## USA COMMENTS IN BLUE FONT

**Annex 17. Item 6.8. – Draft new Chapter 10.X. ‘Infection with *Megalocytivirus pagrus 1*’**

CHAPTER 10.X.

**INFECTION WITH *MEGALOCYTIVIRUS PAGRUS 1***

**Article 10.X.1.**

For the purposes of the *Aquatic Code*, infection with *Megalocytivirus pagrus 1* means *infection* with the *pathogenic agent* *Megalocytivirus pagrus 1* (including the genogroups infectious spleen and kidney necrosis virus, red sea bream iridovirus and turbot reddish body iridovirus) of the Genus *Megalocytivirus* and Family Iridoviridae.

All three genogroups should be notified in accordance with Chapter 1.1.

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

**Article 10.X.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.:

|  |  |  |  |
| --- | --- | --- | --- |
| **Family** | **Species** | **Common name** | **Genotype** |
| Apogonidae | *Pterapogon kauderni* | Banggai cardinalfish |  |
| Butidae | *Oxyeleotris marmorata* | marble goby |  |
| Carangidae | *Pseudocaranx dentex* | white trevally |  |
| *Seriola spp.* (all species) | N/A |  |
| *Trachinotus spp.* (all species) | N/A |  |
| *Trachurus japonicus* | Japanese jack mackerel |  |
| Centrarchidae | *Lepomis macrochirus* | bluegill |  |
| Cichlidae | *Astronotus ocellatus* | Oscar |  |
| *Etroplus suratensis* | pearlspot |  |
| *Oreochromis niloticus* | Nile tilapia |  |
| *Pterophyllum spp.* (all species) | N/A |  |
| Cyprinidae | *Epalzeorhynchos frenatum* | rainbow sharkminnow |  |
| Danionidae | *Danio rerio* | zebrafish |  |
| Ephippidae | *Platax orbicularis* | orbiculate batfish |  |
| Girellidae | *Girella punctata* | largescale blackfish |  |
| Haemulidae | *Parapristipoma trilineatum* | chicken grunt |  |
| *Plectorhinchus cinctus* | crescent sweetlips |  |
| Latidae | *Lates calcarifer* | barramundi |  |
| Lethrinidae | *Lethrinus spp.* (all species) | N/A |  |
| Mugilidae | *Mugil cephalus* | flathead grey mullet |  |
| Nothobranchiidae | *Aphyosemion gardneri* | steel blue killifish |  |
| Oplegnathidae | *Oplegnathus spp.* (all species) | N/A |  |
| Osphronemidae | *Macropodus opercularis* | paradise fish |  |
| *Osphronemus goramy* | giant gourami |  |
| *Trichogaster lalius* | dwarf gourami |  |
| *Trichopodus spp.* (all species) | N/A |  |
| Paralichthyidae | *Paralichthys olivaceus* | bastard halibut |  |
| Percichthyidae | *Maccullochella peelii* | Murray cod |  |
| Pleuronectidae | *Verasper variegatus* | spotted halibut |  |
| Poeciliidae | *Poecilia spp.* (all species) | N/A |  |
| *Xiphophorus spp.* (all species) | N/A |  |
| Procatopodidae | *Poropanchax normani* | Norman's lampeye |  |
| Rachycentridae | *Rachycentron canadum* | Cobia |  |
| Sciaenidae | *Larimichthys crocea* | large yellow croaker |  |
| *Sciaenops ocellatus* | red drum |  |
| Scombridae | *Scomber japonicus* | chub mackerel |  |
| *Scomberomorus niphonius* | Japanese Spanish mackerel |  |
| *Thunnus orientalis* | Pacific bluefin tuna |  |
| Scophthalmidae | *Scophthalmus maximus* | turbot |  |
| Serranidae | *Epinephelus spp.* (all species) | N/A |  |
| Sinipercidae | *Siniperca chuatsi* | Mandarin fish |  |
| Sparidae | *Acanthopagrus schlegelii* | blackhead seabream |  |
| *Dentex tumifrons* | yellowback seabream |  |
| *Pagrus major* | red sea bream |  |
| Stromateidae | *Pampus argenteus* | silver pomfret |  |
| Synanceiidae | *Inimicus japonicus* | no common name |  |
| Tetraodontidae | *Takifugu rubripes* | tiger pufferfish |  |

**Category:** [addition, deletion, change, editorial, general]

Addition.

**Proposed amended texts (or precise suggested deletion):**

We strongly recommend including a column to the susceptible species table above (similar to the VHS Manual Chapter, for example) which will specify which species are considered susceptible to which of the genogroups.

**Rationale:**

While it is helpful to have the species susceptibility listed by genogroup in the manual chapter, it is also important to include this information in the code chapter since it is critical members know which species need to be tested/certified free from which genogroup for trade purposes. The genotype specificity is also important for trade certification since a given diagnostic assay may not cover all genogroups.

**Article 10.X.3.**

**Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *M. pagrus 1* status of the exporting country, zone or compartment**

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *M. pagrus 1*, regardless of the infection with *M. pagrus 1* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates *M. pagrus 1*;

2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates *M. pagrus 1*;

3) fish oil;

4) fish skin leather.

**Article 10.X.4.**

**Requirements for self-declaration of freedom from infection with *M. pagrus 1***

A Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.X.5. to 10.X.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

**Article 10.X.5.**

**Country free from infection with *M. pagrus 1***

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. pagrus 1* if all shared water bodies are within countries or *zones* declared free from infection with *M. pagrus 1* (see Article 10.X.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for its entire *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for infection with *M. pagrus 1*;

OR

2) there has been no occurrence of infection with *M. pagrus 1* for at least the last ten years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. pagrus 1*, as described in in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *M. pagrus 1*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *M. pagrus 1* and subsequently lost its free status due to the detection of *M. pagrus 1* but the following conditions have been met:

a) on detection of *M. pagrus 1*, 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 *M. pagrus 1*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; 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 *M. pagrus 1*; and

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

i) at least the last two years in wild and farmed *susceptible species* without detection of *M. pagrus 1*; or

ii) at least the last one year without detection of *M. pagrus 1* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

**Article 10.X.6.**

**Zone free from infection with *M. pagrus 1***

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *M. pagrus 1* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for a *zone* within its *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for this disease;

OR

2) there has been no occurrence of infection with *M. pagrus 1* for at least the last ten years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. pagrus 1*, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two years without detection of *M. pagrus 1*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *M. pagrus 1* and subsequently lost its free status due to the detection of *M. pagrus 1* in the *zone* but the following conditions have been met:

a) on detection of *M. pagrus 1*, 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 *M. pagrus 1*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; 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 *M. pagrus 1*; and

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

i) at least the last two years in wild and farmed *susceptible species* without detection of *M. pagrus 1*; or

ii) at least the last one year without detection of *M. pagrus 1* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

**Article 10.X.7.**

**Compartment free from infection with *M. pagrus 1***

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one year without detection of *M. pagrus 1*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *M. pagrus 1* and subsequently lost its free status due to the detection of *M. pagrus 1* in the *compartment* but the *following* conditions have been met:

a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus 1*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

b) previously existing *basic biosecurity conditions*, including the *compartment* *biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.X.9. and 10.X.10. as appropriate; and

c) one survey for infection with *M. pagrus 1* has been completed at least six months after restocking (as described in Article 1.4.14.) without detection of the pathogen.

**Article 10.X.8.**

**Maintenance of free status**

A country, *zone* or *compartment* that is declared free from infection with *M. pagrus 1* following the provisions of Articles 10.X.4. to 10.X.7. (as relevant) may maintain its status as free from infection with *M. pagrus 1* provided that the requirements described in Article 1.4.15. are continuously maintained.

**Article 10.X.9.**

**Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *M. pagrus 1***

When importing *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *M. pagrus 1*, 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 10.X.5., 10.X.6. or 10.X.7. (as applicable) and 10.X.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *M. pagrus 1*.

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 Article 10.X.3.

**Article 10.X.10.**

**Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *M. pagrus 1***

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, 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 Article 10.X.3. or other products authorised by the *Competent Authority*; and

c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *M. pagrus 1* in accordance with Chapters 4.4., 4.8. 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 *M. pagrus 1* .

b) In the *importing country*:

i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for *M. pagrus 1* 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 *M. pagrus 1*, and sample and test for *M. pagrus 1* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.8. of the *Aquatic Manual*;

v) if *M. pagrus 1* is not detected in the F-1 population, it may be defined as free from infection with *M. pagrus 1* and may be released from *quarantine*;

vi) if *M. pagrus 1* 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 4.8.

**Article 10.X.11.**

**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 *M. pagrus 1***

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, 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 Article 10.X.3. or in point 1 of Article 10.X.14., 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 *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4.and 4.8.

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 10.X.12.**

**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 *M. pagrus 1***

When importing *aquatic animals* of a species referred to in Article 10.X.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 *M. pagrus 1*, 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 Article 10.X.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 *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

**Article 10.X.13.**

**Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *M. pagrus 1***

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should ensure:

1) 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 *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. 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 *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

**Article 10.X.14.**

**Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *M. pagrus 1*****status of the exporting country, zone or compartment**

1) *Competent Authorities* should not require any conditions related to *M. pagrus 1* regardless of the infection with *M. pagrus 1* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

a) fish fillets or steaks (chilled).

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.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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