

Japan's comments on the Report of the meeting of the OIE Aquatic Animal Health Standards Commission in September 2018

Japan would like to express its appreciation to the Aquatic Animal Standards Commission and *ad hoc* Groups for all the works they have done. Japan also appreciates the Commission for providing us with the opportunity to comment on the proposed revisions to the OIE Aquatic Animal Health Code (hereinafter referred to as the Aquatic Code) and the OIE Manual of Diagnostic Tests for Aquatic Animals (hereinafter referred to as the Aquatic Manual) as well as the Discussion paper on Approaches for determining periods required to demonstrate disease freedom. Japan would like to submit the following comments for consideration by the Commission.

OIE Aquatic Animal Health Code

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OIE Manual of Diagnostic Tests for Aquatic Animals

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OIE Aquatic Animal Health Code

Annex 4 to of the report

Criteria for listing species as susceptible to infection with a specific pathogenic agent (Chapter 1.5.9)

Article 1.5.9.

Listing susceptible species at a taxonomic ranking of Genus or higher

Some *pathogenic agents* have low host species specificity and can infect numerous species across multiple taxa. These *pathogenic agents* are eligible for assessment using this article if they have at least one *susceptible species* in three or more taxa at the ranking of Family. The outcome of applying this article may be that *susceptible species* are listed in Article X.X.2. of each disease-specific chapter at a ranking of Genus or higher. For *pathogenic agents* that have a low host species specificity, a decision to conclude susceptibility of species at a taxonomic ranking of Genus or higher should only be made where:

1) more than one species within the taxonomic ranking has been found to be susceptible in accordance with the approach described in Article 1.5.3.;

AND

2) no species within the taxonomic ranking has been found to be non-susceptible to *infection*;

AND

3) the taxonomic ranking is at the lowest level supported by evidence of points A and B.

Evidence of non-susceptibility of a species to *infection* includes:

A. absence of *infection* over time demonstrated through *targeted surveillance* of a species exposed to the *pathogenic agent* in natural settings where the *pathogenic agent* is causing clinical *disease* in co-located populations of *susceptible species*;

OR

B. absence of *infection* in species exposed to the *pathogenic agent* through appropriately designed experimental procedures.

Comment :

Japan considers that some specific examples (either actual or fictitious cases) should be described to facilitate the understanding of this article. In one of such examples, a case in which a genus (or genera) is listed as a susceptible group should be described.

Rationale:

This article is still difficult to comprehend.

Following points are not very clear.

- (1) For the phrase in the first paragraph, “in three or more taxa at the ranking of Family”, it is not very clear whether the word, taxa (underlined), means different Families or lower taxa within the Family concerned, although we assume the former is correct.
- (2) The first paragraph of the article indicates that there must be susceptible species in more

than three Families for the assessment using this article (if we understand correctly). A genus can be listed as a susceptible host group, however, according to the following paragraphs. Although there is logically no contradiction in these descriptions, as it is stated in p.7 of the commission report of September 2018, it is not immediately clear for readers.

Annex 10 to of the report

Infection with infectious haematopoietic necrosis virus (Chapter 10.6.)

Article 10.6.2. 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: Arctic charr (*Salvelinus alpinus*), Atlantic salmon (*Salmo salar*), brook trout (*Salvelinus fontinalis*), brown trout (*Salmo trutta*), chinook salmon (*Oncorhynchus tshawytscha*), chum salmon (*Oncorhynchus keta*), coho salmon (*Oncorhynchus kisutch*), cutthroat trout (*Onchorynchus clarkii*), lake trout (*Salvelinus namaycush*), **masou masu** salmon (*Oncorhynchus masou*), marble trout (*Salmo marmoratus*), rainbow trout or steelhead (*Oncorhynchus mykiss*), the Pacific salmon species (chinook [*Oncorhynchus tshawytscha*], sockeye [*Oncorhynchus nerka*], chum [*Oncorhynchus keta*], masou [*Oncorhynchus masou*], pink [*Oncorhynchus rhodurus*] and coho [*Oncorhynchus kisutch*]), and sockeye salmon (*Oncorhynchus nerka*) Atlantic salmon (*Salmo salar*). These recommendations also apply to any other susceptible species referred to in the *Aquatic Manual* when traded internationally.

Rationale:

Japan considers that “masu salmon” is appropriate as the common name of *Oncorhynchus masou*. It is because the term is used in the Report of the *ad hoc* Group on Susceptibility of fish species to infection with OIE listed diseases.

Annex 12 to of the report:

New draft chapter on Biosecurity for aquaculture establishments (Chapter 4.X.)

Comment :

Japan shares our recognition that it is important to establish a new chapter on biosecurity on aquaculture. It is because that it will make biosecurity at the level of country, zone or compartment more effective.

With regard to the proposed “Article 4.X.7 Risk analysis”, it is necessary to conduct risk analysis appropriately and to implement biosecurity according to the risk at the level of country, zone, compartment, or establishment. Therefore, "Article 4.X.7 Risk analysis" should not be placed in this chapter, but set up in Section 4 as a separate chapter. In addition, “Article 4.X.7 Risk analysis” should be applied when the biosecurity at any level of country, zone, compartment or establishment is implemented.

Furthermore, the new chapter of risk analysis should be consistent with the “Section 2. Risk Analysis” in the Aquatic Code. In the proposal, examples of risk assessment which is based on matrix of the likelihood estimate and consequence rating, are given. However, we are not sure

how to estimate likelihood and how to rate consequence in five categories. We consider that it is useful for evading the arbitrary assessment to show an objective and scientific criteria.

While the risk assessment in Step 2 will be conducted each pathogen which could be identified as a hazard, it is said that many of the hazards share the same infection pathways, and mitigation measures can be effective against more than one hazard in the risk management of Step 3.

Therefore, it is not important for implementing the risk management to determine the risk level for each pathogen in terms of the risk assessment.

Annex 13 to of the report:

Discussion paper on Approaches for determining periods required to demonstrate disease freedom

The comments on each discussion points summarized in Table 3 of the discussion paper are as follows.

Section 3.1. Pathway 1. Absence of susceptible species

1. Is Pathway 1 likely to be used by Member Countries?

Some Member countries have introduced new species from foreign countries for aquaculture production. They will use Pathway 1 to make self- declaration freedom as an importing country prior to introducing new species from foreign countries.

2. What is an appropriate standard of evidence that susceptible species are absent from a country?

Member countries can use national fisheries production statistics, landing records, and scientific papers on biology of aquatic animals as evidence of the absence of susceptible species.

Section 3.2. Pathway 2. Historical freedom

3. Are the proposed requirements for passive surveillance in farmed and wild aquatic animals appropriate?

There is a requirement of passive surveillance for wild aquatic animals. It requires that they must “be under sufficient observation such that if clinical signs of the disease were to occur they would be observed.” This is not feasible and there is no way to prove whether the requirement is satisfied or not. With this requirement, it is virtually impossible to make self-declaration of freedom by Pathway 2 only with passive surveillance, and then active surveillance is always required.

Occurrence of aquatic animal diseases is often observed in aquaculture establishments, and it is

hardly confirmed an occurrence in wild populations of migratory fish species and demersal fish species. In regards to such fish species, it is difficult to conclude that the occurrence of diseases will be observed only in wild populations, while no occurrence has been confirmed in aquaculture populations.

The requirement of passive surveillance related to wild aquatic animals should be deleted or applied only to animal species which inhabit observable waters and do not migrate (e.g. oysters inhabiting coastal waters).

4. Should historic freedom require that the disease has never been detected (as proposed) or is a period of freedom (e.g. ten years) sufficient?

With regard to historic freedom, a certain period should be set. The requirement of "the disease has never been detected" would cause inconsistency among Member countries because the period after establishment of early detection system differs for each Member country.

5. Are the factors for determining the required period of basic biosecurity conditions for listed diseases appropriate?

Japan thinks that the factor of "Production systems and management practices that would affect observations of clinical signs if they were to occur" should not be included in the criteria because production systems and management practices varies among Member countries and could be changed even in a short time. The period of basic biosecurity conditions, which is determined based on information from only some countries, may not be sufficient. In addition, frequent revisions of the period of basic biosecurity conditions should be avoided when production systems and management practices are changed.

Section 3.3. Pathway 3. Unknown disease status

6. Are the proposed criteria for determining the periods for basic biosecurity conditions for this pathway appropriate?

Japan thinks that the factor of "Production systems and management practices that would affect observations of clinical signs if they were to occur" should not be included in the criteria because production systems and management practices varies among Member countries and could be changed even in a short time. The period of basic biosecurity conditions, which is determined based on information from only some countries, may not be sufficient. In addition, frequent revisions of the period of basic biosecurity conditions should be avoided when production systems and management practices are changed.

7. Is one year an appropriate minimum period for basic biosecurity conditions to be in place

prior to the commencement of active surveillance for declaring freedom for countries or zones?

It is essential that basic biosecurity conditions are in place at the time of the commencement of active surveillance for declaring freedom for countries and zones. Japan believes that the period of basic biosecurity conditions prior to the commencement of active surveillance could be less than one year if there are scientific evidences on the period that prevalence sufficiently gets higher in order to detect specific diseases.

8. Is one survey per year (at least three months apart) for two years an appropriate default requirement?

We support that one survey per year for two years (at least three months apart) is an appropriate default requirement. Japan considers that the number of times of the survey per year could be flexible where passive surveillance can be demonstrated to be a sensitive method for detection of certain diseases.

Section 3.4. Pathway 4. Returning to freedom

9. Should countries and zones be able to return to freedom more quickly following an eradication programme than in an initial self-declaration of freedom for a country or zone (if appropriate criteria are met)?

Japan thinks that it is possible to return to freedom more quickly following the appropriate eradication programme than in an initial self-declaration of freedom in a country and zone. As pointed out in this paper, populations affected by disease are narrowly defined and can be cleaned by disposal of animals and disinfection of establishments. However, it is necessary to identify the pathway of introduction of the disease and to review the biosecurity conditions appropriately when the eradication programme is developed and implemented. After the programme, surveillance of populations at risk (epidemiological contacts or those at downstream) should be conducted adequately. It is because it is necessary for country or zone to confirm whether they meet the criteria of freedom or not.

10. Should compartments be able to regain freedom immediately after destocking and successful decontamination (i.e. with surveillance at the level required to maintain freedom) if basic biosecurity conditions have been reviewed and modified and restocking is with disease free animals (e.g. from a free country, zone or compartment)?

Appropriate biosecurity conditions can be implemented for more clearly defined populations in compartments than in a country or zone. Because of that, Japan supports that compartments regain freedom immediately after reviewing biosecurity conditions, destocking,

decontamination, and restocking disease-free animals.

11. When should the starting time point be for surveillance – e.g. commencement of sampling or at the conclusion of sampling for the first survey with negative results?

The start time for surveillance should be at commencement of sampling because the negative result from tests indicates it is negative at the time of sampling.

12. Should Chapter 1.4. provide clearer guidance on establishing infected and protection zones (perhaps in the proposed new chapter on emergency response) and sampling within them (for farmed and wild animals)?

Since animal species, diseases, and production systems for aquatic animal are diverse, it is difficult to formulate a universal guidance on establishing infected and protection zones. If Member countries would require the guidance, examples of infected and protection zones for typical aquaculture production could be included in the code.

Section 4. Maintaining freedom

13. Do Member Countries require additional guidance on what constitute ‘conditions conducive to clinical expression’?

Member countries can refer to disease information (host factors, transmission mechanism, geographical distribution, environmental factors, etc.) in the Aquatic Manual. Japan does not think that it is necessary to prepare for additional guidance on "conditions conducive to clinical expression".

14. Do Member Countries require additional guidance on how to evaluate or test their ‘early detection system’?

Japan would support development of additional guidance if there is guidance which evaluates and tests performance of early detection system easily and effectively. However, the evaluation and testing should not require significant cost and efforts.

Section 6. Requirements for making a self-declaration of freedom

15. Is the OIE procedure for the publication of a self-declaration of freedom sufficient guidance for Member Countries for making self-declarations of freedom? If not, should a separate chapter be provided within the Aquatic Code?

Publication of a self-declaration of freedom by OIE is useful information for the importing

country of aquatic animals to know the situation of exporting countries. On the other hand, it cannot substitute for consultation and on-site inspection between importing and exporting countries in trade of aquatic animals. Therefore, Japan believes that current OIE procedure is sufficient, and priorities of further improvement and addition to the Code are relatively low.

OIE Manual of Diagnostic Tests for Aquatic Animals

Annex 16 to of the report:

Infection with koi herpesvirus (Chapter 2.3.7.)

Article 2.2.2. Species with incomplete evidence for susceptibility

Species for which there is incomplete evidence for susceptibility according to Chapter 1.5. of the Aquatic Code include: Goldfish (*Carassius auratus*), grass carp (*Ctenopharyngodon idella*) and Syberian crucian carp (*Car~~assius~~ auratus carassius*).

Rationale:

To correct a typo of the scientific name of Syberian crucian carp.

Annex 17 to of the report:

Infection with infectious haematopoietic necrosis virus (Chapter 2.3.4.)

Article 2.2.1. Susceptible host species

Species that fulfil the criteria for listing as susceptible to infection with IHNV according to Chapter 1.5. of the Aquatic Animal Health Code (Aquatic Code) include: ~~The principal hosts for IHNV are members of the family Salmonidae. Species reported to be naturally infected with IHNV include~~ Arctic char (*Salvelinus alpinus*), Atlantic salmon (*Salmo salar*), brook trout (*Salvelinus fontinalis*), brown trout (*Salmo trutta*), chinook salmon (*Oncorhynchus tshawytscha*), chum salmon (*Oncorhynchus keta*), coho salmon (*Oncorhynchus kisutch*), cutthroat trout (*Onchorynchus clarkii*), lake trout (*Salvelinus namaycush*), masou masu salmon (*Oncorhynchus masou*), marble trout (*Salmo marmoratus*), rainbow trout or steelhead (*Oncorhynchus mykiss*) ~~Chinook (*O. tshawytscha*), sockeye (*O. nerka*), chum (*O. keta*), amago (*O. rhodurus*), masou (*O. masou*), coho (*O. kisutch*), and sockeye salmon (*Oncorhynchus nerka*)~~ Atlantic salmon (*Salmo salar*). Other salmonids including brown trout (*S. trutta*) and cutthroat trout (*O. clarki*), some chars (*Salvelinus namaycush*, *S. alpinus*, *S. fontinalis*, and *S. leucomaenis*), ayu (*Plecoglossus altivelis*) and non-salmonids including European eel (*Anguilla anguilla*), herring (*Clupea pallas*), cod (*Gadus morhua*), sturgeon (*Acipenser transmontanus*), pike (*Esox lucius*), shiner perch (*Cymatogaster aggregata*) and tube snout (*Aulorhynchus flavidus*) have occasionally been found to be infected in the wild or shown to be susceptible by a natural route of infection (Bootland & Leong, 1999; EFSA, 2008; Wolf, 1988).

Rationale:

Japan considers that “masu salmon” is appropriate as the common name of *Oncorhynchus masou*. It is because the term is used in the Report of the *ad hoc* Group on Susceptibility of fish species to infection with OIE listed diseases.