

USA COMMENTS
INFECTIOUS SALMON ANAEMIA

Article 10.5.1.

For the purposes of the *Aquatic Code*, infectious salmon anaemia (ISA) means *infection* with any genotype of ISA Virus HPR0 ISA virus or with ISA virus (ISAV) having deletions in the HPR region (hereafter named HPR-deleted ISA virus) (ISAV) of the genus *Isavirus* of the family Orthomyxoviridae.

Rationale : Pathogenic genotypes of ISAV include European and North American virus isolates which have been described as having deletions in the highly polymorphic region (HPR) of segment 6 of the hemagglutinin esterase gene. An apparently non-pathogenic genotype of European ISAV descent, but without HPR deletions, has also been identified. This genotype (referred to as ISAV HPR0) has been detectable to date only through molecular-based assays. The United States recommends that it is more appropriate to use a standard of ‘confirmation’ as a criterion for pathogen detection rather than trying to characterize concerns about ISAV in terms of the known and potential genotypes involving molecular deletions of any sort. If HPR0 (or any similar genotype) turns out to be capable of being isolated through cell culture in the future with associated pathology, then inclusion within the OIE Code would be appropriate.

In addition, listing ISAV HPR0 as separate category is not appropriate based on the Criteria for Listing Aquatic Animal Diseases (Chapter 1.2):

A. Consequences

1. HPR0 has not been shown to cause significant production losses at a national or multinational level.
2. HPR0 has not been shown to cause morbidity or mortality in wild animals
3. HPR0 is not a public health concern.

B. Spread

4. Infectious etiology associated with HPR0 is not proven.
5. Disease associated with HPR0 detections has not been proven.
6. International spread of HPR0 through fish movement is a point of debate.
7. Ability to declare freedom from disease is unclear as tests have not been validated for HPR0 detection, the sensitivity and specificity of the tests is unknown, and the gold standard test for HPR0 is not yet identified. HPR0 detections in the absence of disease occurs in Atlantic Salmon farming regions. HPR0 can exist at very low or relatively high prevalence without apparent consequence. Consequently, appropriate levels of detection are not immediately evident, and would need to be specified for a disease freedom claim to be of any merit.
8. Availability of a repeatable and robust method of detection is debatable. Multiple molecular assays are being used each with varying levels of standardization and validation. The significance of the detection in regards to spread and pathogenesis is unknown at this time.

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

Article 10.5.2.

Scope

The recommendations in this Chapter apply to: Atlantic salmon (*Salmo salar*), brown ~~and sea~~ trout (also called sea 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.

Rationale : Editorial comments.

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 10.5.7. to 10.5.12 ~~11~~. relevant to the ISA status of the *exporting country, zone or compartment*.

Rationale : Since the United States recommends deleting Article 10.5.7., the indicated Articles would need to be renumbered if the suggestion is adopted.

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 based on sufficient scientific evidence 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.

Rationale : Clarifying comment.

Article 10.5.4.

HPR-deleted Infectious salmon anaemia free country

In Article 10.5.4, all statements referring to HPR-deleted ISA freedom are applicable to genotypes of ISA Virus that have been confirmed through virus isolation as present in species listed in 10.5.2 only for detectable ISA virus identified as other than HPR0. A country may make a *self-declaration of freedom* from HPR-deleted 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 HPR-deleted ISA if all the areas covered by the shared water are declared HPR-deleted ISA free countries or *zones* (see Article 10.5.6).

1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from HPR-deleted 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 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 HPR-deleted ISA 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 HPR-deleted 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 HPR-deleted ISAV.

OR

4. A country that has made a *self-declaration of freedom* from HPR-deleted ISA but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from HPR-deleted ISA 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 following re-introduction of clinically-susceptible species 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.

Rationale : Please see the rationale for deleting references to HPR0 under Article 10.5.1.

Article 10.5.5.

Infectious salmon anaemia (including HPR0) free country

In Article 10.5.5, all statements referring to ISA are for any detectable ISA virus, including HPR0. A country may make a self-declaration of freedom from ISA (including HPR0) 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 (including HPR0) if all the areas covered by the shared water are declared ISA (including HPR0) 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 (including HPR0) 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 (including HPR0) may make a self-declaration of freedom from ISA (including HPR0) when:

a) basic biosecurity conditions have been continuously met for at least the past four years; and

b) targeted surveillance, as described in Chapter 1.4. of the Aquatic Code, has been in place for at least the last four years without detection of ISAV, including HPR0.

OR

3. A country that has made a self-declaration of freedom from ISA but in which any ISA virus (including HPR0) is subsequently detected may make a self-declaration of freedom from ISA (including HPR0) again when the following conditions have been met:

a) on detection of any ISA virus (including HPR0), 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 four years without detection of ISAV (including HPR0); 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 four 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 10.5.5.

Rationale : Please refer to our rationale for deleting the references to HPR0 under Article 10.5.1.

Article 10.5.5-6.

HPR-deleted Infectious salmon anaemia free zone or free compartment

In Article 10.5.6, all statements referring to HPR-deleted ISA freedom are applicable to genotypes of ISA virus that have been confirmed through virus isolation as present in species listed in 10.5.2 only for detectable ISA virus identified as other than HPR0. A *zone* or *compartment* within the *territory* of one or more countries not declared free from HPR-deleted ISA 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 HPR-deleted 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 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 HPR-deleted ISA 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 HPR-deleted 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 HPR-deleted ISAV.

OR

4. A *zone* previously declared free from HPR-deleted ISA but in which the *disease* is detected may be declared free from HPR-deleted ISA 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 ~~HPR0~~ 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.

Rationale : Please see the rationale for deleting the references to HPR0 under Article 10.5.1.

Article 10.5.7.

Infectious salmon anaemia (including HPR0) free zone or free compartment

~~In Article 10.5.7, all statements referring to ISA are for any detectable ISA virus, including HPR0. A zone or compartment within the territory of one or more countries not declared free from ISA 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 (including HPR0) 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 (including HPR0) when
 - ~~a) basic biosecurity conditions have been continuously met for at least the past four years; and~~
 - ~~b) targeted surveillance, as described in Chapter 1.4. of the Aquatic Code, has been in place for at least the last four years without detection of ISAV (including HPR0).~~~~

OR

- ~~3. A zone or compartment previously declared free from any ISA virus (including HPR0) but in which any ISA virus (including HPR0) is detected, may be declared free from ISA (including HPR0) again when the following conditions have been met:
 - ~~a) on detection of ISA virus (including HPR0), 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 four years without detection of ISAV (HPR0 or otherwise); 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 four years.~~~~

Rationale : Please see our rationale for deleting the references to HPR0 under Article 10.5.1.

Maintenance of ~~HPR-deleted~~ ISA free status

A country, *zone* or *compartment* that is declared free from ~~HPR-deleted~~ ISA following the provisions of points 1 or 2 of Articles 10.5.4. or 10.5.5~~6~~. (as relevant) may maintain its status as ~~HPR-deleted~~ ISA free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from ~~HPR-deleted~~ ISA following the provisions of point 3 of Articles 10.5.4. or 10.5.5~~6~~. (as relevant) may discontinue *targeted surveillance* and maintain its status as ~~HPR-deleted~~ ISA free 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 infected countries 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* on the basis of the likelihood of *infection*.

Rationale : Please see the rationale for deleting the references to HPR0 under Article 10.5.1.

~~Article 10.5.9.~~

Maintenance of ISA(including HPR0) free status

~~A country, *zone* or *compartment* that is declared free from ISA(including HPR0) following the provisions of point 1 of Articles 10.5.5. 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(including HPR0) following the provisions of point 2 of Articles 10.5.5. or 10.5.7. (as relevant) must continue *targeted surveillance* to maintain its status as ISA(including HPR0) free and *basic biosecurity conditions* are continuously maintained.~~

Rationale : Please see the rationale for deleting the references to HPR0 under Article 10.5.1.

Article 10.5.7~~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 10.5.5. (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 10.5.8.11

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 10.5.9.12

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 10.5.12., 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.~~10~~.13

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.~~11~~.14

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

When importing *aquatic animal products* 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 10.5.5.~~ 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.~~12~~.15

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.~~13~~.16

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 Article 10.5.~~13~~.16. have been fulfilled.

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