

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 23 July 2004

amending Decision 2003/804/EC as regards imports of live molluscs for human consumption

(notified under document number C(2004) 2613)

(Text with EEA relevance)

(2004/623/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

represent a low animal health risk, as these consignments are not for further growth, fattening, or relaying in Community waters.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products⁽¹⁾, and in particular Article 20(1) and Article 21(2) thereof,

Whereas:

(1) Commission Decision 2003/804/EC 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⁽²⁾, sets out the specific animal health conditions for imports of live molluscs into the Community from third countries.

(2) It is necessary to take into consideration that imports of small quantities of molluscs, often high-value products, directly for retail sale to supermarkets or restaurants, may

(3) The requirements laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs⁽³⁾, 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⁽⁴⁾, give the appropriate level of protection as regards live molluscs packed in packages of a size suitable for retail sale to restaurants or directly to the consumer, provided the molluscs do not come in contact with Community waters. Additional animal health certification for such consignments should not be necessary.

(4) It is further necessary to take into consideration the possibility that imports of live molluscs, which would not fully comply with the requirements laid down in Article 3 of Decision 2003/804/EC for situations where the molluscs are bound for further processing, could be channelled to import centres approved according to Article 8 of Decision 2003/804/EC, and packed in packages of a size suitable for retail sale to restaurants or directly to the consumer. In such situations, the imported molluscs will not come in direct contact with natural waters in the Community.

⁽¹⁾ OJ L 46, 19.2.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 302, 20.11.2003, p. 22. Decision as amended by Decision 2004/319/EC (OJ L 102, 7.4.2004, p. 73).

⁽³⁾ OJ L 268, 24.9.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003.

⁽⁴⁾ OJ L 268, 24.9.1991, p. 15. Directive as last amended by Regulation (EC) No 806/2003.

- (5) Live bivalve molluscs should be treated as live aquatic animals where they are for further breeding and production, but they may also be considered as products where they are for immediate human consumption, except that they are transported in the live state to preserve freshness. However, as regards veterinary checks, all live bivalve molluscs should be examined in facilities approved to handle products of animal origin, which are more appropriate for handling such consignments.
- (6) Live bivalve molluscs imported from third countries should therefore be subject to veterinary checks according to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries⁽¹⁾.
- (7) Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community⁽²⁾, has replaced Commission Decision 92/527/EC⁽³⁾. Where live bivalve molluscs are destined for breeding or production the control procedure in Article 8 of Directive 97/78/EC should be used and the common veterinary entry document in Regulation (EC) No 282/2004 completed accordingly by the official veterinarian.
- (8) Where live bivalve molluscs are imported and intended for human consumption the common veterinary entry document set down in Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down the procedures for the veterinary checks at Community border inspection posts on products imported from third countries⁽⁴⁾ should be used and completed accordingly by the official veterinarian.
- (9) In order not to interrupt imports unnecessarily, taking into account the low animal health risk such consignments represent, the control procedures laid down in Article 6 of Decision 2003/804/EC should be amended accordingly, and Annex IV deleted.
- (10) 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

Decision 2003/804/EC is amended as follows:

1. Article 4 is replaced by the following:

'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

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.'

2. Article 6 is replaced by the following:

'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.

⁽¹⁾ OJ L 24, 30.1.1998, p. 9. Directive as last amended by Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 165, 30.4.2004, p. 1).

⁽²⁾ OJ L 49, 19.2.2004, p. 11. Regulation as amended by Regulation (EC) No 585/2004 (OJ L 91, 30.3.2004, p. 17).

⁽³⁾ OJ L 332, 18.11.1992, p. 22.

⁽⁴⁾ DO OJ L 21, 28.1.2004, p. 11.

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.
3. Annex II is replaced by the Annex to this Decision.
4. Annex IV is deleted.
5. Annex V(A)(2) is replaced by:
- ‘2. Viable molluscs may only leave approved import centres if they are packaged and labelled according to Article 4(2)(a) of this Decision.’
- Article 2*
- This Decision is addressed to the Member States.
- Done at Brussels, 23 July 2004.
- For the Commission*
David BYRNE
Member of the Commission
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ANNEX

'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] ⁽¹⁾ [live molluscs for further processing before human consumption] ⁽¹⁾

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)

| | | | | | |
|--|--------------|--|---|--|--|
| 1. Exporting country and authorities involved 1.1. Exporting country: 1.2. Competent authority: 1.3. Competent issuing authority: | | 4. Destination of the consignment 4.1. Member State: [4.2. Zone or part ⁽³⁾ of the Member State:] ⁽¹⁾ [4.3. Farm, name:] ⁽¹⁾ 4.4. Address: 4.5. Name, address and phone number of the consignee: | | | |
| 2. Place of origin of the consignment 2.1. Code of territory of origin ⁽²⁾ : [2.2. Farm of origin, name:] ⁽¹⁾ [2.3. Address or location of farm:] ⁽¹⁾ 2.4. Name, address and phone number of the consignor: | | 5. Means of transport and consignment identification ⁽⁴⁾ 5.1. [Lorry] ⁽¹⁾ [Rail-wagon] ⁽¹⁾ [Ship] ⁽¹⁾ [Aircraft] ⁽¹⁾ : 5.2. [Registration number(s)] ⁽¹⁾ [Ship name] ⁽¹⁾ [Flight number] ⁽¹⁾ : 5.3. Consignment identification details: | | | |
| 3. Place of harvest (if different from place of origin) 3.1. Country: 3.2. Code of territory of harvest ⁽²⁾ : [3.3. Farm of harvest, name:] ⁽¹⁾ [3.4. Address or location of farm:] ⁽¹⁾ | | | | | |
| 6. Description of the consignment <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] ⁽¹⁾ [Volume of gametes] ⁽¹⁾ | [Number of molluscs] ⁽¹⁾ [Mean size of molluscs (cm)] ⁽¹⁾ | 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 |

Reference code No

ORIGINAL

7. Animal health attestation for importation of⁽¹⁾ [live molluscs, their eggs and gametes for further growth or fattening or relaying]⁽¹⁾ [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:

(¹) [They originate from, and are harvested in, the territory⁽²⁾ 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⁽³⁾; 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⁽⁶⁾;

(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⁽⁵⁾ and keep track of the health situation of the susceptible⁽⁷⁾ stocks, in particular as regards bonamiosis (*Bonamia ostreae*, *B. exitiosa* and *Mikrocytos roughleyi*); marteiliosis (*Marteilia refringens* and *Marteilia sydneyi*); mikrocitososis (*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⁽⁵⁾ 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⁽⁵⁾, 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⁽⁸⁾, 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⁽⁵⁾ or abnormal mortality⁽⁵⁾ 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⁽⁵⁾ and no suspicion of the presence of any of the disease listed in point 7.1(d) of this certificate, and];

or

(¹) [They originate from, and are harvested in, the territory⁽²⁾ with the code: (¹) 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*); mikrocitososis (*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⁽⁵⁾; 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⁽⁶⁾, and

(d) the farm has have to notify as soon as possible to the competent authority any abnormal mortality⁽⁵⁾ 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⁽⁵⁾ caused by any other pathogen;
- (c) showed no clinical signs of disease on the day of loading, including abnormal mortality⁽⁵⁾;
- ⁽¹⁾⁽⁸⁾ [(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].

⁽¹⁰⁾ [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⁽¹¹⁾ or approved programme⁽¹¹⁾ in the Community or in accordance with the relevant chapters of the most recent edition of the OIE⁽⁸⁾ International Aquatic Animal Health Code, with regard to [*Bonamia ostreae*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾ — as they originate from:

either

- ⁽¹⁾ [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*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾ 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⁽⁸⁾, 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*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾;
- or [a designated farm, where the water is supplied by means of a system which ensures also the complete inactivation of [*Bonamia ostreae*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾; 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*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾ 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⁽⁸⁾ 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*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾;

or

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

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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⁽¹²⁾ information referred to at points 1, 2, 3 and 4 of this certificate and with the following statement:

either:

“[Live molluscs]⁽¹⁾ [and]⁽¹⁾ [eggs]⁽¹⁾ [and]⁽¹⁾ [gametes]⁽¹⁾ 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]⁽¹⁾ [and]⁽¹⁾ [eggs]⁽¹⁾ [and]⁽¹⁾ [gametes]⁽¹⁾ 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*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾”];

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*]⁽¹⁾ [and]⁽¹⁾ [*Marteilia refringens*]⁽¹⁾”].

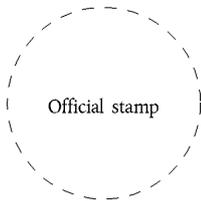
or:

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

or:

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

Done at....., on.....
 (Place) (Date)



.....
 (Signature of official inspector)

.....
 (Name in capital letter, qualifications and title)

Reference Code No

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Indicative notes

- (1) Retain as appropriate.
- (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.
- (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.
- (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.
- (5) As laid down in Article 2.2 of Council Directive 95/70/EC.
- (6) As applicable.
- (7) Known susceptible species, see table below.

| 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/atlanticus</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>). |

(*) 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.

- (8) World Organisation for Animal Health.
- (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.
- (10) Specific requirements needed in the case of exports to farms or zones within the EC with a Community approved programme or status for:
- *Bonamia ostreae*, except for the following species (**): *Crassostrea gigas*, *Mytilus edulis*, *M. galloprovincialis*, *Ruditapes decussatus* and *Ruditapes philippinarum*
 - *Marteilia refringens*, except for the following species (**): *Crassostrea gigas*.
- (**) In accordance with Commission Decision 2003/390/EC.
- (11) As laid down in Council Directive 91/67/EEC.
- (12) Country and territory of origin (code) and of destination.'