

Japan's Comments on the Proposed Amendments of the Terrestrial Code in the Code Commission Report of the February 2011 Meeting and Topics Raised at the Previous General Session

List of comments

- 1. Chapter 1.2 – Criteria for listing diseases (Annex29)**
- 2. Chapter 1.6 – Procedures for self declaration and for official recognition by the OIE (Annex33)**
- 3. Discussion on Chapter of animal welfare and broiler chicken production at the 79th General Assembly**
- 4. Development of official standard setting procedure in the OIE**

NOTE

Please find the following specific comments in which proposed insertion is underlined and proposed deletion is ~~struck-out~~. Any deletion or insertion by Japan shall be shaded in grey on this paper.

1. CHAPTER 1.2. Criteria for listing diseases

1. General Comments

Japan agrees with the discussion made at the previous General Session that listed diseases should be focused on important diseases which have a significant economic and health effect to Member countries.

2. Specific Comments

CHAPTER 1.2. CRITERIA FOR LISTING DISEASES

Article 1.2.1.

The criteria for the inclusion of a *disease* in the OIE List are as follows:

1. International spread of the agent (via live animals, their products or fomites) has been proven on three or more occasions.

AND

i) A number of countries with populations of susceptible animals are free of the disease/infection or applies official control program toward the disease/infection or face impending freedom (based on including the animal health surveillance provisions of the *Terrestrial Code*, in particular those contained in Chapter 1.4.)

OR

ii) OIE annual reports indicate that a number of countries with susceptible populations have reported absence of the disease for several consecutive years (based on the animal health surveillance information notified in WAHIS)

AND

i) Transmission to humans has been proven, and human infection is associated with severe consequences (death or serious illness)

OR

ii) The disease/infection has been shown to cause significant production losses in domestic animals due to significant mortality or morbidity at the level of a country or a *zone*, excepting the situation where there is an efficient and affordable vaccine and vaccination is carried out by most Members

OR

iii) The disease/infection has been shown to, or scientific evidence indicates that it would, spread through international trade and have a significant negative effect on wild animal populations due to significant mortality

AND

i) A repeatable and reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

OR

2. The disease is an *emerging disease* with apparent zoonotic properties with severe consequences (death or serious illness), rapid spread, or possible significant production losses a case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

The Terrestrial Manual should be available for proving the repeatability and reliability of the means, when the disease is listed.

【Rationale】

As for paragraph 1 of point 1, objectives of listing disease include not only protection of disease free countries but also eradication of certain animal diseases. Therefore, if a number of OIE Members are making their effort to control certain disease, that disease should also be listed as an OIE listed disease. Japan notes that this addition also contributes to evaluation of listing wildlife diseases, because it might be difficult to decide wildlife disease freedom (original paragraph 1 and 2 of point 1) accurately.

As for paragraph 4 of point 1, “significant mortality” and “significant morbidity” mentioned in the existing Terrestrial Code are very important element for the criteria. Therefore, we suggest keeping these important elements being in the criteria as distinct indexes for the significant production losses in domestic animals at the level of a country or a zone.

As for paragraph 5 of point 1, in order to avoid imposing unnecessary burden on Members, we need to focus on listing the diseases that are truly necessary to be listed. Considering that certain wildlife and their products may not be subject to international trade and have extremely low risk of spreading diseases, Japan proposes to add words to list the wildlife diseases that would spread through international trade and that may pose significant adverse effect due to high mortality.

As for point 2, “with severe consequences” should be added. Please note, whether or not the disease is included in the OIE listed disease, the occurrence of emerging disease need to be immediately notified to OIE headquarters in accordance with paragraph e) of point 1 on Article 1.1.3.

Japan also suggests adding new paragraph regarding the Terrestrial Manual considering that the official diagnosis methods can be only found in this Terrestrial Manual.

2. CHAPTER 1.6. Procedures for self declaration and for official recognition by the OIE

Specific Comments

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.6.

Questionnaire on African horse sickness

AHS FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as a AHS free country

3. Veterinary system

- a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.
- b. Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how *Veterinary Services* supervise and control all AHS related activities. Provide maps and tables wherever possible.
- c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).
- d. Role of private veterinary profession in AHS *surveillance* and control.
- e. Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS pathway if exist.

【Rationale】

Some Members do not undergo the PVS evaluation. It is considered that the information on the compliance of the *Veterinary Service* of the country with the *Terrestrial Code* and the *Terrestrial Manual* provided based on the point b has the same value as that on any OIE PVS evaluation of the country and follow-up steps within the PVS pathway. Therefore, we suggest to add “if exist” to the end of the point e. to express that the information may be provided when the country undergo the program.

3. Discussion on Chapter of Animal Welfare and Broiler Chicken Production at the 79th General Assembly

General Comments

In response to the request from the president of the OIE at previous General Session, Japan would like to comment on two different major guidances on development of livestock production system chapters.

Japan requests the Code Commission to develop flexible standards that can be implemented by all OIE Members, rather than to develop too prescriptive standards that some OIE Members, especially developing countries, cannot implement.

It is our position, that animal welfare standards should be elaborated in accordance with both the discussion paper on the Development of Animal Welfare Guidelines for Production Systems and guidance from the AWWG to ad hoc Groups on the development of animal welfare standards. Particularly, we request the Code Commission to take following aspects into consideration when developing the animal welfare codes.

1. Flexibility

Animals are raised under extremely diverse cultural, geographical, and social backgrounds in the world, under the conditions ranging from intensive to extensive systems. Therefore, flexibility should be noted when developing the animal welfare standards.

2. Outcome Based Criteria and Inclusion of Numeric Value

In order to meet different production systems of all 178 OIE Members, outcome-based or animal-based criteria should be used where possible and resource-based criteria should be used to supplement outcome-based criteria. Numeric values should be assigned only if there are any good scientific bases. If there is no broadly recognized and accepted scientific information or if there are significant conflicts among existing reviews, a new study may be needed before developing a new standard.

4. Development of official Standard Setting Procedure in the OIE

GENERAL COMMENTS

As mentioned at the previous Assembly, Japan would like to reiterate the importance of developing official (i.e. conducts Members consultation and adopted at the Assembly) standard setting procedure in the OIE.

Please be reminded that we have been asking for this new work since we started discussing the revision of Basic Text on 2008. Annex on this document is as almost the same as those attached to our comment sent on September 10th last year.

The OIE and Members have been encouraging ourselves to elaborate international standard (i.e. OIE Codes) in transparent, democratic and science based procedure. By reviewing and describing this procedure in a document, OIE can clearly show legitimacy of such procedure. Japan believes that it is also beneficial from following points of view:

1. Promote participation of Members in standards setting

Official standard setting procedure facilitates Members' involvement in standards setting by:

- clearly showing the several opportunities to submit written comments to the Code Commission before the Assembly. (This gives the Code Commission a time to fully review Member comments and appropriately reflecting them to the proposed Codes before the Assembly); and
- providing clear instruction for Members and other organizations to propose new works related to their concerns.

Members and other stakeholders (e.g. producers) may become more active in implementing the Codes if they understand that the Codes are developed or revised in acceptable procedure thoroughly incorporating Member comments and addressing their concerns.

2. Focus on important issues by reviewing proposed works

Japan believes that systematic approach for reviewing and approving the new works by Members will clarify the need of new works and optimize limited resources by focusing on new works that Members agree on their needs. With this procedure those responsible for developing and revising the OIE Codes (i.e. Code Commission and Aquatic Animal Commission) can dedicate themselves to discussion on important issues even more.

3. Clarify the roles and responsibilities

Official standard setting procedure clarifies the roles and responsibilities of players involved in standard setting (e.g. Specialist Commissions, Working Groups and ad hoc Groups)

3. Joint Standards with Codex Alimentarius Commission

Considering that the OIE has been seeking way to jointly elaborate standards with the Codex Alimentarius Commission, and the Codex has basic rule saying "(T)he cooperating Intergovernmental Organization shall have ...equivalent principles of standards setting," Japan again suggests OIE to develop official standards setting procedure which may help to move this issue forward.

In conclusion, Japan proposes to develop official standard setting procedure. More specifically,

Japan requests the Code Commission to draft the official standard setting procedure and circulate it for Members consultation and finally adopt it at the Assembly by consensus.

Japan hereby outlines the procedures (see annex) as a basis of discussion. Japan is ready to contribute to the work and hopes that the proposal would be accepted.

**Draft Outline of Procedures for the Elaboration of the OIE Codes¹
Proposal by Japan**

I. Proposals to undertake new work

Proposal

1. OIE Members, individual scientists, other international organisations, industry organisations and non-governmental organizations which have agreement with OIE (hereinafter referred to as “Members and related organizations”) may propose to undertake new work to the relevant Specialist Commission² in a letter to the OIE Director General. Each proposal should contain the following on, but not limited to:

- a) Type of the topic (revision, addition or deletion);
- b) Outline of the proposal;
- c) Reason for the proposal;
- d) Scope and purpose (including intended outcome); and
- e) Availability of data supporting the proposal.

2. The Specialist Commissions themselves may propose new work. The proposal should contain the information mentioned in para. 1.

3. The World Assembly of Delegate may request the Specialist Commissions to prepare the proposal for the new work

4. The proposer may provide an initial draft text at the time of the proposal.

Approval

5. The Code Commission or the Aquatic Animal Health Commission (hereinafter referred to as “the Code related Commission”) examines the proposal in case of para. 1. If proposal does not accompany sufficient information mentioned in paragraph 1, the Code related Commission asks proposer to provide required information.

6. If Specialist Commission other than the Code related Commission proposes the new work in paras 2 and 3, the mentioned Specialist Commission should provide the required information mentioned in para.1 to the Code related Commission.

7. The Code related Commission issues a report containing the proposal and required information mentioned in paragraph 1 and sends it to all Members and related organisations (see para. 1) and if necessary to relevant Specialist Commission for comments.

8. The Code related Commission decides whether to approve the proposal or not, after reviewing the comments from Members and related organisations and taking opinion from other relevant Specialist Commission into account.

9. Following the approval by the Code related Commission:
The Code related Commission should make proposal to the Director General for the involvement of Working Group and establishment of ad hoc Group(s) with TOR; and
The Director General decides the work program including designation of responsible Specialist Commission for collecting necessary information to draft text, creation of ad hoc Group(s) and

¹ The procedures apply to both the Terrestrial Animal Health Codes and the Aquatic Animal Health Codes.

² Examples of new work include addition and /or deletion of a Chapter(s) and an Article(s); and revision which may have a significant effect on international trade.

involvement of Working Group(s) with taking proposal from the Code related Commission into account. TOR of ad hoc Group(s) should be included in the report of the Code related Commission mentioned in para. 14 for Members information.

II. Development of draft code

Preparation of Draft

10. If involvement of Working Group(s) and creation of ad hoc Group(s) are included in the working program mentioned in para. 8, those groups should provide opinions with appropriate data to support them to the designated Specialist Commission mentioned in para. 8 (hereinafter referred to as “the designated Specialist Commission”).

11. The designated Specialist Commission decides whether the available data, including those in para. 1.(e) and para. 9, are sufficient or not. If insufficient, the designated Specialist Commission collects necessary data with assistance from the OIE Headquator and OIE reference centre.

12. The designated Specialist Commission may ask an appropriate other Specialist Commission(s) for opinion on the proposal and information mentioned in para. 10, if necessary.

13. If the Specialist Commission other than the Code related Commission is designated as responsible Specialist Commission in para.8, the designated Specialist Commission develops a draft text or supporting document containing information necessary to develop draft text.

14. The Code related Commission develops a draft text based on the relevant information, including:

- the initial draft text mentioned in para. 4, if provided;
- the comments from Members and related organisation mentioned in para. 6;
- the opinion from the ad hoc Groups and Working Group mentioned in para. 9;
- the data mentioned in para. 10;
- the opinion from the appropriate Specialist Commission(s) mentioned in para. 11; and
- the draft text or information document mentioned in para. 12.

Member consultation

15. The Code related Commission issues a report containing the draft text and supporting information mentioned in para13, and send it to all Members and related organisations for comments. Subsequently the Code related Commission revises the draft text, taking into account the comments from Members and related organisations. In revising the draft text, the Code related Commission may seek opinions of related ad hoc Group(s), Working Group(s) or designated Specialist Commission.

16. The Code related Commission issues a report. The rationales for reflecting Member’s comments or not into modified draft text should be a part of the report.

17. The Code related Commission decides whether to forward the modified draft to the Assembly for adoption, or circulate it for another round of Member consultation mentioned in para. 14. It should be noted that the normal timeframe for the adoption is no less than two years from the initial consultation in Para.5 and opportunity to make comments on the draft text should be ensured for at least once.

18. Members are provided with opportunities to make comments until consensus is reached.

III. Adoption at the Assembly

19. The draft text is sent to the Assembly for adoption, following the approval by the Code related Commission.

IV. Special process

20. The draft text may be adopted within one year, in case of an emergency situation or when consensus is reached. However Members and related organizations should be provided with opportunities to make comments on the draft text at least once before forwarding the draft text for adoption at the Assembly.

Flow of Draft Outline of Procedures for the Elaboration of the OIE Codes Proposed by Japan

