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**COMMISSION DECISION**

**of 14 November 2003**

**laying down the animal health conditions and certification requirements for imports of molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption**

*(notified under document number C(2003) 4153)*

**(Text with EEA relevance)**

(2003/804/EC)

(OJ L 302, 20.11.2003, p. 22)

Amended by:

	Official Journal		
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► <b><u>M1</u></b> Commission Decision 2004/319/EC of 30 March 2004	L 102	73	7.4.2004
► <b><u>M2</u></b> Commission Decision 2004/609/EC of 18 August 2004	L 274	17	24.8.2004
► <b><u>M3</u></b> Commission Decision 2004/623/EC of 23 July 2004	L 280	26	31.8.2004
► <b><u>M4</u></b> Commission Decision 2005/409/EC of 31 May 2005	L 139	16	2.6.2005



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**(Text with EEA relevance)**

(2003/804/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products <sup>(1)</sup>, as last amended by Regulation (EC) No 806/2003 <sup>(2)</sup>, and in particular Article 19(1), Article 20(1) and Article 21(2) thereof,

Whereas:

- (1) A list of third countries or parts thereof, from which Member States are authorised to import live molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption in the Community, should be established.
- (2) It is necessary to lay down specific animal health conditions and model certificates for those third countries, taking into account the animal health situation of the third country concerned and of the molluscs, eggs or gametes to be imported, in order to prevent the introduction of disease agents that could cause significant impact to the mollusc stock in the Community.
- (3) Attention should be paid to emerging diseases and diseases which are exotic to the Community and which could have a serious impact on the mollusc stock in the Community. Furthermore, the disease situation as regards the mollusc diseases referred to in Annex D to Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs <sup>(3)</sup>, as last amended by Regulation (EC) No 806/2003, and in list II, column 1, of Annex A to Directive 91/67/EEC, at the place of production and where appropriate at the place of destination should be taken into account.
- (4) It is necessary that the countries or parts thereof from which Member States are authorised to import molluscs, their eggs and gametes for further growth or fattening, relaying or human consumption, apply conditions for disease control and monitoring at least equivalent to Community standards as laid down in Directives 91/67/EEC and 95/70/EC. The sampling and testing methods used should be at least equivalent to Commission Decision 2002/878/EC <sup>(4)</sup>. In cases where sampling and testing methods are not laid down in the Community legislation, the sampling and testing methods used should be in accordance with those laid down in the International Office of Epizootics (OIE) Manual of diagnostic tests for aquatic animals.
- (5) It is necessary that the responsible competent authorities of these third countries undertake to notify, by fax, telegram or electronic mail, the Commission and the Member States within 24 hours of any occurrence of diseases referred to in Annex D to Directive 95/70/EC, and list II, column 1 of Annex A to Directive 91/67/

<sup>(1)</sup> OJ L 46, 19.2.1991, p. 1.

<sup>(2)</sup> OJ L 122, 16.5.2003, p. 1.

<sup>(3)</sup> OJ L 332, 30.12.1995, p. 33.

<sup>(4)</sup> OJ L 305, 7.11.2002, p. 57.

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EEC, as well as any other disease outbreaks causing a significant abnormal mortality in molluscs within their territory or parts thereof from which imports covered by this Decision are authorised. In such event, the responsible competent authorities of those third countries must take measures to prevent the disease spreading into the Community.

- (6) Taking into account the international practical and scientific experiences gained, the animal health provisions laid down by Commission Decision 95/352/EC of 25 July 1995 laying down the animal health conditions and the certification requirements for the importation from third countries of *Crassostrea gigas* for relaying in Community waters<sup>(1)</sup> needs to be updated and amended as appropriate. For the sake of clarity, those provisions should be included in this Decision and Decision 95/352/EC should be repealed.
- (7) Therefore, it is necessary to supplement the public health certification requirements relating to the importation of live molluscs and unprocessed products thereof, in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing of the market of live bivalve molluscs<sup>(2)</sup>, as last amended by Regulation (EC) No 806/2003, with the animal health certification requirements for import of live molluscs.
- (8) This Decision should apply without prejudice to the public health conditions established under Directive 91/492/EEC and Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products<sup>(3)</sup>, as last amended by Decision 806/2003/EC.
- (9) The risk of introducing diseases that can cause significant impact on molluscs within the community by imports of non-viable molluscs is considered low. The requirements laid down in Directive 91/493/EEC, in particular Articles 11 of that Directive, gives the appropriate level of protection as regards non-viable molluscs, and therefore additional animal health certification for non-viable molluscs is not necessary.
- (10) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products<sup>(4)</sup> lays down standards of certification. The rules and principles applied by third country certifying officers in accordance with this Decision should provide guarantees which are equivalent to those laid down in that Directive.
- (11) The principles laid down in Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption<sup>(5)</sup>, in particular Article 3 of that Directive should be taken into account.
- (12) It would reduce the possibility to control and eradicate diseases which are exotic to the Community and which could have serious impact on the mollusc stocks in the Community, if molluscs that could carry the disease are released into free waters in the Community. Live molluscs, eggs and gametes, should therefore be imported into the Community only if they are introduced into a farm registered by the competent authority in the Member State in accordance with Article 3(1) of Directive 95/70/EC.
- (13) This Decision should not apply to the importation of ornamental molluscs kept permanently in aquariums.

<sup>(1)</sup> OJ L 204, 30.8.1995, p. 13.

<sup>(2)</sup> OJ L 268, 24.9.1991, p. 1.

<sup>(3)</sup> OJ L 268, 24.9.1991, p. 15.

<sup>(4)</sup> OJ L 13, 16.1.1997, p. 28.

<sup>(5)</sup> OJ L 18, 23.1.2003, p. 11.

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- (14) A transitional period of time should be provided for the implementation of these new import certification requirements.
- (15) Annex I to this Decision should be reviewed before the date of application.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

**Scope**

1. This Decision establishes harmonised animal health rules for the importation of:
  - (a) live molluscs, their eggs and gametes, for further growth, fattening or relaying; and
  - (b) live molluscs and non-viable molluscs for immediate human consumption or further processing before human consumption.
2. This Decision shall not apply to the importation of ornamental molluscs kept permanently in aquariums.

*Article 2*

**Definitions**

1. For the purpose of this Decision, the definitions in Article 2 of Directives 91/67/EEC and 95/70/EC shall apply.
2. The following definitions shall also apply:
  - (a) ‘approved import centre’ means any establishment, dispatch centre or purification centre in the Community, approved according to Directives 91/492/EEC or 91/493/EEC where special biosecurity measures have been put in place, approved by the competent authority of the Member State concerned for further processing of imported live molluscs;
  - (b) ‘coastal zone’ means a zone consisting of a part of the coast or sea water or an estuary:
    - (i) which has a precise geographical delimitation and consists of a homogeneous hydrological system or a series of such systems; or
    - (ii) which is situated between the mouths of two watercourses; or
    - (iii) where there are one or more farms and all farms are surrounded by appropriate buffer zones on both sides of the farm or farms;
  - (c) ‘designated farm’ means 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;
  - (d) ‘further processing’ means preparation and processing before human consumption, by any kind of measures and techniques that produce waste or by-products which could cause a risk of spreading of diseases, including: putting live molluscs into water in order to allow them to recover during or after transport (immersion), conditioning, cleaning, purification, thawing, and operations affecting the anatomical wholeness such as shucking;
  - (e) ‘immediate human consumption’ means that molluscs imported for the purpose of human consumption do not undergo any further processing within the Community before being placed on the retail market for human consumption;
  - (f) ‘molluscs’ means aquatic organisms belonging to the *Phylum Mollusca*, classes *Bivalvia* and *Gastropoda*; originating from a

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farm, including any establishment, harvested natural bed or, in general, any geographical defined installation in which molluscs are reared or kept with a view to their being placed on the market;

- (g) 'non-viable molluscs' means molluscs no longer able to survive as living animals if returned to the environment from which they were obtained, and includes mollusc products intended for immediate human consumption or further processing before human consumption;
- (h) 'relaying' means an operation whereby live molluscs are transferred to approved sea or lagoon areas or approved estuarine areas under the supervision of the competent authority for the time necessary to remove contamination as defined in Directive 91/492/EEC, but excluding the specific operation of transferring molluscs to areas more suitable for further growth or fattening, as this is considered as farming;
- (i) 'territory' means either a whole country, a coastal zone, a designated farm, a farming area, or a harvested natural bed which is authorised by the central competent authority of the third country concerned for exportation to the Community.

*Article 3*

**Conditions for importation of live molluscs, their eggs and gametes intended for further growth, fattening or relaying in European Community waters**

1. Member States shall authorise the importation into their territory of live molluscs, their eggs and gametes for further growth or fattening or relaying only if:

- (a) the molluscs originate and have been harvested in a territory listed in Annex I;
- (b) the consignment complies with the guarantees, including those for packaging and labelling and the appropriate specific additional requirements, as laid down in the animal health certificate, drawn up in conformity with the model in Annex II, taking into account the explanatory notes in Annex III; and
- (c) the molluscs have been transported under conditions not altering their health status.

2. Member States shall ensure that imported molluscs, their eggs and gametes intended for further growth, fattening or relaying in Community waters, only are introduced into farms registered by the competent authority in accordance with Article 3(1) of Directive 95/70/EC.

3. Member States shall ensure that imported live molluscs, eggs and gametes are transported directly to the farm of destination, as stated on the animal health certificate.

▼M3*Article 4*

**Conditions related to the importation of live molluscs intended for human consumption**

1. Member States shall authorise the importation into their territory of live molluscs intended for further processing before human consumption only if the consignment:

- (a) complies with the conditions laid down in Article 3(1); or
- (b) is sent directly to an approved import centre for further processing.

2. Member States shall authorise the importation into their territory of live molluscs intended for immediate human consumption only if the molluscs originate in third countries and establishments authorised under Article 9 of Directive 91/492/EEC and Article 11 of Directive 91/493/EEC and comply with the public health certification requirements laid down under those Directives; and

**▼ M3**

either

- (a) the consignment consists of molluscs packed in packages of a size suitable for retail sale to restaurants or directly to the consumer; and the packages are clearly labelled with the following text '*Live molluscs for immediate human consumption. Not to be relayed in Community waters.*';

or

- (b) the consignment is sent directly to an approved import centre where the molluscs are further processed. However, viable molluscs can only leave such premises if they are packaged and labelled as required in (a) above.

**▼ B***Article 5***Conditions related to importation of non-viable molluscs intended for human consumption**

Member States shall authorise the importation into their territory of non-viable molluscs for immediate human consumption or for further processing before human consumption only if the molluscs originate in third countries and establishments authorised under Article 9 of Directive 91/492/EEC and Article 11 of Directive 91/493/EEC and comply with the public health certification requirements laid down under those Directives.

**▼ M3***Article 6***Control procedures**

1. 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.
2. In the case of live molluscs, their eggs and gametes, imported into the Community for the purpose of further growth, fattening or relaying, the common veterinary entry document provided for in Regulation (EC) No 282/2004 shall be completed accordingly.
3. In the case of live molluscs imported into the Community for immediate human consumption or for the purpose of further processing before human consumption, the common veterinary entry document provided for in Regulation (EC) No 136/2004 shall be completed accordingly.

**▼ B***Article 7***Preventing contamination of natural waters**

1. Member States shall ensure that imported molluscs intended for immediate human consumption or further processing before human consumption are not introduced into, and do not contaminate any natural waters within their territory.
2. Member States shall ensure that transport water from imported consignments does not lead to contamination of natural waters within their territory.

*Article 8***Approval of import centres**

1. The competent authority of the Member States shall approve an establishment as an approved import centre provided that it satisfies the minimum animal health conditions of Annex V to this Decision.
2. The competent authority of the Member States shall draw up a list of approved import centres, each of which shall be given an official number.

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3. The list of approved import centres, and any subsequent amendments thereto, shall be communicated by the competent authority of each Member State, to the Commission and to the other Member States.

*Article 9*

**Repeal**

Decision 95/352/EC is repealed.

*Article 10*

**Review**

Annex I to this Decision should be reviewed before 1 May 2004.

*Article 11*

**Date of application**

This Decision shall apply from 1 May 2004.

*Article 12*

This Decision is addressed to the Member States.

▼ **M4***ANNEX I*

**Territories from which importation of certain species of live molluscs, their eggs and gametes intended for further growth, fattening, or relaying in European Community waters, or importation of live molluscs intended for further processing before human consumption is authorised**

Country		Territory		Comments
ISO code	Name	Code	Description	
CA	Canada			Live molluscs only for further processing before human consumption
MA	Morocco			Live molluscs only for further processing before human consumption
NZ	New Zealand			Live molluscs only for further processing before human consumption
TN	Tunisia			Live molluscs only for further processing before human consumption
TR	Turkey			Live molluscs only for further processing before human consumption
US	United States	US-01 Version 1/2005	<ul style="list-style-type: none"> <li>— Humboldt Bay (California)</li> <li>— Netarts Bay (Oregon)</li> <li>— Wilapa Bay, Totten Inlet, Oakland Bay, Quilcence Bay and Dabob Bay (Washington)</li> <li>— NELHA (Hawaii)</li> </ul>	Live molluscs for further growth, fattening or relaying, and for further processing before human consumption

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## ANNEX II

**Model animal health certificate for the importation into the European Community (EC) of [live molluscs, eggs and gametes for further growth, fattening or relaying] <sup>(1)</sup> [live molluscs for further processing before human consumption] <sup>(1)</sup>**

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

Reference code No ORIGINAL

Reference code No of public health certificate (where relevant)

<b>1. Exporting country and authorities involved</b> 1.1. Exporting country:..... ..... 1.2. Competent authority: ..... ..... 1.3. Competent issuing authority: ..... .....		<b>4. Destination of the consignment</b> 4.1. Member State: ..... ..... [4.2. Zone or part <sup>(3)</sup> of the Member State:..... ..... ] <sup>(1)</sup> [4.3. Farm, name: ..... ..... ] <sup>(1)</sup> 4.4. Address:..... ..... 4.5. Name, address and phone number of the consignee: ..... .....			
<b>2. Place of origin of the consignment</b> 2.1. Code of territory of origin <sup>(2)</sup> : ..... ..... [2.2. Farm of origin, name: ..... ..... ] <sup>(1)</sup> [2.3. Address or location of farm: ..... ..... ] <sup>(1)</sup> 2.4. Name, address and phone number of the consignor: ..... .....		<b>5. Means of transport and consignment identification <sup>(4)</sup></b> 5.1. [Lorry] <sup>(1)</sup> [Rail-wagon] <sup>(1)</sup> [Ship] <sup>(1)</sup> [Aircraft] <sup>(1)</sup> : ..... ..... 5.2. [Registration number(s)] <sup>(1)</sup> [Ship name] <sup>(1)</sup> [Flight number] <sup>(1)</sup> : ..... ..... 5.3. Consignment identification details:..... ..... .....			
<b>3. Place of harvest (if different from place of origin)</b> 3.1. Country: ..... ..... 3.2. Code of territory of harvest <sup>(2)</sup> : ..... ..... [3.3. Farm of harvest, name: ..... ..... ] <sup>(1)</sup> [3.4. Address or location of farm: ..... ..... ] <sup>(1)</sup>					
<b>6. Description of the consignment</b> <input type="checkbox"/> Farmed stocks <input type="checkbox"/> Harvested natural beds <input type="checkbox"/> Gametes <input type="checkbox"/> Eggs <input type="checkbox"/> Larvae					
Mollusc species		Total weight (kg) of molluscs	[Volume of eggs] <sup>(1)</sup> [Volume of gametes] <sup>(1)</sup>	[Number of molluscs] <sup>(1)</sup> [Mean size of molluscs (cm)] <sup>(1)</sup>	Age of live molluscs
Scientific name:	Common name:				
					<input type="checkbox"/> > 24 months <input type="checkbox"/> 12-24 months <input type="checkbox"/> 0-11 months; <input type="checkbox"/> unknown

7. **Animal health attestation for importation of<sup>(1)</sup> [live molluscs, their eggs and gametes for further growth or fattening or relaying]<sup>(1)</sup> [live molluscs for further processing before human consumption]**

I, the undersigned official inspector, hereby certify that the live molluscs, their eggs or gametes referred to in point 6 of this certificate fulfil the following requirements:

7.1. *either:*

- (<sup>1</sup>) [They originate from, and are harvested in, the territory<sup>(2)</sup> with the code: .....]
- (a) where all farms rearing live molluscs, their eggs or gametes are officially registered by the competent authority;
- (b) 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<sup>(5)</sup>; 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<sup>(6)</sup>;
- (c) which during the last two years have been considered free from bonamiosis (*Bonamia exitiosa* and *Mikrocytos roughleyi*); marteiliosis (*Marteilia sydneyi*); microcitososis (*Mikrocytos mackini*); perkinsosis (*Perkinsus marinus* and *P. olseni/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* y *H. costale*) and withering syndrome (*Candidatus Xenohaliotis californiensis*);
- (d) 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<sup>(5)</sup> and keep track of the health situation of the susceptible<sup>(7)</sup> stocks, in particular as regards bonamiosis (*Bonamia ostreae*, *B. exitiosa* and *Mikrocytos roughleyi*); marteiliosis (*Marteilia refringens* and *Marteilia sydneyi*); mikrocitosis (*Mikrocytos mackini*); perkinsosis (*Perkinsus marinus* and *P. olseni/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* and *H. costale*) and withering syndrome (*Candidatus Xenohaliotis californiensis*);
- (e) where all farms rearing live molluscs, their eggs or gametes have to notify as soon as possible to the competent authority any abnormal mortality<sup>(5)</sup> and suspicion of the diseases above;
- (f) subject to appropriate disease control measures as necessary and at least equivalent to those required in 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<sup>(5)</sup>, 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<sup>(8)</sup>, Manual of Diagnostic Tests for Aquatic Animals, Fourth edition, 2003;
- (g) where all farms rearing live molluscs, their eggs or gametes have had no unexplained abnormal mortality<sup>(5)</sup> or abnormal mortality<sup>(5)</sup> caused by a pathogen during the last two years prior to shipment;
- (h) where all farms rearing live molluscs, their eggs or gametes have not, during the last two years prior to shipment introduced live molluscs, eggs or gametes with a lower health status;
- (i) where there are, on the day of loading, no abnormal mortality<sup>(5)</sup> and no suspicion of the presence of any of the disease listed in point 7.1(d) of this certificate, and];

or

- (<sup>1</sup>) [They originate from, and are harvested in, the territory<sup>(2)</sup> with the code: ..... (<sup>1</sup>) and:
- (a) they originate 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 (*Bonamia exitiosa* and *Mikrocytos roughleyi*); marteiliosis (*Marteilia sydneyi*); mikrocitosis (*Mikrocytos mackini*); perkinsosis (*Perkinsus marinus* and *P. olseni/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* and *H. costale*) and withering syndrome (*Candidatus Xenohaliotis californiensis*);
- (b) the farm is officially registered by the competent authority,
- (c) the farm keeps an updated record open to scrutiny by the official service at all time of: observed abnormal mortality<sup>(5)</sup>; 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 source, their suppliers and their destination<sup>(6)</sup>, and
- (d) the farm has have to notify as soon as possible to the competent authority any abnormal mortality<sup>(5)</sup> and suspicion of the diseases referred to above, and]

7.2. they:

- (a) have not, since the time of harvest, been in contact with other live molluscs, their eggs or gametes of a lower health status;
- (b) are not intended for destruction or slaughter for the eradication of any of the diseases bonamiosis (*Bonamia ostreae*, *B. exitiosa* and *Mikrocytos roughleyi*); marteiliosis (*Marteilia refringens* and *Marteilia sydneyi*); mikrocytosis (*Mikrocytos mackini*); perkinsosis (*Perkinsus marinus* and *P. olseni/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* and *H. costale*) and withering syndrome (*Candidatus Xenohaliotis californiensis*), or due to abnormal mortality<sup>(5)</sup> caused by any other pathogen;
- (c) showed no clinical signs of disease on the day of loading, including abnormal mortality<sup>(5)</sup>;

<sup>(1)</sup><sup>(8)</sup> [(d) were subject to an individual visual check of at least 1 000 molluscs randomly selected from each part of the consignment having a different origin, and no mollusc species other than those specified in point 6 of this certificate were detected].

<sup>(10)</sup> [8. **Specific animal health requirements as regards *Bonamia ostreae* and *Marteilia refringens***

I, the undersigned official inspector, hereby certify that the live molluscs, or the eggs or gametes, referred to in point 6 of this certificate, 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<sup>(11)</sup> or approved programme<sup>(11)</sup> in the Community or in accordance with the relevant chapters of the most recent edition of the OIE<sup>(8)</sup> International Aquatic Animal Health Code, with regard to [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup> — as they originate from:

either

- <sup>(1)</sup> [ a coastal zone in which all farms and harvested natural beds
  - are under the supervision of the competent authority,
  - are subject to health inspections, carried out at intervals adapted to the development of [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup> 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<sup>(8)</sup>, Manual of Diagnostic Tests for Aquatic Animals, Fourth Edition, 2003, Chapters: 1.1.4, 3.1.1 and 3.1.3 and
  - for at least two years have been free of clinical and other signs of [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>;

or [a designated farm, where the water is supplied by means of a system which ensures also the complete inactivation of [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>; and

- is under the supervision of the competent authority,
- is subject to health inspections, carried out at intervals adapted to the development of [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup> 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<sup>(8)</sup> 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 two years have been free of clinical and other signs of [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>;

or

- <sup>(1)</sup> [a farm that is not connected with coastal or estuarial waters and does not contain any molluscs of the species referred to as susceptible<sup>(7)</sup> to [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>.]

▼ **M3**

Reference Code No

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**9. Transport requirements**

Furthermore, they:

- are transported under conditions that do not alter their health status, and
- have been placed in sealed watertight containers which were cleaned and disinfected beforehand using an authorised disinfectant and which bear on the exterior a legible label with the relevant<sup>(12)</sup> information referred to at points 1, 2, 3 and 4 of this certificate and with the following statement:

either:

“[Live molluscs]<sup>(1)</sup> [and]<sup>(1)</sup> [eggs]<sup>(1)</sup> [and]<sup>(1)</sup> [gametes]<sup>(1)</sup> intended for further growth, fattening or relaying in EC coastal zones and farms without a Community approved programme or status, with regard to *Bonamia ostreae* and *Marteilia refringens*”;

or:

[“Live molluscs]<sup>(1)</sup> [and]<sup>(1)</sup> [eggs]<sup>(1)</sup> [and]<sup>(1)</sup> [gametes]<sup>(1)</sup> intended for further growth, fattening or relaying in EC coastal zones and farms with a Community approved programme or status, with regard to [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>”];

or:

[“Live molluscs intended for further processing in EC establishments not located in Community territory with approved programme or status with regard to [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>”].

or:

[“Live molluscs intended for further processing in EC establishments located in Community territory with approved programme or status with regard to [*Bonamia ostreae*]<sup>(1)</sup> [and]<sup>(1)</sup> [*Marteilia refringens*]<sup>(1)</sup>”].

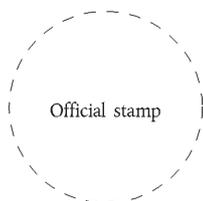
or:

[“Live molluscs intended for further processing in approved import centres in the Community]<sup>(1)</sup>”].

Done at....., on.....

(Place)

(Date)

.....  
(Signature of official inspector).....  
(Name in capital letter, qualifications and title)

## ▼ M3

Reference Code No

ORIGINAL

Indicative notes		
<p>(1) Retain as appropriate.</p> <p>(2) Territory (a whole country, a coastal zone, a farming area or a harvested natural bed) and code of territory as appearing in Annex I to Decision 2003/804/EC.</p> <p>(3) Specify as applicable: zone and/or farming areas, harvested natural beds, dispatch centres, purification centres or storage tanks, or in case of import for further processing before human consumption, establishment.</p> <p>(4) The registration number(s) of rail-wagon or lorry or 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 5.3.</p> <p>(5) As laid down in Article 2.2 of Council Directive 95/70/EC.</p> <p>(6) As applicable.</p> <p>(7) Known susceptible species, see table below.</p>		
Disease	Pathogen	Susceptible host species (*)
Bonamiosis	<i>Bonamia exitiosa</i>	<i>Tiostrea chilensis</i> and <i>Ostrea angasi</i>
	<i>Mikrocytos roughleyi</i>	<i>Saccostrea (commercialis) glomerata</i>
Marteiliosis	<i>Marteilia sydneyi</i>	<i>Saccostrea (commercialis) glomerata</i>
Microcytosis	<i>Mikrocytos mackini</i>	<i>Crassostrea gigas</i> ; <i>C. virginica</i> ; <i>Ostrea edulis</i> ; <i>O. conchaphila</i>
Perkinsosis	<i>Perkinsus marinus</i>	<i>Crassostrea virginica</i> and <i>C. gigas</i>
	<i>Perkinsus olseni/atlantius</i>	<i>Haliotis ruber</i> , <i>H. cyclobates</i> ; <i>H. scalaris</i> ; <i>H. laevigata</i> ; <i>Ruditapes philippinarum</i> and <i>R. decussatus</i>
MSX disease	<i>Haplosporidium nelsoni</i>	<i>Crassostrea virginica</i> and <i>C. gigas</i>
SSO disease	<i>Haplosporidium costale</i>	<i>Crassostrea virginica</i>
Withering syndrome of abalones	<i>Candidatus Xenohaliotis californiensis</i>	Members of the genus <i>Haliotis</i> including black abalone ( <i>H. cracherodii</i> ), red abalone ( <i>H. rufescens</i> ), pink abalone ( <i>H. corrugata</i> ), green abalone ( <i>H. fulgens</i> ) and white abalone ( <i>H. sorenseni</i> ).
<p>(*) And any other species referred to in the most recent edition of the OIE International Aquatic Animal Health Code as being susceptible for the pathogen/disease in question.</p>		
<p>(8) World Organisation for Animal Health.</p> <p>(9) Only applicable to live molluscs for further growth, fattening or relaying. For consignments smaller than 1 000 molluscs, all molluscs shall be visually inspected.</p> <p>(10) Specific requirements needed in the case of exports to farms or zones within the EC with a Community approved programme or status for:</p> <ul style="list-style-type: none"> <li>— <i>Bonamia ostreae</i>, except for the following species (**): <i>Crassostrea gigas</i>, <i>Mytilus edulis</i>, <i>M. galloprovincialis</i>, <i>Ruditapes decussatus</i> and <i>Ruditapes philippinarum</i></li> <li>— <i>Marteilia refringens</i>, except for the following species (**): <i>Crassostrea gigas</i>.</li> </ul> <p>(**) In accordance with Commission Decision 2003/390/EC.</p> <p>(11) As laid down in Council Directive 91/67/EEC.</p> <p>(12) Country and territory of origin (code) and of destination.</p>		

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## ANNEX III

*Explanatory notes for certification and labelling*

- (a) The certificates shall be produced by the competent authorities of the exporting country, based on the appropriate model appearing in Annex II to this Decision taking into account the use to which the molluscs are to be put after the arrival to the EC.
- (b) Considering the status of the place of destination as regards *Bonamia ostreae* and *Marteilia refringens* in the EC Member State, the appropriate specific additional requirements shall be incorporated and completed in the certificate.
- (c) The original of each certificate shall consist of a single page, double-sided, or, where more than one page is required, it shall be in such a form that all pages form part of an integrated whole and are indivisible.

It shall, on the right-hand side of the top of each page, be marked as 'original' and bear a specific code number issued by the competent authority. All pages of the certificate shall be numbered — (page number) of (total number of pages).

- (d) The original of the certificate and the labels referred to in the model certificate shall be drawn up in at least one official language of the EC Member State in which the inspection at the border post shall be carried out and of the EC Member State of destination. However, these Member States may allow other languages, if necessary, accompanied by an official translation.
- (e) The original of the certificate must be completed on the day of loading the consignment for exportation to the European Community with an official stamp and signed by an official inspector designated by the competent authority. In doing so, the competent authority of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.

The stamp, unless embossed, and the signature shall be in a colour different to that of the printing.

- (f) If for reasons of identification of the items of the consignment, additional pages are attached to the certificate, these pages shall be considered as forming part of the original and be signed and stamped by the certifying official inspector on each page.
- (g) The original of the certificate must accompany the consignment until it reaches the EC border inspection post.
- (h) The certificate 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 the journey at sea.
- (i) The molluscs, their eggs and gametes, shall not be transported together with other molluscs, eggs or gametes that, either are not destined to the European Community, or are of a lower health status. Furthermore, they must not be transported under any other conditions that alter their health status.
- (j) The possible presence of pathogens in the water is a relevant factor when considering the health status of molluscs. The certifying officer should therefore consider the following:

the 'place of origin' should be the localisation of the farm or harvested natural bed where the molluscs were reared reaching their commercial size relevant for the consignment covered by this certificate.

The 'place of harvest' should be the last place the molluscs were in contact with natural waters in the exporting country, like purification centres or intermediate storage places where molluscs are kept before exported to the Community.

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**▼B***ANNEX V***MINIMUM ANIMAL HEALTH CONDITIONS FOR THE APPROVAL OF  
'APPROVED IMPORT CENTRES'****A. General Provisions**

1. Member States shall only approve centres and establishments as import centres for further processing of imported molluscs provided that the conditions at the import centre are such that risks of contamination of molluscs in Community waters via discharges or other waste, or by other means, with pathogens capable of causing significant abnormal mortality in molluscs are avoided.

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2. Viable molluscs may only leave approved import centres if they are packaged and labelled according to Article 4(2)(a) of this Decision.

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3. The minimum animal health conditions as laid down in part B of this Annex shall apply, in addition to the public health provisions laid down under Directive 91/492/EEC for any centres and establishments, including dispatch centres and purification centres, as well as to the health rules laid down by Community legislation concerning animal by-products not intended for human consumption.

**B. Management Provisions**

1. Approved import centres must be under the control and responsibility of the competent authority.
2. Approved import centres must have an efficient disease control, and monitoring system; in application of Directive 95/70/EC, cases of suspected disease and mortality shall be investigated by the competent authority; the necessary analysis and treatment must be carried out in consultation with and under the control of the competent authority, taking into consideration the requirement in Article 3(1)(a) of Directive 91/67/EEC.
3. Approved import centres must apply a management system, approved by the competent authority, including hygiene and disposal routines for transport, transport containers, facilities, and equipment. The guidelines laid down for disinfection of mollusc farms in the OIE International aquatic animal health code, sixth edition, 2003, Appendix 5.2.2, should be followed. The disinfectants used must be approved for the purpose by the competent authority and appropriate equipment must be available for cleaning and disinfection. Discharges of by-products and other waste materials including dead molluscs and their products must be carried out in accordance with Regulation (EC) No 1774/2002. The management system at the approved import centre shall be such that risks of contamination of molluscs in Community waters with pathogens capable of causing significant impact to mollusc stocks, in particular diseases referred to in Annex D to Directive 95/70/EC, are avoided.
4. Approved import centres must keep an updated record of observed abnormal mortality, and of all the live molluscs, eggs and gametes entering the centre and products leaving the centre including their source, their suppliers and their destination.
5. Approved import centres must be cleaned and disinfected regularly in accordance with the programme described in point 3 above.
6. Only authorised persons may enter approved import centres and must wear protective clothing including appropriate footwear.