

## **Japan's comments on the Terrestrial Code and the proposed amendment of the Terrestrial Code in the Code Commission Report of the March 2008 meeting**

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## **1. General Comments**

Japan appreciates the Commission's work at its March meeting. However, Japan recognizes the exceedingly heavy workload made the Commission to defer some issues to the next meeting in October. In this regard, Japan prefers this deferral, rather than haste proposal for final adoption or country consultation, believing that thorough scientific consideration is essential for elaboration of the Code.

Japan would also like to emphasize the importance of Members' involvement. Taking into account that interaction between Members and the Commission is another key for elaboration of the Code, Japan requests the OIE to maintain the 2 year-adoption procedure, as announced by the OIE in October 2005.

## 2. Chapter 2.4.8. Scrapie (Annex XXXIII)

### General Comments

The draft chapter is significantly different from the existing chapter but lacks scientific justification to be properly understood by Members. Therefore, Japan believes that the scientific justification should be provided to member countries to consider proposed modification on the Code in order to make meaningful comments. The scientific justification should be similar form with “the Supporting document for Terrestrial Animal Health Code, Chapter 2.3.13 on BSE, 2006”, and distributed to Members. Areas requiring definitive scientific justification should be included, such as the inclusion of atypical scrapie, the use of culling based on genotype as an effective means to manage classical scrapie infection, additions and deletions to the list commodities that can be traded without scrapie related conditions etc.

### Specific Comments

We submit the following comments on the proposed revised chapter at this stage.

#### 1) **Article2.4.8.1**

Scientific justification for list of commodities that can be traded without Scrapie-related conditions should be provided.

For instance, taking the scientific data described below into consideration, we believe that “meat and meat products” in Article2.4.8.1 should not be listed.

“Several tests under development are described to have potential capacity to detect PrP<sup>SC</sup> in blood. Ruminant tissue are grouped by the World Health Organization (WHO) into two major categories of infectivity in relation to the demonstration of PrP<sup>SC</sup> and/or infectivity. The CNS and those tissues are considered to be high-infectivity tissues. The lower-infectivity tissues are: the peripheral nervous system, lymphoreticular system, bone marrow, gut, liver, kidney, adrenal gland, pancreas and placenta. Infectivity has been found in blood vessels, skeletal muscles, tongue, salivary gland, nasal mucosa and body fluids such as blood and cerebrospinal fluid...”

(References: see attached)

G.M.Cosseddu et al., Advances in Scrapie research, Rev.sci.tech.Off.int.Epiz.,2007,26(3),657-668)

#### 2) **Article2.4.8.15**

Scientific justification for each commodity (including month age requirement) in this Article should be provided.

#### 3) **Article2.4.8.1**

The first paragraph in this Article, the phrase of “...atypical scrapie which may not be contagious...” in the last sentence should be reconsidered in light of the following evidence.

(Rationale)

The transmissibility of atypical Scrapie was confirmed by ovinized transgenic mice.

(References: see attached)

Le Dur et al.,2005,Proc.Natl.Acad.Sci.USA.102:16031

The diagnosis of “atypical Scrapie” should be added in the Chapter 2.7.13- Scrapie in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals-

#### 4) **Article2.4.8.13.1 and Article2.4.8.14.1**

Both paragraphs are same. Reconfirmation should be needed.

#### 5) **Article2.4.8.6.1 (Negligible risk establishment or compartment) and Article2.4.8.3.3 (Negligible scrapie risk)**

It is difficult to interpret the reciprocal references in the following provisions.

Article2.4.8.6.1. "the establishment or compartment is situated within a country that meets the requirements for negligible scrapie risk according to Article2.4.8.3.,...or..."

Article2.4.8.3.a) "all establishment containing sheep or goats have been accredited as negligible scrapie risk as described in Article2.4.8.6.; OR..."

6) **Article2.4.8.6**

The definition of "establishment" and "compartment" should be clarified.

7) **Article2.4.8.6.2.c)**

The interpretation of "...establishment of an equal or higher in the process of accreditation" should be clarified in the provision below.

"introductions of animals are allowed only from establishments of an equal or higher stage in the process of accreditation; however , rams of the ARR/ARR genotype may also be introduced; "

8) **Article2.4.8.6.2.**

To be considered eligible for as negligible scrapie risk, we believe that feed ban provision should be included somewhere in Article2.4.8.6.2a)-h).

### 3. Chapter X.X.X. Guidelines on the Detection, Control and Prevention of *Salmonella* spp. in Poultry (Annex XXXIV)

#### General Comments

Japan appreciates the work done by the Commission, APFSWG and the Ad hoc Group, and supports the approach developing the General Guidelines regarding *Salmonella* spp. in the production of the both egg laying poultry and broiler in collaboration with Codex.

Japan notes that the Chapter 2.10.2 “*Salmonella enteritidis* and *Salmonella typhimurium* in Poultry” provides criteria for international trade in breeding birds, day-old birds and hatching eggs. Taking into account Chapter 2.10.2 includes reference to the revised Chapter, Japan believes Chapter 2.10.2 should also be reviewed and be modified as necessary to clarify relevance to the proposed revisions.

#### Specific Comments

##### **(Proposed Text)**

##### **Article 2**

##### **Purpose and scope**

These guidelines deal with methods for on farm detection, control and prevention of *Salmonella* spp. In poultry. These guidelines complement the Codex Alimentarius “[Code of Hygiene Practice for Meat \(CAC/RCP 58-2005\)](#)” and “Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 Revision 2007)”. A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in producing eggs and meat that are safe to eat.

##### **(Rationale)**

“Code of Hygiene Practice for Meat (CAC/RCP 58-2005) should also be referred to since the proposed guidelines refer to the hygiene of poultry meat.

## 4. Appendix 3.4.1. Hygiene and Biosecurity Procedures in Poultry Production (Annex XXXIV)

### Specific Comments

#### (Proposed Text)

##### Article 3.4.1.2.

##### Recommendations applicable to hatching egg hygiene and transport

1. The litter in the poultry house should be kept dry and in good condition. The nest box litter should be kept clean and an adequate quantity maintained. Cages should be maintained in good condition and kept clean.
2. Eggs or their conveyances should be marked to assist traceability and veterinary investigations.
3. Eggs should be collected at frequent intervals and placed in new or clean and disinfected packing materials.
4. Grossly dirty, broken, cracked, or leaking eggs should be collected separately and should not be used as hatching ~~or table~~ eggs. If eggs are cleaned on the farm, this should be done in accordance with the requirements of the Veterinary Authority.
5. ~~Table eggs should be stored in a cool and dry room used only for this purpose. Storage conditions should minimise the potential for microbial contamination and growth. The room should be well ventilated, kept clean, and regularly disinfected. Cooling should be undertaken as soon as possible after collection. If available, refrigeration is recommended.~~
6. Refer to Article 3.4.1.7. regarding the specific requirements for the sanitization of hatching eggs and hatchery equipment.

#### (Rationale)

Taking into account of the scope of this Appendix and the title of this article which only refers to “hatching eggs”, paragraph 5 is not necessary.

## 5. Appendix 3.7.1. Introduction to the Guidelines for Animal Welfare (Annex XXIV)

### Specific Comments

#### (Proposed Text)

##### Article 3.7.1.1.

“ Animal welfare” means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Animal welfare measures are normally implemented taking into account of other concurring priorities of each country.

#### (Rationale)

The proposed definition of “animal welfare” was modified and adopted by the last General Session of the OIE International Committee. During the discussion at the Committee, Japan proposed an addition of above provision, believing that implementation of animal welfare standards should take into account other concurring priorities, such as needs of people for animal products, cultural backgrounds or different infrastructure of each member country. This proposal was supported by some member countries and Japan welcomes that the Committee concluded this proposal to be further considered at the Code Commission and AWWG.<sup>1</sup> Japan believes that introductory part of animal welfare should be thoroughly discussed after seeking member’s comments, taking into account that the definition was proposed by the March meeting of the Code Commission and directly presented to the last OIE International Committee for adoption without country consultation.

Japan points out that the examples of components in the adopted definition of animal welfare include some subjective elements (e.g. “comfortable” and “distress”) and advanced measures (e.g. “able to express innate behaviour” and “appropriate shelter”). Japan concerns expensive animal welfare measures would result in an obstacle to small industries to follow the standard, especially where such measures do not contribute to improve productivity, animal health or sanitary status of animal products.

Considering that these issues are of higher priority than animal welfare in many countries including both developing and developed countries, Japan believes “the introduction to the guidelines for animal welfare” should contain a provision for flexibility. Flexibility in animal welfare standards is important to facilitate countries to implement animal welfare measures according to its diverse situations including difference in social awareness.

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<sup>1</sup> Final Report of 76<sup>th</sup> General Session, Paris, 25-30 May, at paragraph 401

## 6. 1) CHAPTER 1.3.5 Zoning and Compartmentalization

### Specific Comments

#### (Proposed Text)

##### **Article 1.3.5.1: Introduction**

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Establishing and maintaining a disease free-status throughout the country should be the final target for OIE Member countries.

Given the difficulty of establishing and maintaining a *disease* free status for an entire country, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

#### (Rationale)

In the light of the comments of the President of the OIE at 76<sup>th</sup> General Session, "The President of the OIE confirmed that the comments of Japan and the EU would be addressed by the Terrestrial Code Commission at its September 2008 meeting" (Final Report of 76<sup>th</sup> General Session, Paris, 25-30 May, at paragraph 385), Japan re-submits its former comments and requests to the Terrestrial Code Commission for their consideration:

Compartments can only be established and managed by a limited number of large scale enterprises having enough capital to implement biosecurity measures for the compartments. Even if compartments have been established when an outbreak of disease is detected, many small and medium size farmers in the country will be left behind. Therefore, eradication of disease for an entire country as the final target should be clearly described, so as to contribute to accelerate the improvement of the animal health situation on such small and medium size farms.

## 6. 2) APPENDIX 3.X.X. General Guidelines for the Application of Compartmentalization

### Specific Comments

#### 1 . Article 3.x.x.1: Introduction and objectives

##### (Proposed Text)

##### **Article 3.x.x.1: Introduction and objectives**

The guidelines in this ~~appendix~~ Appendix provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 1.3.5. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be final goal for OIE Member countries.

However, establishing and maintaining a disease-free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members ~~Countries~~ have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

##### (Rationale)

In the light of the comments of the President of the OIE at 76<sup>th</sup> General Session, “The President of the OIE confirmed that the comments of Japan and the EU would be addressed by the Terrestrial Code Commission at its September 2008 meeting” (Final Report of 76<sup>th</sup> General Session, Paris, 25-30 May, at paragraph 385), Japan re-submits its former comments and requests to the Terrestrial Code Commission for their consideration:

Compartments can only be established and managed by a limited number of large scale enterprises having enough capital to implement biosecurity measures for the compartments. Even if compartments have been established when an outbreak of disease is detected, many small and medium size farmers in the country will be left behind. Therefore, eradication of disease for an entire country as the final target should be clearly described, so as to contribute to accelerate the improvement of the animal health situation on such small and medium size farms.

## **7. CHAPTER 2.2.10 Foot and Mouth Disease**

### **General Comments**

With regard to the definition for “buffer zone”, Japan notes the comments by the President at 76<sup>th</sup> General Session<sup>4</sup> and believes that the outcome of discussion between the Terrestrial Code Commission and Scientific Commission should be provided to member countries to consider the revised proposal on the code in order to make meaningful comments.

We will make our comments when the outcome of discussion of the two Commissions and their proposal is presented.

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<sup>4</sup>“The President of the OIE urged the Terrestrial Code Commission to work with the Scientific Commission and with the International Trade Department and the Scientific Department to review the definition for buffer zone and appropriate modifications to the FMD Chapter, for consideration by the International Committee in future.” (Final Report of 76<sup>th</sup> General Session, paragraph 387)

## 8. CHAPTER 2.3.13 Bovine Spongiform Encephalopathy

### Specific Comments

#### **Month age requirement for deboned skeletal muscle meat (Article 2.3.13.1 g)**

With regard to month age requirement for deboned skeletal muscle meat, Japan reiterates its previous comments: We strongly object to the proposal to delete the month age requirement, as was suggested by some member countries during the 75<sup>th</sup> and 76<sup>th</sup> General Session. In light of the part of the Supporting Document below, which was distributed by OIE as scientific background for OIE Code, we believe that the month age requirement should be retained, with considering the risk of possible contamination from tissues listed in Article 2.3.13.13 and the fact of PrP<sup>BSE</sup> detection in peripheral nerves of case of BSE.

**(Excerpt from “Supporting Document for Chapter 2. 3. 13. of the Terrestrial Animal Health Code on Bovine Spongiform Encephalopathy”)**

#### **1) 2.3.13.1, 1g Deboned skeletal muscle meat and 2.3.13.9-11 fresh meat and meat products**

(Paragraph 5)

The application of the 30 months age cut off for skeletal muscle meat in Article 2.3.13.1 is based on the significantly reduced risk associated with SRM from animals younger than that age (see Article 2.3.13.13 for list of SRM). For controlled risk countries, a lower age cut off could be considered. However, since Article 2.3.13.1 addresses meat from all categories of BSE risk, it was considered that 30 months should be retained as it added an element of safety regarding possible contamination from tissues listed in Article 2.3.13.13 originating from countries of undetermined BSE risk.

#### **2) Section 2.3.13.1**

**Infectivity/ PrP<sup>BSE</sup> detected in natural clinical cases**

(Paragraph 3)

PrP<sup>BSE</sup> detection has been reported in the peripheral nerves of a case of BSE in Japan (Iwamaru et al., 2005). Additionally, three 80- to 95-month-old Holstein dairy cattle slaughtered at abattoirs in Japan were examined for the distribution of PrP<sup>BSE</sup> by immunohistochemistry (IHC) and Western blot (WB) analyses. The cattle are reported to have shown no clinical signs relevant to BSE but were screened as positive by the Bio-Rad TeSeE test. These positive results were confirmed by IHC or WB in a specimen of the medulla oblongata. Histopathologically, these cattle showed no vacuolation in tissue sections from the central nervous system except for the medulla oblongata. Both IHC and WB analyses revealed PrP<sup>BSE</sup> accumulation in the brain, spinal cord, satellite and ganglionic cells of the dorsal root ganglia, and the myenteric plexus of the distal ileum. In addition, small amounts of PrP<sup>BSE</sup> were detected in the peripheral nerves of two of the cattle by WB. No PrP<sup>BSE</sup> was demonstrated by either method in the Peyer's patches of the distal ileum, additional lymphoid tissues including the palatine tonsils, lymph nodes, and spleen, or other tissues. These Japanese researchers noted that the distribution of PrP<sup>BSE</sup> accumulation in this naturally-occurring, preclinical stage was different from that reported for cattle inoculated experimentally with the BSE agent (Iwata et al., 2006), although the clinical signs recorded as being present at slaughter are considered consistent with some BSE cases identified in the UK (D Matthews, pers. comm.).

## **9. CHAPTER 2.6.7 Classical Swine Fever**

### **General Comments**

Japan generally supports the amendment of the code adopted during the last General Session. The amendment makes the chapter easier to understand. We also welcome the disease status of wild pig population is appropriately taken into account in the proposed amendment.

## 10. CHAPTER 2.7.12 Avian Influenza

### Specific Comments

#### (Low Pathogenic Avian Influenza)

#### (Proposed Text)

##### **Article 2.7.12.19.**

When importing from an HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:  
for fresh meat of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from birds:

1. which have been kept in an ~~HP~~NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections to rule out the presence of NAI with favorable results.

#### (Rationale)

Japan would like to requests the response by OIE to our following previous comments with scientific evidence:

- 1) Judging from the scientific evidence described bellow i) and ii), Japan believes that LPNAI (H5 and H7) can contaminate the meat and bone marrow.
  - i) Japan experienced that H9N2 influenza viruses were frequently isolated from imported chicken meat and bone marrow.
  - ii) Experimental infection demonstrated that H9N2 viruses were recovered from the blood of the chickens co-infected with *S.aureus* or *H. paragallinarum* and CK/Y-55/2001 (H9N2) virus.
- 2) Based on the scientific knowledge that poultry infected with LPNAI shows no specific clinical and pathological signs, it is almost impossible to exclude infected poultry by ante-mortem and post mortem inspections as described in Article 2.7.12.19. 2.

Japan would like to request the Code Commission and the Scientific Commission to modify Article 2.7.12.19.2 as proposed above.

(References: see attached)

- Mase. M *et al.* Characterization of H9N2 influenza A viruses isolated from chicken products imported into Japan from China. *Epidemiol Infect* (2007) 135: 386-391
- Kishida. N *et al.* Co-infection of *Staphylococcus aureus* or *Haemophilus paragallinarum* exacerbates H9N2 influenza A virus infection in chickens. *Arch Virol* (2004) 149: 2095-2104

**(Proposed Text)**

**Article 2.7.12.1.**

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in poultry and are not a consequence of vaccination, have to be immediately further investigated. In the case of isolated serological positive results, NAI *infection* may be ruled out on the basis of a thorough epidemiological investigation including serological and virus detection test in the concerned establishment that does not demonstrate further evidence of NAI *infection*. Otherwise the case should be defined as NAI infection.
7. The following defines the occurrence of *infection* with NAI virus:
- a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or
  - b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry.

**(Rationale)**

In order to make this article more precise, Article 2.7.12.1.5 should be modified as above.

- 1) Japan notes that the Code previously recognized detection of antibody to NAI to be outbreak of NAI and understands such a change was adopted to rule out the isolated cases, which should not be subject to trade restrictions. However, taking into account the fact that NAI is spreading across the globe these years and that immediate disease control measures are critical to effectively contain and to eradicate the NAI, further investigation to rule out isolated cases should not justify delay of disease control measures. Therefore, detection of antibody to NAI should be regarded as an outbreak of NAI.
- 2) Japan also has experienced, in the past outbreaks of LPAI, that seroconversion in sentinel birds has been observed during the course of the epidemiological investigation on the concerned establishments which were put under control measures, although virus has not been detected. We believe such cases should be defined as occurrence of AI infection.

## **11. Chapter2.2.6 Paratuberculosis**

### **Specific Comments**

Considering the global spread of the Paratuberculosis , we think that the OIE code on the disease should be developed. However, we recognize the difficulty to establish the code because of the predominantly subclinical nature of the disease and lack of tests for accurate detection of subclinically infected animals.

In this connection, and considering needs of Members, the technical guide on control and eradication of the disease could be developed first and distribute to Members. We are pleased to contribute to this work, including nomination of an expert, if the ad hoc group to deal with this task will be established.