

CHAPTER 11.1.

INFECTION WITH *BONAMIA EXITIOSA*

Article 11.1.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia exitiosa* means *infection* only with *B. exitiosa*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 11.1.2.

Scope

The recommendations in this Chapter apply to: Australian mud oyster (*Ostrea angasi*) and Chilean flat oyster (*O. chilensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.1.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *B. exitiosa* related conditions, regardless of the *B. exitiosa* status of the *exporting country, zone or compartment*:
 - a) For the species referred to in Article 11.1.2. intended for any purpose:
 - i) *commodities* treated in a manner that inactivates the *disease agent* e.g. canned or pasteurised products;
 - ii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.
 - b) The following *commodities* destined for human consumption from the species referred to in Article 11.1.2. which have been prepared and packaged for direct retail trade:
 - i) off the shell (chilled or frozen);
 - ii) half-shell (chilled).
 - c) All *commodities* from *Crassostrea gigas* and *Saccostrea glomerata*, including the live *aquatic animal*.

For the *commodities* referred to in point 1b), OIE Members may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 11.1.2., other than *commodities* referred to in point 1 of Article 11.1.3., the *Competent Authorities* should require the conditions prescribed in Articles 11.1.7. to 11.1.11. relevant to the *B. exitiosa* status of the *exporting country, zone or compartment*.

3. When considering the importation/transit from an *exporting country, zone or compartment* not declared free of infection with *B. exitiosa* of a *commodity* from bivalve species not covered in Article 11.1.2. or in point 1c) of Article 11.1.3. but which could reasonably be expected to be a potential mechanical vector for *B. exitiosa*, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 11.1.4.

***B. exitiosa* free country**

A country may make a *self-declaration of freedom* from *B. exitiosa* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *B. exitiosa* if all the areas covered by the shared water are declared *B. exitiosa* free *zones* (see Article 11.1.5.).

1. A country where none of the *susceptible species* referred to in Article 11.1.2. is present may make a *self-declaration of freedom* from *B. exitiosa* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 11.1.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from *B. exitiosa* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with *B. exitiosa* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the *Aquatic Manual*) may make a *self-declaration of freedom* from *B. exitiosa* when:
 - a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the past 2 years without detection of *B. exitiosa*.

OR

4. A country that has previously made a *self-declaration of freedom* from *B. exitiosa* but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from *B. exitiosa* again when the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

- c) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the past 2 years without detection of *B. exitiosa*; and
- d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 11.1.5.

Article 11.1.5.

B. *exitiosa* free zone or free compartment

A *zone* or *compartment* free from *B. exitiosa* may be established within the *territory* of one or more countries of infected or unknown status for infection with *B. exitiosa* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *B. exitiosa* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *B. exitiosa*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 11.1.2. is present may be declared free from *B. exitiosa* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *B. exitiosa*, a *zone* or *compartment* where any *susceptible species* referred to in Article 11.1.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from *B. exitiosa* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with *B. exitiosa* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the *Aquatic Manual*) may be declared free from *B. exitiosa* when:
 - a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the past 2 years without detection of *B. exitiosa*.

OR

4. A *zone* previously declared free from *B. exitiosa* but in which the *disease* is detected may be declared free from *B. exitiosa* again when the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

- b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
- c) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the past 2 years without detection of *B. exitiosa*; and
- d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 11.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *B. exitiosa* following the provisions of points 1 or 2 of Articles 11.1.4. or 11.1.5. (as relevant) may maintain its status as *B. exitiosa* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *B. exitiosa* following the provisions of point 3 of Articles 11.1.4. or 11.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *B. exitiosa* free provided that conditions that are conducive to clinical expression of infection with *B. exitiosa*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *B. exitiosa*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 11.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *B. exitiosa*

When importing live *aquatic animals* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* declared free from *B. exitiosa*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 11.1.4. or 11.1.5. (as applicable), whether the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from *B. exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.10.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.

Article 11.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *B. exitiosa*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *B. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of all effluent and waste material in a manner that ensures inactivation of *B. exitiosa*.
2. If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.
3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: <http://www.ices.dk/indexfla.asp>) may be summarised to the following main points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health/disease history;
 - c) take and test samples for *B. exitiosa*, pests and general health/disease status;
 - d) import and quarantine in a secure facility a founder (F-0) population;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *B. exitiosa* and perform general examinations for pests and general health/disease status;
 - g) if *B. exitiosa* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as free of infection with *B. exitiosa* or specific pathogen free (SPF) for *B. exitiosa*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.

Article 11.1.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *B. exitiosa*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *B. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *B. exitiosa*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.

Article 11.1.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *B. exitiosa*

When importing *aquatic animal products* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* declared free from *B. exitiosa*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 11.1.4. or 11.1.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *B. exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.10.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.

Article 11.1.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *B. exitiosa*

When importing *aquatic animal products* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *B. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk mitigation* measures.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.