

Japan's Comments on The Terrestrial Animal Health Standards Commission Reports of the September 2021 meeting

Japan would like to express its appreciation to the Terrestrial Animal Health Standards Commission (TAHSC) and other relevant Commissions, Working Groups and ad hoc Groups for all the works they have done. Japan also appreciates the TAHSC for providing us with the opportunity to comment on the proposed revisions to the texts of Terrestrial Animal Health Code.

Please find our comments on the following texts and Annex:

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1. Code Commission's work programme

Comment

Japan supports the Code Commission's initiative to develop a new chapter on biosecurity and to address a definition for 'swill' in the work. Japan considers it necessary to clarify what is included in the term 'swill' when we refer to the chapters which prescribe recommendation or requirements on swill. Specifically, it would be necessary to clarify what kind of recycled feed materials poses risk to spread animal pathogens and thus need to be subject to proper control.

2. Chapter 11.4. BOVINE SPONGEFORM ENCEPHALOPATHY

General Comment

Japan considers that the proposed revisions of the Chapter are scientifically sound and acceptable.

With regard to the level of surveillance required to maintain the BSE risk status, stipulated in Article 11.4.18., Japan has noted that the Scientific Commission held in September 2021 recommended the OIE to develop guidelines on BSE surveillance to help Members to revise their surveillance programmes in accordance with the new BSE standards. This kind of guidelines would be of great help for Members to apply the new standards in their countries.

In addition, with regard to 'the date from which the risk of BSE agents being recycled within the cattle population has been negligible' (referred to in Article 11.4.2., 11.4.3., 11.4.7., 11.4.10., 11.4.12., 11.4.13., 11.4.14.), Japan has noted that the Scientific Commission is going to provide the criteria that could be used in determining the 'starting date' in case a Member wishes to demonstrate that the effective implementation of the control measures was earlier than those in relation to the year of OIE recognition.

Since those guidelines and criteria would be referred to in bilateral discussions between trading partners, Japan requests that the OIE provide Members chances to review and to make comments on them before they are finalised.

3. CHAPTER 8.8. INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

1) General Comment

Japan appreciates the TAHSC took into account our comments and made some improvements on the revised draft Chapter. However, we still have a concern in general on the currently proposed draft Chapter since the overhaul of this chapter seems to promote use of vaccine in FMD prevention and control rather than pursuing FMD eradication. In particular, we have a concern on the revision to enable the introduction of vaccinated animals into an FMD-free country or zone where vaccination is not practised.

With regard to the concept note examining the implications of introducing vaccinated animals into an FMD-free country or zone where vaccination is not practised (Annex 8 of the September 2021 meeting report of the Scientific Commission for Animal Diseases (SCAD)), which was drafted by the joint taskforce of the TAHSC and SCAD (the Taskforce), Japan has comments on the discussion points from i) to iii) as follows:

- i) Requirements that would provide the necessary assurances for the importation of vaccinated animals into a country or zone free from FMD where vaccination is not practised

Although the concept note states that the Taskforce agreed the tests required for vaccinated animals in point 4 of the revised Article 8.8.11. were sufficient to prevent the introduction of the infection, Japan would like to highlight that the Chapter 3.1.8. (FMD) of the OIE Manual indicates that those tests are not fit for the purpose to prove individual animal freedom from infection prior to movement. Thus, Japan would like to request further clarification on how the tests could assure the freedom from infection of individual vaccinated animals.

- ii) Impact on traceability and surveillance for demonstrating absence of FMDV infection/transmission

Japan agrees with the Taskforce that it is necessary to modify the surveillance strategy and design to substantiate the absence of FMDV following the introduction of vaccinated animals into a country or zone free from FMD where vaccination is not practised. Thus, Japan would like to request the TAHSC to review the relevant Articles on surveillance of FMD in Chapter 8.8. as suggested by the Taskforce.

- iii) Implications on the OIE's official animal health status recognition and maintenance procedure

As stated in the comments to the discussion point i), Japan considers the revised Article 8.8.11. is not sufficient to assure the safe trade of vaccinated animals into an FMD-free country or zone where vaccination is not practised. Japan considers

that the Code should be practically applicable as well as scientifically appropriate. Thus, Japan would like to request the TAHSC to provide the scientific rationale on the tests to assure individual vaccinated animals be free from infection, and then to provide necessary practical measures for the process of importation and management of animals, including identification and separation of vaccinated animals from unvaccinated animals and increased surveillance, which are equivalent to those required in a protection zone.

2) Comment on Article 8.8.1.bis

Article 8.8.1.bis

Safe commodities

When authorising import or transit of the following commodities, Veterinary Authorities should not require any type of FMD-related conditions regardless of the FMD status or zone

- 1) UHT milk and derivatives thereof,
- 2) meat in hermetically sealed container with a F0 value of 3 or above,
- 3) protein meal
- 4) gelatine,
- 5) in vivo derived embryos collected processed and stored in accordance with Chapter 4.8

Other commodities of susceptible species can be traded safely if in accordance with the relevant articles in this chapter.

Comment

Japan reiterates the submitted comment to the September 2020 meeting report of the TAHSC and requests that the TAHSC discuss the issue with due consideration.

3) Comment on Article 8.8.2.

Article 8.8.2.

Country or zone free from FMD where vaccination is not practised

A country or *zone* may be considered free from FMD where *vaccination* is not practiced when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or zone for at least the past 12 months:

3) the *Veterinary Authority* has current knowledge of the distribution, habitat and indication of disease occurrence through passive *surveillance* of *wild* and *feral* susceptible animals in the country or *zone*;

...

A country or *zone* free from FMD may maintain its free status despite an incursion of African buffalo from a neighbouring infected country or *zone* provided that the relevant conditions are met and documented evidence has been submitted to and accepted by the OIE.

Comment

With regard to point 3 of Article 8.8.2., Japan notes that the proposed amendments were made to harmonise the articles with those of the Chapters 14.7. (Infection with peste des petits ruminants (PPR) virus) and 15.2. (Infection with classical swine fever (CSF) virus). However, Japan has a question if the passive surveillance of wild and feral susceptible animals could effectively provide the knowledge on the occurrence of foot and mouth disease (FMD) since the range of susceptible animals of FMD is much wider than PPR or CSF and since the clinical signs of FMD in wild animals may be unclear to be detected.

This comment is also relevant to point 1d) of Article 8.8.3.

With regard to the condition for the maintenance of FMD free status despite an incursion of African buffalo, Japan proposes that the necessary information required for the assessment of the Scientific Commission should be clearly indicated in the questionnaire for the reassessment of the official status, to improve the transparency of the assessment.

4) Comment on Article 8.8.11.

Article 8.8.11.

Recommendations for importation from countries, zones or compartments free from FMD where vaccination is practised

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

Comment

Japan considers the current revision of Article 8.8.11. is not sufficient to prevent the introduction of the infection into countries or zones free from FMD where vaccination is not practised and that the FMD free status without vaccination stipulated in Article 8.8.2. may be compromised unless the following concerns are addressed:

First, Japan would like to request the detailed explanation on the scientific rationale on that the virological and NSP serological tests for FMD with negative results on individual animals are sufficient to assure the safe trade of vaccinated animals. Japan considers that the explanation described in the concept note of the Taskforce is contradictory to the description of the OIE Manual on the applicability of the tests to prove individual animal freedom from infection prior to movement.

Second, Japan considers that the management measures which are equivalent to those for the establishment of a protection zone, including identification and separation of vaccinated animals from unvaccinated animals and increased surveillance, would be necessary when the importing countries or zones are free from FMD without vaccination.

Accordingly, Japan requests recommendations on management measures when a country or zone free from FMD where vaccination is not practised imports vaccinated animals be considered and added in Article 8.8.11.