Japan's Comments on the Terrestrial Animal Health Standards Commission Report of the September 2022 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 work they have done. Japan also thanks the WOAH and the TAHSC for providing us with the opportunity to comment on the proposed draft texts of the Terrestrial Animal Health Code.

Please find our comments on the following texts:

Contents

1. GLOSSARY DEFINITION FOR “POULTRY”

Comment

Japan does not support the proposed amendment to the glossary definition for “poultry”, which allows for wider coverage of birds that are not considered poultry.

As described in our previous comments submitted, Japan places emphasis on the fact that high pathogenicity avian influenza (HPAI) outbreaks confirmed in trader/commercial holdings of pet birds in developed countries had spread domestically and internationally in 2020-2021 winter season. These events have clearly demonstrated that businesses that keep pet birds for breeding or selling have a non-negligible risk of virus transmission from the perspectives of both animal and public health.

Rather Japan believes that, considering the recent unprecedent level of HPAI global epidemics, not only pet birds for breeding or selling but also other bird populations that are already excluded from “poultry” in the current definition, i.e. those that are kept for shows, racing, exhibitions, zoological collections and competitions, and for breeding or selling for these purposes, as well as pet birds kept in households, should be reviewed to see whether these types of birds are not playing an important epidemiological role in year-round persistent occurrences and geographical expansion of HPAI outbreaks.

In conclusion, taking into account the rapid change in global dynamics of HPAI and the subsequent significant loss to poultry farmers and industry across countries and assuming that relevant scientific evidence has been and will be accumulated which could be a basis for a variety of discussions onward, Japan requests that the definition for ‘poultry’ be reviewed by a relevant expert group. Japan also requests the ongoing discussion on the revision of definition be suspended until then.

2. CHAPTER 6.10. RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

General Comment

1) The same measures cannot necessarily be applied to food producing animals and non-food producing animals because of different purposes of rearing and treatment policy. Therefore, parts for food producing and non-food producing animals should be separately described in this chapter.

2) Texts relating to non-food producing animals have been newly proposed this time. There may be instances in which the appropriate measures could not be taken because more rapid treatment or life-saving is prioritized in veterinary medicine practices for non-food producing animals. For this reason, feasibility should be considered in the description regarding veterinary medicine for non-food producing animals.

Specific Comment

Article 6.10.3 on responsibilities of the Competent Authority

1) Proposal of amendment to Point 6 of Article 6.10.3 (insertion/~~deletion~~)

Article 6.10.3
6. Establishment of clinical breakpoints In order to interpret the result of a susceptibility test, there is a need for clinical breakpoints for each bacteria-antimicrobial-animal species combination. Those clinical breakpoints should be established by ~~independent~~ objective experts or organisations based on scientific evidence taking into account of animal rearing situations and disease outbreaks in each country or region.

Rational

With respect to ‘clinical breakpoints’ stated in Point 6 of Article 6.10.3, they should be established based on scientific evidence taking into account of animal rearing situations and disease outbreaks in each country or region.

Regarding the ‘independent experts’ who establish the clinical breakpoints, Japan would appreciate a clarification regarding whether relevant experts or organisations that have objectivity are sufficient in this context.

2) Comment on Point 8 of Article 6.10.3.

"Assessment of the impact on the relevant animal environment" is newly proposed but there are neither international guidelines available, nor supporting documents with scientific evidence, nor established methods for assessment of the impact on the relevant animal environment. Therefore, Japan thinks it is premature to propose the risk assessment as stipulated in this paragraph.

Article 6.10.4 on responsibilities of the veterinary pharmaceutical industry with regards to veterinary medicinal products containing antimicrobial agents

1) Proposal of amendment to Point 1 (c) of Article 6.10.4 (insertion/~~deletion~~)

Article 6.10.4
1. Regulatory approval ~~Marketing authorisation~~ The veterinary pharmaceutical industry has responsibilities to: […] c) implement and promptly or regularly report on a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data. […]

Rational

Regarding Point 1 (c) of Article 6.10.4, "regularly report" is proposed to be added. Japan, however, focuses on promptness, and requests immediate reporting on pharmacovigilance information for veterinary medical products on a case-by-case basis. As the frequency or way of reporting can be different among Members, the text should not be too prescriptive and certain level of discretion should be allowed for each Member.

Article 6.10.6 on responsibilities of veterinarians

1) Proposal of amendment to Point 3 of Article 6.10.6 (insertion/~~deletion~~)

Article 6.10.6
3. Appropriate use of the selected ~~VMP~~ veterinary medicinal product containing antimicrobial agents ~~chosen~~ […] When prescribing, dispensing or administering a veterinary medicinal product containing antimicrobial agents intended for veterinary medical use to an individual or a group of animals to treat, control or prevent infectious disease as defined in Chapter 6.9, the veterinarian should give specific consideration to their categorisation in the OIE List of Antimicrobial Agents of Veterinary Importance as well as to the WHO List of Critically Important Antimicrobials or national lists, where available. Preference should be given to the least important antimicrobial agent as categorised by WHO that is appropriate for use. […]

Rational

In Point 3 of Article 6.10.6, new text saying that 'the veterinarian should give specific consideration to their categorisation in the OIE List of Antimicrobial Agents of Veterinary Importance as well as to the WHO List of Critically Important Antimicrobials' is being proposed to be added. Despite that it had been agreed that this draft chapter should be harmonized with the Codex Code of Practice (CoP) on antimicrobial resistance, the current draft text is not in line with the Codex CoP. Japan requests the draft text be amended following the relevant description in the CoP (see below) developed in October 2021.

* Principles on AMR risk management (from the Codex CoP)
Principle 4: The WHO List of Critically Important Antimicrobials for Human Medicine, the OIE List of Antimicrobial Agents of Veterinary Importance, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain AMR.

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

General Comment

While recognizing the “Progressive Control Pathway for FMD”, a WOAH-endorsed framework to guide endemic countries to progressively improve the management of FMD, and agreeing that vaccination is a key tool for FMD control programs, Japan believes that the WOAH and its Members should ultimately aim to achieve eradication of FMD and this point should be stressed in this chapter. Therefore, Japan proposes to include in appropriate article (e.g. Article 8.8.1 or Article 8.8.3bis) a provision regarding exit strategy for free countries with vaccination to cease vaccination and transition to free countries without vaccination. The proposed text is as follows: Exit strategy of the FMD vaccination programme should be made in accordance with Article 4.18.10 and based on relevant epidemiological data and should be reviewed periodically to steadily progress toward FMD free status without vaccination.

Specific Comment

Article 8.8.11 on importation of domestic ruminants and pigs from countries, zones or compartments free from FMD where vaccination is practised

Japan thinks that the TAHSC’s response in its September 2022 meeting to our previous comments did not appropriately reflect the views of the Biological Standards Commission (BSC).

The BSC concluded in its September 2022 meeting that, for vaccinated animals, neither serological nor virological testing of samples collected from an individual animal at a single time point can exclude the possibility of infection with FMDV with a high level of confidence. It also presented a pragmatic suggestion to retain the requirement for virology and serological (NSP) testing for this scenario, where virological (probang) testing could provide a modest increase in the confidence of the negative status of animals. It finally agreed that it is not possible to guarantee that virological and NSP serological tests for FMD with negative results on individual animals are sufficient to assure the safe trade of vaccinated animals, and emphasised that Members must mitigate against these risks.

Based on the BSC’s views, Japan considers it is evident that neither virological testing and serological testing in parallel, as suggested by the TAHSC, or increase in test sensitivity using probang samples, as suggested by the BSC, cannot rule out natural infection of animals at individual level prior to the movement. As this will leave a non-negligible risk of disease incursion, this draft provision should be reconsidered. If this draft provision is to retain, additional risk mitigation measures such as individual identification for imported animals and keeping the imported animals in isolation for a certain period should be included.

Article 8.8.40 – Article 8.8.42 on FMD surveillance

Japan noted that, in February 2022 meeting of the Scientific Commission (SCAD), it had recommended the WOAH to develop FMD surveillance guidelines to assist Members on the design of surveillance that will address the impact arising from importation of vaccinated animals into an FMD free country or zone without vaccination. This point was also noted in the September 2022 meeting of the TAHSC. Japan requests practical and useful guidelines be developed and published as soon as possible and, when relevant, the surveillance provisions in this draft chapter be modified in line with the guidelines.

4. CHAPTER 11.4. BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

General Comment

While Japan understands that the TAHSC amended the draft text based on the conclusion of the SCAD that atypical BSE does not meet the criteria for listing, we have a concern relating to the resultant impact of cession of Members' notification of atypical BSE. As atypical BSE has not been elucidated scientifically, Japan believes that the WOAH should somehow put in place an international system to collect global occurrence data of atypical BSE and monitor epidemiological change.

Specific Comment

Articles 11.4.10 and 11.4.13 etc. on trade of commodities

It is understandable that, in September 2022 TAHSC meeting, the provisions of import for fresh meat/meat products and blood/blood products were relaxed as more stringent trade requirements than the current chapter cannot be justified for countries having "negligible" BSE risk status, in light of the significantly reduced global BSE risk. The latest draft text allows for import of fresh meat/meat products and blood/blood products from countries with "negligible" or "controlled" risk status regardless of whether cattle from which those commodities are derived were born after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible. This means that revised trade provisions will have more reliance on the existing granted risk status. Thus, Japan believes that WOAH should continue to rigorously assess the application for a status or reconfirmation of an existing status and monitor the Members' compliance with the WOAH standards.

Article 11.4.18 on BSE surveillance

Regarding the BSE surveillance guidelines which is currently under development, Japan reiterates that the WOAH should finalize and publish it as soon as possible.

In addition, Japan requests sufficient transition period be allowed to ensure that Members can prepare for and effectively implement the revised surveillance provisions. To be concrete, the transition period should be at least two years due to the following reasons: i) Members normally can seek for additional budget allocation only after the revised standards are adopted, ii) period for a fiscal year differs among Members, and iii) surveillance data required for annual reconfirmation of status every November inevitably come from the previous fiscal year.