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

- Annex 4 to of the report
  Criteria for listing species as susceptible to infection with a specific pathogenic agent (Chapter 1.5.9)

- Annex 10 to of the report
  Infection with infectious haematopoietic necrosis virus (Chapter 10.6.)

- Annex 12 to of the report:
  New draft chapter on Biosecurity for aquaculture establishments (Chapter 4.X.)

- Annex 13 to of the report:
  Discussion paper on Approaches for determining periods required to demonstrate disease freedom

OIE Manual of Diagnostic Tests for Aquatic Animals

- Annex 16 to of the report:
  Infection with koi herpesvirus (Chapter 2.3.7.)

- Annex 17 to of the report:
  Infection with infectious haematopoietic necrosis virus (Chapter 2.3.4.)

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 we should describe some specific examples (either actual or imaginary cases) into the report. It will facilitate the understanding of this article because these examples list the susceptible species at a taxonomic ranking of Genus or higher.

分類階級が属以上の感受性種の具体例（実例でも仮定でも）を記載した方が、この条を理解しやすくなるのではないか。

Rationale:

It is difficult to understand the meaning of this article. Following points are not very clear.

(1) The phrase in the first paragraph, “in three or more taxa at the ranking of Family”, is not very clear. It is because the word, taxa (underlined), means both different Families and lower taxa within the Family. We cannot confirm the accurate meaning of the term. We assume that

the former is correct.

(2) According to this article, the first paragraph indicates that there are susceptible species in the disease which belong to more than three Families (this assessment is based on our understanding.). However, a genus is listed as a susceptible host group into the following paragraph. Indeed, there is no logical contradiction in these descriptions because you can see the same explanations in page 7 of the commission report of September 2018. However, it is still not clear for readers.

この条を理解するのは難しい。以下の点が、あまり明確でない。

（1）最初の段落の「科の中に、３つ以上の分類群がある」という文章の分類群とは、異なる科のことを意味するのか、それとも科より低い分類群を意味するのか明確ではなく、前者が正しいともとれる。

（2）（もし我々の理解が正しいのであれば）この条によると、最初の段落は、ある疾病には、３つ以上の科にまたがる感受性種がいることを示す。しかしながら、次の段落では、 属が感受性種としてリストされている。2018年9月の水生委員会のレポートの７ページに記載されているように、これらの説明に論理的に矛盾はないが、読者にとって、すぐにはわかるものではない。

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.

日本は、OIEリスト疾病の感受性種に関するアドホックグループの報告書で使用されているように、*Oncorhynchus masou*の標準名としては「masu salmon」が適当と考える。

Annex 12 to of the report:
New draft chapter on Biosecurity for aquaculture establishments (Chapter 4.X.)

日本は、国、地域、区画レベルでのバイオセキュリティを効果的にするため、養殖施設のバイオセキュリティに関する新たな章の策定が重要であるとの認識を共有する。

提案されている「Article 4.X.7　リスク分析」について、リスク分析を適切に行い、国、地域、区画、施設のレベルでのリスクに応じたバイオセキュリティを実施する必要がある。そのため、「4.7　リスク分析」は本章の中に設けるのではなく、第4部の中に別の章として設けて、国、地域、区画、施設のいずれのレベルでのバイオセキュリティの実施においても適用できるものとすべきである。

また、水生コードの「第2部　リスク分析」にある輸入リスク分析と整合をとる必要がある。新たな本章の提案中には、Likelihood estimateとConsequence ratingのマトリックスによるリスク評価が例示されているが、Likelihood estimateとConsequence ratingを5段階で行う基準が不明である。恣意的な評価を避けるため、客観的かつ科学的な基準を明示すると有用だろう。

Step 2 のリスク評価は、ハザードとなる病原体ごとに行われる一方、Step 3のリスク管理では、多くのハザードは同じ感染経路を共有し、緩和措置は1以上のハザードに有効とされている。そのため、リスク評価において病原体ごとにリスクレベルの決定はリスク管理の実施のためにあまり重要とは言えない。

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.
本紙のTable 3.にまとめられた各論点についてコメントは以下のとおりである。

Section 3.1. Pathway 1. Absence of susceptible species
1. Is Pathway 1 likely to be used by Member Countries?
養殖のため外国から新たな種を導入している加盟国はある。これら加盟国は，新たな種を導入前に、輸入国として無病宣言を行うために経路 1 を使用するであろう。
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?

加盟国は、感受性種の不在の根拠として、各国の漁業生産統計や水揚げ記録、生物学的な生態に関する学術論文を使用可能である。
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?

野生の水生動物のパッシブサーベイランスの要件として、「疾病の臨床症状を発現した場合、観察される状況でなければならない。」という要件は、実行可能なものではなく、この要件を満たすことを証明する方法もない。この要件があれば事実上、パッシブサーベイランスのみで経路２による無病を宣言することは不可能であり、必ずアクティブサーベイランスが必要となる。

水生動物の疾病の発生は通常養殖施設で見られ、回遊性の魚種や底生性の魚種の野生の個体群で発生が確認されることはほとんどない。このような魚種について、養殖の個体群で発生が確認されていない一方で、野生のもののみ疾病の発生が観察されると考えられない。

野生の水生動物に関するパッシブサーベイランスの要件は、削除するか、又は観察可能な水域に定着し移動しない種（例えば、岩礁域に定着するカキ）のみに適用すべきである。

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?

歴史的無病については、一定期間を設定するべきである。「疾病がこれまでに検出されていない」という要件は、各国で検出体制が構築された後の期間が異なるので、加盟

国感で不整合が生じる。
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?
　生産システムや管理方法は加盟国で様々であり、短期間で変わり得るので、日本は、「生産システムや、臨床症状があるなら、その観察に影響する管理方法」という要因は基準に含まれるべきでないと考える。一部の国のみの情報に基づくバイオセキュリティ期間は十分でない可能性がある。また、生産システムや管理方法が変化した場合に、バイオセキュリティ期間を頻繁に改訂するのは避けるべきである。
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?
　生産システムや管理方法は加盟国で様々であり、短期間で変わり得るので、日本は、「生産システムや、臨床症状があるなら、その観察に影響する管理方法」という要因をは基準に含まれるべきでないと考える。一部の国のみの情報に基づくバイオセキュリティ期間は十分でない可能性がある。また、生産システムや管理方法の変化した場合に、バイオセキュリティ期間を頻繁に改訂するのは避けるべきである。
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?
　国及び地域の無病宣言のために能動的サーベイランスを開始する時点で基本的なバ

イオセキュリティが実施されていることは不可欠である。能動的サーベイランスの開始以前のバイオセキュリティ期間は、特定の疾病について検出されるために有病率が十分高くなる期間に関して科学的な根拠があれば、１年よりも短い期間にできると考える。
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?

初期要件を2年間に毎年1回（最低3ヶ月以上の間隔）のサーベイとすることは支持する。パッシブサーベイランスが特定の疾病を検出するために感度がよい方法であることが立証できる場合に調査の回数は柔軟にできると考える。
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)?

国や地域において、適切な疾病撲滅プログラムの実施後に、当初の無病宣言より早く無病を回復することは可能と考える。本紙で指摘されているとおり、疾病の影響を受けた個体群は狭い範囲で特定され、その処分や施設の消毒により清浄化することが可能である。ただし、疾病撲滅プログラムの策定及び実施に当たって、感染経路の解明とバイオセキュリティの見直しが適切に行われる必要がある。プログラム実施後には、その国または地域が無病の基準に合致することを確認するため、疫学関連のある個体群や下流の個体群などリスクのある個体群を対象にサーベイランスを十分に行うべきである。
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 s 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 necessarily 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)?

コンパートメントは国、地域よりも、より明確に限定された個体群に対して適切なバイオセキュリティが実施可能であるため、バイオセキュリティを見直し、処分・消毒、無病の動物を再導入した後、即座に無病とすることを支持する。

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?

検査の陰性結果は、サンプリング時点での陰性を示すものであるので、サーベイランスの開始時点はサンプリング開始時とすべきである。

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)?

水生動物は、動物種、疾病、生産システムが多岐にわたり、統一的な感染地域及び保護地域の設定のガイダンスを策定することは困難である。加盟国が感染地域と保護地域のガイダンスを必要とするなら、コードには代表的な養殖生産の感染地域及び保護地域の事例を入れることはできる。

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’?

水生生物診断マニュアルに疾病情報（宿主要因、疾病の感染メカニズム、地理的分布、環境要因等）を参考にできるので、「臨床症状を出現させる状態」について追加のガイダンスを作成する必要はないと考える。

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 conductive to clinical expression".

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

早期発見システムの能力を簡易かつ効果的に評価するガイダンスがあれば、追加で策定することを支持するが、多大なコストや労力を要するものとすべきでない。

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?

OIEによる無病宣言の公表は、水生動物の輸入国にとって輸出国の状況を知るために有用な情報ではある。一方で、水生動物の貿易に当たっての輸入国と輸出国での協議や現地査察を代替するものにはならない。そのため、現在作成された手続と形式で問題はなく、更なる改善や、水生コードに追加する優先度は相対的に低い。

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~~r~~assius ~~auratus~~ carassius*).

Rationale:

To correct a typo of the scientific name of Syberian crucian carp.
Syberian crucian carpの学名の修正。

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 pallasi*), cod (*Gadus morhua*), sturgeon (*Acipenser transmontanus*), pike (*Esox lucius*), shiner perch (*Cymatogaster aggregata*) and tube-snout (*Aulorhychus 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.
日本は、OIEリスト疾病の感受性種に関するアドホックグループの報告書で使用されているように、*Oncorhynchus masou*の標準名としては「masu salmon」が適当と考える。