

Aquatic Animal Health Standards Commission

September 2012 Report

USA Comments - recommended changes shown in blue font

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

Article 10.5.1.

For the purposes of the *Aquatic Code*, infectious salmon anaemia (ISA) means *infection* with all genetically differentiated variants of ISA virus (ISAV) of the genus *Isavirus* of the family Orthomyxoviridae.

Rationale: Added text provided for additional scientific accuracy.

General comment: This Article will necessitate changes to the corresponding *Manual* chapter on ISAV which requires confirmation of ISAV by virus isolation in cell culture, rather than by molecular techniques.

~~There is a link between non-pathogenic HPR0 ISAV and the emergence of pathogenic HPR-deleted ISAV, with some outbreaks potentially occurring as a result of the emergence of HPR-deleted from HPR0.~~

Rationale: This statement is not technically correct. Field evidence is still inconclusive on this topic. Local studies (e.g., Norway) show a spatial relationship between deleted and non-deleted ISAV. However, whether and how these are linked temporally (and whether one precedes the other) is unclear. Other regions have not had the same experience. For example, outbreaks of ISA in North America are typically classified as North American genotype, while the HPR0 findings have been classified as European genotype.

~~There are 3 possible levels of disease status with respect to ISAV: (i) HPR-deleted ISAV and HPR0 ISAV free; (ii) HPR0 ISAV endemic (but HPR-deleted ISAV free); (iii) HPR-deleted ISAV and HPR0 ISAV endemic.~~

Rationale: This proposed disease status designation is based on the sequence of highly polymorphic regions (HPR) of genomic segment six which encodes the haemagglutinin esterase (HE) protein. Determining that there are only “3 possible levels of disease status with respect to ISAV” based on this very narrow view of genetic diversity limits the vision of scientific research.

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

Article 10.5.2.

Scope

The recommendations in this Chapter apply to: Atlantic salmon (*Salmo salar*), brown trout (*S. trutta*) and rainbow trout (*Oncorhynchus mykiss*). These recommendations also apply to any other *susceptible species*

referred to in the *Aquatic Manual* when traded internationally.

Article 10.5.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infectious salmon anaemia

1. *Competent Authorities* should not require any ISA related conditions, regardless of the ISA status of the *exporting country, zone or compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.5.2. intended for any purpose and complying with Article 5.3.1.:
 - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate ISAV);
 - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate ISAV);
 - d) fish oil;
 - e) fish *meal*; and
 - f) fish skin leather.
2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.5.2., other than those referred to in point 1 of Article 10.5.3., *Competent Authorities* should require the conditions prescribed in Articles 10.5.10. to 10.5.17. relevant to the ISA status of the *exporting country, zone or compartment*.
3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country, zone or compartment* not declared free of ISA of a species not covered in Article 10.5.2. but which could reasonably be expected to pose a *risk* of transmission for ISA, *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 10.5.4.

Country free of infectious salmon anaemia

In this article, all statements refer to a country free of infection with ISAV for any detectable ISAV, including HPR0 ISAV.

A country may make a *self-declaration of freedom* from ISA 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 ISA if all the areas covered by the shared water are declared ISA free countries or *zones* (see Article 10.5.5.).

1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from ISA when *basic biosecurity conditions* have been continuously met in the country for at least the past two years.

OR

2. A country where the species referred to in Article 10.5.2. are present but there has been no detectable

occurrence of the any ISA virus may make a *self-declaration of freedom* from ISA when:

- a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
- b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV.

OR

3. A country that has made a *self-declaration of freedom* from ISA but in which any ISAV is subsequently detected may make a *self-declaration of freedom* from ISA again when the following conditions have been met:
 - a) on detection of any ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past two 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 10.5.6.

Article 10.5.5.

Country free of infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country free of infection with HPR-deleted ISAV but not necessarily free from HPR0 ISAV.

A country may make a *self-declaration of freedom* from infection with HPR-deleted ISAV 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 infection with HPR-deleted ISAV if all the areas covered by the shared water are declared countries or *zones* free of infection with HPR-deleted ISAV (see Article 10.5.6.).

1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the country for at least the past two years.

OR

2. A country where the species referred to in Article 10.5.2. are present but there has been no observed occurrence of the *disease* for at least the past ten years despite conditions 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 infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the country for at least the past ten years.

OR

3. A country where the last observed occurrence of the *disease* was within the past ten 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 infection with HPR-deleted ISAV when:
 - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at

least the last two years without detection of HPR-deleted ISAV.

OR

4. A country that has made a *self-declaration of freedom* from infection with HPR-deleted ISAV but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from infection with HPR-deleted ISAV again when the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection 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 last two years without detection of HPR-deleted ISAV; 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 two 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 10.5.6.

Article 10.5.6.

Zone or compartment free of infectious salmon anaemia virus

In this article, all statements referring to a zone or compartment free of ISAV are for any detectable ISAV, including HPR0.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from infection with ISAV may be 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.

1. A *zone* or *compartment* where none of the *susceptible species* is present may be declared free from ISA when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past two years.

OR

2. A *zone* or *compartment* where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of ISA virus (including HPR0) may be declared free from ISA when
 - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV.

OR

3. A *zone* or *compartment* previously declared free from any ISA virus but in which any ISA virus is detected, may be declared free from ISA again when the following conditions have been met:
 - a) on detection of ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary

and have continuously been in place for at least the past two years.

Article 10.5.7.

Zone or compartment free of infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements referring to a zone or compartment free of infection with HPR-deleted ISAV but not necessarily free from HPR0 ISAV.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from infection with HPR-deleted ISAV may be 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.

1. A *zone* or *compartment* where none of the *susceptible species* is present may be declared free from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past two years.

OR

2. A *zone* or *compartment* where the species referred to in Article 10.5.2. are present but there has been no observed occurrence of the *disease* for at least the past ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past ten years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past ten 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 infection with HPR-deleted ISAV when:
 - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of HPR-deleted ISAV.

OR

4. A *zone* previously declared free from infection with HPR-deleted ISAV but in which the *disease* is detected may be declared free from infection with HPR-deleted ISAV again when the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection 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 last two years without detection of HPR-deleted ISAV; 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 two years.

Article 10.5.8.

Maintenance of free status for infectious salmon anaemia virus

A country, *zone* or *compartment* that is declared free from ISA following the provisions of point 1. of Articles

10.5.4. or 10.5.7. (as relevant) may maintain its status as ISA free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from ISA following the provisions of point 2 of Articles 10.5.4. or 10.5.7. (as relevant) must continue *targeted surveillance* to maintain its status as ISA free and *basic biosecurity conditions* are continuously maintained.

Article 10.5.9.

Maintenance of free status for infection with HPR-deleted infectious salmon anaemia virus

A country, *zone* or *compartment* that is declared free from infection with HPR-deleted ISAV following the provisions of points 1 or 2 of Articles 10.5.4. or 10.5.6. (as relevant) may maintain its free status provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from infection with HPR-deleted ISAV following the provisions of point 3 of Articles 10.5.4. or 10.5.6. (as relevant) may discontinue *targeted surveillance* and maintain its free status provided that conditions that are conducive to clinical expression of ISA, 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 an infected country and in all cases where conditions are not conducive to clinical expression of ISA, *targeted surveillance* needs to be continued at a level determined by the ~~*Aquatic Animal Health Service*~~ *Competent Authority* on the basis of the likelihood of infection.

Rationale: Suggested change is the more appropriate use of the terminology

Article 10.5.10.

Importation of live aquatic animals from a country, zone or compartment declared free from infectious salmon anaemia

When importing live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from ISA, 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* certifying that, on the basis of the procedures described in Articles 10.5.4. or 10.5.6. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from ISA.

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 10.5.3.

Article 10.5.11.

Importation of live aquatic animals from a country, zone or compartment declared free from infection with HPR-deleted infectious salmon anaemia virus

When importing live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from infection with HPR-deleted ISAV, 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* certifying that, on the basis of the procedures described in Articles 10.5.5. or 10.5.7. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from infection with HPR-deleted ISAV.

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 10.5.3.

Article 10.5.12.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious salmon anaemia

1. When importing, for *aquaculture*, live *aquatic animals* of the species referred to in Article 10.5.2. from a country, zone or compartment not declared free from ISA, 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 materials in a manner that ensures inactivation of ISAV.
2. If the intention of the introduction is the establishment of a new stock, relevant aspects of 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 considered.
3. For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/pubs/Miscellaneous/ICESCodeofPractice.pdf>) may be summarised to the following 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 ISAV, 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 ISAV and perform general examinations for pests and general health/disease status;
 - g) if ISAV 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 ISA free or specific pathogen free (SPF) for ISAV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, zone or compartment.
4. With respect to point 3e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

Article 10.5.13.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infectious salmon anaemia

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.5.2. from a country, zone or compartment not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1 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 10.5.3., or products described in point 1 of Article 10.5.16., or other products authorised by the *Competent Authority*; and
- 2 all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* 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.

Article 10.5.14.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from infectious salmon anaemia

When importing, for use in animal *feed*, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require that:

- 1 the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the *Competent Authority*; and
- 2 all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.15.

Importation of aquatic animal products from a country, zone or compartment declared free from infection with infectious salmon anaemia virus

When importing *aquatic animal products* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from infection with ISAV, 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* certifying that, on the basis of the procedures described in Articles 10.5.4., 10.5.5., 10.5.6. or 10.5.7. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from ISA.

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 10.5.3.

Article 10.5.16.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infectious salmon anaemia

1. *Competent Authorities* should not require any ISA related conditions, regardless of the ISA status of the *exporting country, zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:
 - a) fish fillets or steaks (frozen or chilled).

For these *commodities* 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 importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.5.17.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infectious salmon anaemia

1. When importing disinfected eggs of the species referred to in Article 10.5.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:
 - a) the ISA virus status of the water to be used during the *disinfection* of the eggs;
 - b) the level of *infection* with ISA virus in broodstock (ovarian fluid and milt); and
 - c) the temperature and pH of the water to be used for *disinfection*.
2. If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:
 - a) the eggs should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* (under study) or those specified by the *Competent Authority* of the *importing country*; and
 - b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status.

OIE Members may wish to consider internal measures, such as renewed *disinfection* of the eggs upon arrival in the *importing country*.
3. When importing disinfected eggs of the species referred to in Article 10.5.2. for aquaculture, from a country, *zone* or *compartment* not declared free from ISA, 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* attesting that the procedures described in point 2 of this article have been fulfilled.

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