling procedure), regardless of their intended use in the Community. This is due to the fact that the border inspection posts approved for controlling products are better equipped to receive consignments of molluscs (cold stores, ice, etc.) The common veterinary entry document provided for in Regulation (EC) 136/2004 shall be completed where the live molluscs are intended for human consumption.

However, where the live molluscs, their eggs and gametes, are imported into the Community for the purpose of further growth, fattening or relaying, the common veterinary entry document provided for in Commission Regulation (EC) 282/2004 shall be completed.

6.2. Fish

Consignments of live fish, eggs or gametes entering the Community for the purpose of further farming must be accompanied by an animal health certificate drawn up according to the model laid down in Annex II to Decision 2003/858/EC. This applies also to live fish of aquaculture origin imported for the purpose of restocking of put and take fisheries.

Consignments of live fish or aquaculture origin entering the Community for the purpose of human consumption must be accompanied by the public health certificate drawn up pursuant to Directive 91/493/EC, or special certificates drawn up pursuant to equivalence agreements with third countries where such exists. In addition the consignment must either

- (a) be accompanied by an animal health certificate drawn up according to the model laid down in Annex II to Decision 2003/858/EC;
- or
- (b) the consignment must be sent directly to an approved import centre where the fish are slaughtered and eviscerated.

In the case described in (a), the consignment must comply with all the animal health provisions which are applicable if the fish were intended for farming at the place of destination, and the relevant statement indicated under point 8 of the certificate should have been added to the label of the consignment. In the case described in (b), the consignment does not have to comply with the animal health provisions of the certificate, but the statement "*Live fish of aquaculture origin intended for further processing in approved import centres before human consumption*" must be added to the label.

Where the consignment consists of fish of aquaculture origin that have been slaughtered, but will be subject to further processing in the Community, the consignment must in addition to the public health certificate drawn up according to Directive 91/493/EC, be accompanied by a certificate drawn up according to Annex IV of Decision 2003/858/EC. In this respect, further processing is considered any kind of measures and techniques, which produces waste or by-products which could cause a risk of spreading diseases, including: operations affecting the anatomical wholeness such as bleeding, gutting/evisceration, heading, slicing, filleting. Repacking solely is not considered further processing.

Where the consignment consists of fish of aquaculture origin that have been slaughtered, but will NOT be subject to further processing (see above) in the Community, the consignment must in addition to the public health certificate drawn up according to Directive 91/493/EC, be accompanied by a certificate drawn up according to Annex V of Decision 2003/858/EC.

It should also be noted that if the consignment consists of species other than those susceptible to EHN, ISA, VHS and/or IHN, the animal health requirements in Annex IV and Annex V are the same.

However, live fish for human consumption is considered “fishery products” under Directive 91/493, and shall be subject to border inspection control according to Directive 97/78/EC (see Commission Decision 2002/349/EC). Consequently live fish of aquaculture origin imported for further processing before human consumption, as well as products thereof imported for further processing before human consumption or for immediate 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) 136/2004 shall be completed accordingly.

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 Commission Regulation (EC) 282/2004 shall be completed accordingly.
