CHAPTER 9.3.

INFECTION WITH HEPATOBACTER PENAEI (NECROTISING HEPATOPANCREATITIS)

Article 9.3.1.

For the purposes of the *Aquatic Code*, infection with *Hepatobacter penaei* means *infection* with the *pathogenic agent Candidatus Hepatobacter penaei*, an obligate intracellular bacterium of the Order alpha-Proteobacteria. The *disease* is commonly known as necrotising hepatopancreatitis.

Information on methods for diagnosis is provided in the Aquatic Manual.

Article 9.3.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: whiteleg shrimp (*Penaeus vannamei*).

Article 9.3.3.

Importation or transit of aquatic animal products for any purpose regardless of the infection with *H. penaei* status of the exporting country, zone or compartment

- 1) Competent Authorities should not require any conditions related to *H. penaei*, regardless of the infection with *H. penaei* status of the exporting country, zone or compartment, when authorising the importation or transit of the following aquatic animal products derived from a species referred to in Article 9.3.2. that are intended for any purpose and comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent that has been demonstrated to inactivate *H. penaei*);
 - b) cooked crustacean products that have been subjected to heat treatment at 100°C for at least three minutes (or any time/temperature equivalent that has been demonstrated to inactivate *H. penaei*);
 - c) pasteurised crustacean products that have been subjected to heat treatment at 63°C for at least 30 minutes (or any time/temperature equivalent that has been demonstrated to inactivate *H. penaei*);
 - d) crustacean oil;
 - e) crustacean meal;
 - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animal products* derived from a species referred to in Article 9.3.2., other than those referred to in point 1 of Article 9.3.3., *Competent Authorities* should require the conditions prescribed in Articles 9.3.7. to 9.3.12. relevant to the infection with *H. penaei* status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of *aquatic animal products* derived from a species not referred to in Article 9.3.2. but which could reasonably be expected to pose a *risk* of transmission of *H. penaei*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this analysis.

Article 9.3.4.

Country free from infection with H. penaei

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with *H. penaei* if all the areas covered by the shared water bodies are declared countries or *zones* free from infection with *H. penaei* (see Article 9.3.5.).

As described in Article 1.4.6., a country may make a self-declaration of freedom from infection with H. penaei if:

1) none of the *susceptible species* referred to in Article 9.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the susceptible species referred to in Article 9.3.2. are present and the following conditions have been met:
 - a) there has been no occurrence of infection with H. penaei for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the Aquatic Manual); and
 - b) basic biosecurity conditions have been continuously met for at least the last two years;

OR

- 3) the infection with *H. penaei* status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) basic biosecurity conditions have been continuously met for at least the last two years; and
 - b) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of *H. penaei*;

OR

- 4) it previously made a *self-declaration of freedom* from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* but the following conditions have been met:
 - a) on detection of *H. penaei*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *H. penaei*, and the appropriate *disinfection* procedures (as described in Chapter 4.3.) have been completed; and
 - c) previously existing basic biosecurity conditions have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *H. penaei*; and
 - d) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of H. penaei.

In the meantime, part or all of the unaffected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 9.3.5.

Article 9.3.5.

Zone or compartment free from infection with *H. penaei*

If a zone or compartment extends over more than one country, it can only be declared a zone or compartment free from infection with *H. penaei* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from infection with *H. penaei* may be declared free by the *Competent Authority* of the country concerned if:

 none of the susceptible species referred to in Article 9.3.2. are present in the zone or compartment and basic biosecurity conditions have been continuously met for at least the last two years; OR

- 2) any of the susceptible species referred to in Article 9.3.2. are present in the zone or compartment and the following conditions have been met:
 - a) there has not been any occurrence of infection with H. penaei for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the Aquatic Manual); and
 - b) basic biosecurity conditions have been continuously met for at least the last two years;

OR

- 3) the infection with *H. penaei* status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) basic biosecurity conditions have been continuously met for at least the last two years; and
 - b) targeted surveillance, as described in Chapter 1.4., has been in place, in the zone or compartment, for at least the last two years without detection of *H. penaei*;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* in the *zone* but the following conditions have been met:
 - a) on detection of *H. penaei*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *H. penaei*, and the appropriate *disinfection* procedures (as described in Chapter 4.3.) have been completed; and
 - c) previously existing basic biosecurity conditions have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *H. penaei*; and
 - targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of *H. penaei*.

Article 9.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *H. penaei* following the provisions of points 1 or 2 of Articles 9.3.4. or 9.3.5. (as relevant) may maintain its status as free from infection with *H. penaei* provided that *basic biosecurity conditions* are continuously maintained.

A country, zone or compartment that is declared free from infection with *H. penaei* following the provisions of point 3 of Articles 9.3.4. or 9.3.5. (as relevant) may discontinue targeted surveillance and maintain its free status provided that conditions that are conducive to clinical expression of infection with *H. penaei*, as described in the corresponding chapter of the *Aquatic Manual*, 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 *H. penaei, targeted surveillance* should be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.3.7.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *H. penaei*

When importing aquatic animals of a species referred to in Article 9.3.2., or aquatic animal products derived thereof, from a country, zone or compartment declared free from infection with *H. penaei*, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.3.4. or 9.3.5. (as applicable) and 9.3.6., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *H. penaei*.

The international aquatic animal health certificate should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to aquatic animal products listed in point 1 of Article 9.3.3.

Article 9.3.8.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *H. penaei*

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.3.2. from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

- 1) If the intention is to grow out and harvest the imported aquatic animals, consider applying the following:
 - a) the direct delivery to and lifelong holding of the imported aquatic animals in a quarantine facility; and
 - b) before leaving quarantine (either in the original facility or following biosecure transport to another quarantine facility) the aquatic animals are killed and processed into one or more of the aquatic animal products referred to in point 1 of Article 9.3.3. or other products authorised by the Competent Authority; and
 - c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *H. penaei* in accordance with Chapters 4.3., 4.7. and 5.5.

OR

- 2) If the intention is to establish a new stock for aquaculture, consider applying the following.
 - a) In the exporting country:
 - i) identify potential source populations and evaluate their aquatic animal health records;
 - ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of aquatic animals with a high health status for infection with *H. penaei*.
 - b) In the importing country:
 - i) import the F-0 population into a *quarantine* facility;
 - ii) test the F-0 population for *H. penaei* in accordance with Chapter 1.4. to determine their suitability as broodstock;
 - iii) produce a first generation (F-1) population in *quarantine*;
 - iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *H. penaei*, and sample and test for *H. penaei* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.3. of *Aquatic Manual*;
 - v) if *H. penaei* is not detected in the F-1 population, it may be defined as free from infection with *H. penaei* and may be released from *quarantine*;
 - vi) if *H. penaei* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.7.

Article 9.3.9.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *H. penaei*

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.3.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- the consignment is delivered directly to, and held in, quarantine or containment facilities until processing into one
 of the products referred to in point 1 of Article 9.3.3. or in point 1 of Article 9.3.12., or other products authorised by
 the Competent Authority; and
- 2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.3., 4.7. and 5.5.; and
- 3) all effluent and waste materials are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.3. and 4.7.

For these aquatic animals or aquatic animal products Member Countries may wish to consider introducing internal measures to address the *risks* associated with the aquatic animal or aquatic animal product being used for any purpose other than for human consumption.

Article 9.3.10.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *H. penaei*

When importing aquatic animals of a species referred to in Article 9.3.2., or aquatic animal products derived thereof, intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with H. penaei, the Competent Authority of the importing country should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in point 1 of Article 9.3.3. or other products authorised by the *Competent Authority*; and
- 2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.3., 4.7. and 5.5.; and
- all effluent and waste materials are treated to ensure inactivation of H. penaei or disposed of in a biosecure manner in accordance with Chapters 4.3. and 4.7.

Article 9.3.11.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *H. penaei*

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.3.2. from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should ensure:

- the consignment is delivered directly to, and held in, quarantine facilities authorised by the Competent Authority;
 and
- 2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.3., 4.7. and 5.5.; and
- 3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.3. and 4.7.; and
- 4) the carcasses are disposed of in accordance with Chapter 4.7.

Article 9.3.12.

Importation (or transit) of aquatic animal products for retail trade for human consumption regardless of the infection with *H. penaei* status of the exporting country, zone or compartment

1) Competent Authorities should not require any conditions related to *H. penaei*, regardless of the infection with *H. penaei* status of the *exporting country*, zone or compartment, when authorising the importation (or transit) of frozen peeled shrimp (shell off, head off) that have been prepared and packaged for retail trade and comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions

- For these aquatic animal products Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.
- When importing aquatic animal products, other than those referred to in point 1 above, derived from a species referred to in Article 9.3.2. from a country, zone or compartment not declared free from infection with H. penaei, the Competent Authority of the importing country should assess the risk and apply appropriate risk mitigation measures.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2019.