

**Japan's Comments on
The Code Commission Report of the February 2017 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 appreciate the TAHSC for providing us the opportunity to comment on the proposed revisions to the texts of Terrestrial Animal Health Code.

Please find our comments on the following texts:

1. Chapter 4.X. Vaccination
2. Chapter 4.Y. Management of Outbreaks of Listed Diseases
3. Chapter 6.7. Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes
4. Chapter 6.8. Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Food-producing Animals
5. Chapter 7.1. Introduction to the Recommendations for Animal Welfare
6. Chapter 7.X. Animal Welfare and Pig Production Systems
7. Chapter 8.8. Infection with Foot and Mouth Disease virus
8. Chapter 8.15. Infection with Rinderpest virus
9. Chapter 15.2. Infection with Classical Swine Fever virus

1. Chapter 4.X. Vaccination

Article 4.X.2.

Purposes of this chapter: Vaccination programme

Vaccination programme: means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of prevention and disease control.

Rationale

Japan suggests to harmonise the wording with Article 4.X.1.

Article 4.X.3.

Vaccination programmes

The objectives and strategy of a vaccination programme should be defined by the Veterinary Authority before the implementation of the *vaccination*, taking into account the epidemiology of the *disease*, its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the Veterinary Authority should liaise with the Veterinary Authorities of neighbouring countries. When appropriate, a regional approach to harmonise vaccination programmes is recommended.

Veterinary Authorities should liaise with Public Health Authorities in developing vaccination programme against zoonoses.

Rationale

Japan proposes it should be stated in this article that planning would be prepared in cooperation with public health authorities, because vaccination targeting zoonoses may impact on the public health risk and epidemiology of the disease concerned.

Article 4.X.7.

1. Legal basis

The legal basis for a vaccination campaign, including a legal obligation for the vaccination and compensation for farmers for possible side effects accidental damage caused by the vaccination, should be in place.

Rationale

Japan would like to propose to revise this sentence because not only side effects of vaccine but also accidents or miscarriages may be caused by the vaccination.

Article 4.X.8.

1. Procurement of vaccine and related goods

The vaccine selected for use in a *vaccination* programme should have been be subjected to the registration marketing authorisation procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Medicinal Products (VICH).

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine and related goods should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

Rationale

Japan would like to propose to revise the article as above since in carrying systematic *vaccination* campaigns, materials needed to be considered to be procured in advance are not just vaccine itself, but also including needles, cylinders and other goods to implement effective vaccination campaign promptly.

Article 4.X.8.

2. Implementation of the vaccination programme

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables as well as the establishment of standard operating procedures to:

g) ensure health condition safety and welfare of animals and vaccination teams;

g bis) ensure safety and welfare of vaccination teams:

Rationale

Japan would like to propose to revise the article as above since before vaccination, the health condition of the target animals should be confirmed.

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Disease-free countries or zones applying systematic or emergency vaccination in response to an change in the increased risk of occurrence of a disease should inform trading partners and the OIE, as appropriate. In the absence of cases and unless otherwise specified in the relevant disease-specific chapters, vaccination of animals does not affect the disease status of the country or zone, and should not disrupt trade.

Comment

Considering that vaccination may be used in response to a change in the risk of introduction or emergence of disease, as described in the article 4.X.3, Japan would like to confirm that importing countries have authority to take temporary import suspension in order to evaluate the risk that leads an exporting country to implement vaccination program when systematic vaccination or emergency vaccination has been implemented.

In addition to the above, Japan would like the Code Commission to revise wording as following table to clarify the meaning and to harmonise with other articles.

| <i>Article</i> | <i>Comments (words to be amended)</i> | <i>Amended</i> |
|----------------|---------------------------------------|--|
| 4.x.1, 4) | vaccine production | vaccine production and quality control |
| 4.x.3, 2)d) | introduction or | <i>Delete: "introduction" should be used for pathogens but not for diseases. "emergency" seems sufficient for the sentence.</i> |
| 4.x.4, 3) | introduction or | <i>Delete: "introduction" should be used for pathogens but not for diseases. "emergency" seems sufficient for the sentence.</i> |
| 4.x.4, 7b) | <i>ADD</i> | the availability of the system for animal identification to differentiate vaccinated and unvaccinated target populations. |
| 4.x.6, 2. a) | <i>ADD</i> | stability in ambient conditions; |
| 4.x.7, 7., bc) | <i>ADD</i> | functionality of the animal identifying system; |
| 4.x.8, 2. | <i>ADD</i> | ancillary items |
| 4.x.8, ebis) | containers | <i>The meaning is unclear and needs to be clarified, such as U.N. grade packing box, ample/vials etc..</i> |
| 4.x.8, 5 | carried out | implemented |
| 4.x.10, 2) | introduction or | <i>Delete: "introduction" should be used for pathogens but not for diseases. "emergency" seems sufficient for the sentence.</i> |

2. Chapter 4.Y. Management of Outbreaks of Listed Diseases

Article 4.Y.1.

Introduction

The purpose of this chapter is to provide recommendations to prepare, develop and implement control plans in response to outbreaks of listed diseases, including zoonoses. It is not aimed at giving ready-made fit-for-all solutions, but rather at outlining principles to follow when combating animal diseases through organised control plans. The Veterinary Authority should decide which listed diseases are subject to each article in this chapter based on a potential risk of each disease.

Rationale

It should be clarified that the Veterinary Authority can decide which article should be applied to which disease based on each risk, because this chapter covers broader ranges of guidelines and there are some articles which are not appropriate for all of the listed diseases.

3. Chapter 6.7. Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes

Article 6.7.2.

Purpose of surveillance and monitoring

Active surveillance and monitoring are core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). The OIE encourages cooperation between all Member Countries conducting antimicrobial resistance surveillance and monitoring.

Rationale

Japan suggests to add “and monitoring” for consistent use of terms throughout this chapter.

Article 6.7.3.

General aspects of antimicrobial resistance surveillance and monitoring programmes

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

- 1) statistically based surveys;
- 2) sampling and testing of food producing animals on the farm, at live animal markets or at *slaughter*;
- 3) an organised sentinel programme, for example targeted sampling of food producing animals, *herds, flocks, and vectors* (e.g. birds, rodents);
- 4) analysis of veterinary practice and diagnostic *laboratory* records;
- 5) sampling and testing of products of animal origin intended for human consumption;
- 6) sampling and testing of **feed ingredients or** feed.

Rationale

Japan proposes to delete ‘feed ingredients or’, since the word ‘feed’ covers ‘feed ingredients’ and ‘feed’ is used throughout this chapter.

4. Chapter 6.8. Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Food-producing Animals

Comment on the proposed definitions (therapeutic use, preventive use and growth promotion)

First of all, Japan would like to seek clarification on the purpose of proposing these definitions while they are not used in the current chapter. It is difficult to make comments on the proposed definitions without knowing exactly their expected use in the chapter.

Nonetheless, if the proposed definitions are used in the revised chapter to recommend that Member Countries collect quantitative data of antimicrobial use (AMU) classified by the type of use in accordance with them, i.e. AMU of therapeutic, preventative and growth promotion, Japan has a concern about such classification. Japan is of the view that it is almost impossible to clearly differentiate preventative use from treatment use and gather quantitative data of each AMU in the field, particularly within a same herd. Japan alternatively proposes to create two distinct categories of AMU, for example, “disease-related use” and “growth promotion”.

5. Chapter 7.1. Introduction to the Recommendations for Animal Welfare

Article 7.1.3.

Scientific basis for recommendations

- 1) Welfare is a broad term which includes the many elements that contribute to an animal's quality of lifestate of well-being, including those referred to in the 'five freedoms' listed above.

Rationale

Rhetorical correction

For consistency with Article 7.1.1 as proposed 'the state of well-being of an animal'.

It was noted in the report of the meeting of the OIE terrestrial animal health standards commission (Paris, 13-24 February) that "this subjective wording might have different interpretations for some Member Countries and could not be included in an OIE standard".

Article 7.1.X.

Guiding principles for the use of measures to assess animal welfare

- 1) For the OIE *animal welfare* standards to be applicable globally, they should put more emphasis on good outcomes for the animals than on specific conditions of the animals' environment and management. Outcomes are generally measured by assessing animals' enjoyment of the "five freedoms" described in Article 7.1.2.
- 2) For each principle listed in Article 7.1.4., the most relevant criteria(or measurable), ideally animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.

Rationale

The terminology is to be consistent with the heading of Article 7.1.X and proposed Article 7.X.4 of the chapter on animal welfare and pig production systems.

6. Chapter 7.X. Animal Welfare and Pig Production Systems

Article 7.X.8.

Painful procedures

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing are performed in pigs. These procedures should only be performed to facilitate management, to meet market or environmental requirements or safeguard *animal welfare*.

These procedures are painful or have the potential to cause pain and thus should be performed only when necessary and in such a way as to minimise any pain and distress to the animal, e.g. using anaesthesia or analgesia under the recommendation or supervision of a *veterinarian*.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised 'three Rs': replacement (e.g. using entire or immunocastrated males rather than castrated males), reduction (e.g. tail docking and teeth clipping only when necessary) and refinement (e.g. providing analgesia or anaesthesia under the recommendation of a *veterinarian*) (Bonastre *et al.*, 2016 and Hansson *et al.*, 2011).

Rationale

For preventing duplication and improving clarification between paragraph 2 and paragraph 3, Japan proposes to delete 'e.g. using anaesthesia or analgesia under the recommendation or supervision of a *veterinarian*'.

Article 7.X.12.

Housing (including outdoor production systems)

When new facilities are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals should be soughtconsidered

Rationale

All member countries can't always seek professional advice based on this article because of their limited capacity.

Weaning

Weaning is a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglets' size and physiological maturity. Early weaning systems require good management and nutrition of the piglets.

Piglets should be weaned at three weeks or older unless early weaning is required for the purpose of preventing infectious diseases (Hameister et al., 2010; Smith et al., 2010; Gonyou et al., 1998; Worobec et al., 1999; Bara., 2000; Rotto and Swart, 2010; Dee., 1994; Baldry et al., 2015; Dritz et al., 1996; Clark et al., 1994; Fangman and Tubbs, 1997).

Rationale

Rhetorical correction

According to the following references, early weaning before three weeks is effective to prevent important infectious diseases, e.g. Porcine pleuropneumonia, *Mycoplasma hyopneumoniae*, Influenza A, etc.

Reference:

Bara, M.R. Eradication and control of *Actinobacillus pleuropneumoniae* serovar 1 and 12 using a modified segregated early weaning program. The 16th International Pig Veterinary Society Congress, Melbourne, Australia, 17-20 Sept, 2000. https://www.researchgate.net/publication/274254218_Eradication_and_control_of_Actinobacillus_pleuropneumoniae_serovar_1_and_12_using_a_modified_segregated_early_weaning_program

Rotto, H. and Swart, J. *Actinobacillus pleuropneumoniae* (APP) elimination with injectable Enrofloxacin and early weaning. Proceedings of the 21st IPVS congress, Vancouver, Canada-July 18-21, 2010. <http://agris.fao.org/agris-search/search.do?recordID=ES2010002146>

Dee SA. Apparent prevention of *Mycoplasma hyopneumoniae* infection in growing pigs with a low-cost modified-medicated-early-weaning program. SHAP. 1994; 2 (6): 7-12. <https://www.aasv.org/shap/issues/v2n6/v2n6p7.pdf>

Baldry, H., Allerson, M., Diaz, A., Yang, M., Culhane, M., Perez, A. and Torremorell, M. Impact of piglet weight and weaning age on influenza A virus infection and nucleoprotein antibody levels at weaning. AASV (American Association of Swine Veterinarians) 2015. <https://www.aasv.org/search.php?q=Impact%20of%20piglet%20weight%20and%20weaning%20age%20on>

Dritz SS, Chengappa MM, Nelssen JL, Tokach MD, Goodband RD, Nietfeld JC, Staats JJ. Growth and microbial flora of nonmedicated, segregated, early weaned pigs from a commercial swine operation. J Am Vet Med Assoc. 1996; 208(5):711-5.

<http://europepmc.org/abstract/med/8617629>

Clark LK, Hill MA, Kniffen TS, VanAlstein W, Stevenson G, Meyer KB, Wu CC, Scheidt AB, Know K, Albregts S. An evaluation of the components of medicated early weaning. SHAP. 1994; 2(3): 5–11.

<https://www.aasv.org/shap/issues/v2n3/v2n3p5.pdf>

Fangman, T.J. and Tubbs, R.C. Segregated early weaning. Swine Health and Production—September and October, Volume 5, number 5, 1997. <https://www.aasv.org/shap/issues/v5n5/v5n5p195.pdf>

7. Chapter 8.8. Infection with Foot and Mouth Disease virus

General Comment

Japan notes that the chapter has been progressively revised to promote vaccination instead of eradicating FMD by stamping out and consequently allows status not free from FMD. While supporting the policy to avoid scientifically unjustified trade restriction from the perspective of trade facilitation, Japan has a concern that the effort to achieve global freedom from FMD would be undermined by the fact that a country can maintain its international trade even in the presence of FMD virus, through establishing international recommendations on import measures from countries with status not free from FMD or with vaccination. Therefore, Japan requests that the OIE clarify its policy to eventually achieve FMD free status without vaccination and encourage its Member Countries to reach the eventual goal.

Article 8.8.2.

Country or zone free from FMD where vaccination is not practised

A country or zone free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the surveillance programme in accordance with Articles 8.8.40. to 8.8.42. substantiates the absence of transmission of FMDV.

Rationale

Japan is of the opinion that it needs to be clearly stated that the surveillance in this situation is in accordance with the Articles 8.8.40 to 8.8.42.

Article 8.8.4bis.

~~Compartment free from FMD where vaccination is practised~~

(deletion of the article)

Rationale

Japan reiterates its previous comment on the Code Commission report in September 2015 since no clear answer has been provided by the Code Commission, Scientific Commission or *ad hoc* group. Indeed, control measures expecting the entry of virus in a compartment contradict to the OIE policy on compartmentalisation described in existing OIE guidelines. Moreover, considering the frequency of the test required to detect infection in early stage and the fact that there is no practical test to differentiate the antibody originated in vaccination from the antibody in the result of infection in individual level, it is practically impossible to keep complied with the provisions in this chapter. Therefore, it is not appropriate to include such provision in the Code.

Article 8.8.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a ~~FMD free~~ country or zone previously free from FMD where vaccination is not practised, one of the following waiting periods is required to regain this free status:
 - c) six months after the disposal of the last animal killed or the last vaccination, whichever occurred last, where a *stamp-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate no evidence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of vaccination is demonstrated by a serological survey and serological surveillance for antibodies to nonstructural proteins is carried out in all vaccinated *herds* by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species.

Comment and Rationale

Japan would like the Code Commission to reconsider the waiting period coloured in blue. There is significant difference whether all vaccinated animals are killed or not. Because it is too difficult to implement appropriate surveillance to demonstrate the effectiveness of vaccination considering the fact that FMDV survives for one month in cow's or buffalo's pharynx without symptoms by experimental infection and there is no practical test to differentiate the antibody originated in vaccination from the antibody in the result

of infection in individual level.

8. Chapter 8.15. Infection with Rinderpest virus

Article 8.15.2.

Definitions and general provisions

For the purpose of the *Terrestrial Code*:

- 1) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other ~~clinical pathological material from animals known or suspected to be infected~~; diagnostic specimen and material containing or encoding live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ribonucleic acid (RNA) and cDNA copies of virus RNA;

Rationale

Specimen should be added in the definition of RPV-containing material.

9. Chapter 15.2. Infection with Classical Swine Fever virus

Article 15.2.1.

~~For the purposes of the *Terrestrial Code*, the *incubation period* shall be 14 days. Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life and may have an *incubation period* of several months before showing signs of disease. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections. Pigs exposed to CSFV postnatally have an *incubation period* up to 3 months in case of chronic infections.~~

Rationale

As there is chronic infection case of CSF, it should be defined in the chapter.