

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

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## **1. Comments on paragraph 36 of the report of the meeting of the OIE Terrestrial Animal Health Standards Commission (Commodities)**

### **General Comments**

Japan appreciates the OIE clarified importance of commitment of Veterinary Authorities/Services for “establishing and maintaining a disease free-status throughout the country” as the “final goal for OIE member” (i.e., the proposed modification to Chapter 4.3 and 4.4 as contained in Annex VII). Japan strongly believes that the OIE should encourage Members to make every commitment to eradicate animal diseases whenever feasible.

Japan, same as the concept of zoning and compartment, recognises positive implication of “commodity approach” to international trade in animal products by preventing unnecessary trade disruption. However, Japan considers such stability in trade should not undermine motivation of Members to allocate enough resources to eradication of animal diseases. Japan requests the OIE to make similar clarification as above when the OIE proposes a specific chapter on commodity approach.

## **2. Chapter 4.3. Zoning and Compartmentalization and**

### **Chapter 4.4. Application of Compartmentalization (Annex VII)**

#### **General Comments**

Japan supports the modification inserting “Establishing and maintaining a disease free-status throughout the country should be the final target for OIE Member countries.” to Article 4.3.1. and Article 4.4.1. respectively.

### 3. Chapter 8.13 Rinderpest (Annex XIX)

#### Specific Comments

##### (Proposed text)

##### Article 8.13.26

(3<sup>rd</sup> paragraph)

If investigations show the *outbreak* virus originated from outside the country, provided the *outbreak* was localised, rapidly contained and speedily eliminated, and provided there was no serological evidence of virus spread outside the index infected area, accreditation of freedom could proceed rapidly. ~~The Member must satisfy the OIE Scientific Commission for Animal Diseases~~ It should be established that the *outbreaks* were contained, eliminated and did not represent endemic *infection*.

##### (Rationale)

Japan recognizes the OIE has established “Procedures for members for the official recognition and maintenance of status of certain animal diseases” as a formal resolution (Resolution No. XXII of 76<sup>th</sup> General Session of the OIE International Committee). In this context, Japan supports the draft RP chapter includes deletion of the procedural provisions. In the paragraph presented above, specific reference to internal procedure of the OIE should not remain in the Code. Procedure for recovery to the previous status is well stipulated in the 5<sup>th</sup> recommendation of the resolution.

Excerpt from Resolution No. XXII “Update on procedures for Members for the official recognition and maintenance of status of certain animal diseases”.

THE COMMITTEE  
RECOMMENDS

5. To delegate to the Scientific Commission the authority to recognise, without further International Committee consultation, that a Member country or a zone within its territory has regained its previously recognised status of the same zone following outbreaks or infections as appropriate, in accordance with the relevant provisions of the *Terrestrial Code*.

(Adopted by the International Committee of the OIE on 28 May 2008)

## 4. Chapter 10.4. Avian Influenza (Annex XX)

### Specific Comments

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

##### **Article 10.4.1.**

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.
6. 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 10.4.1. should be modified as above. Japan has experienced, in the past outbreaks of LPAI (H5N2), 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. Japan believe such cases should be defined as occurrence of AI infection.

## 5. Chapter 11.6 Bovine Spongiform Encephalopathy (Annex XXII)

### Specific Comments

#### (Proposed Text)

##### Article 11.6.1.

##### General provisions and safe commodities

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos Taurus* and *B. indicus*) only.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone or compartment*:

g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle ~~30 months of age or less~~, 30 months of age or less, which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.6.14.;

#### (Rationale)

Japan strongly objects to the proposal to delete the age requirement.

Japan takes into consideration the following the part of the Supporting Document, which was distributed by OIE as scientific background for OIE Code, and recent articles published in scientific literature including ones by Japanese experts:

1) To make recommendation practical, an element of safety have been added to prevent possible contamination from tissues listed in Article 11.6.13 especially originating from countries of undetermined BSE risk where no BSE measures including surveillance may have been in place.

2) There have been the scientific evidences, that PrP<sup>BSE</sup> can be detected in peripheral nerves in BSE cases and that BSE positive cattle were found among asymptomatic cattle. Therefore, there is a concern over a possibility that skeletal muscle meat of these cattle might contain BSE agent even if SRMs are duly removed.

For the reason above, Japan believes that the age requirement should be retained in order to exclude skeletal muscle meat from cattle over 30 months of age with potential infection risk of BSE from distribution.

(Reference documents)

**1) Excerpt from “Supporting Document for Chapter 2.3.13.(currently 11.6.) of the Terrestrial Animal Health Code on Bovine Spongiform Encephalopathy”**

**i) 2.3.13.1.g (currently 11.6.1.g) Deboned skeletal muscle meat and 2.3.13.9-11(currently 11.6.10.-12.) fresh meat and meat products**

(Paragraph 5)

Since Article 2.3.13.1.(currently 11.6.1.) 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.(currently 11.6.13.) originating from countries of undetermined BSE risk.

(for more information, please refer to the original document)

**ii) Section 2.3.13.1.(currently 11.6.1.)**

**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. [irrelevant texts omitted] In addition, small amounts of PrP<sup>BSE</sup> were detected in the peripheral nerves of two of the cattle by WB.

(for more information, please refer to the original document)

**2) Prion in the peripheral nerves of BSE-affected cattle (Masujin et. al., J. General Virology, 2007, 88, 1850-1858)**

To determine whether parts of the PNS other than those implicated directly in the hypothetical pathogenetic spread of agent from the intestine to the CNS become involved before or after the CNS is affected, PrP(Sc) distribution was investigated by a highly sensitive Western blotting technique in dorsal root ganglia, stellate ganglion, phrenic, radial and sciatic nerves, adrenal gland and CNS of cattle that were inoculated orally with BSE-affected brain and culled sequentially. In experimentally BSE-affected cattle, PrP(Sc) was first detected in the CNS and dorsal root ganglia; subsequently, PrP(Sc) accumulation was detected in the peripheral nerve trunks. PrP(Sc) was also detected in the adrenal glands of cattle that showed clinical signs. No PrP(Sc) was detected in the PNS of BSE-negative cattle. This study shows that, with respect to dorsal root ganglia, a paravertebral sympathetic ganglion and the somatic nerves examined, PrP(Sc) is detected in the PNS during the disease course at the same time as, or after, it accumulates in the CNS.

**(Proposed Text)**

**Article 11.6.15.**

**Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

1. the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk; OR
2. they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that a) skulls ~~and vertebral columns~~ have been excluded and, when gelatin extraction process is not validated for inactivation/elimination of infectivity of BSE agent, vertebrae (excluding tail vertebrae) as well;

**(Rationale)**

1. It is the principle that products potentially contaminated with BSE agent should not be used for human consumption. Only if there is no alternative, government may consider using them after conducting appropriate risk assessment.
2. With regard to "Inactivation of the bovine-spongiform-encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine" in *Biotechnol. Appl. Biochem*, 2004 39, 329-338, which Japan recognizes that OIE uses as one of bases for this revision, notwithstanding justifiable method and conclusion, Japan points out that the report itself mentions the following concerns:
  - 1) Extraction process of gelatine consists of several steps and it is unknown how these steps are efficiently inactivate/eliminate contaminating BSE agents;
  - 2) Initial treatments are known to influence the effectiveness of later steps of the removal/inactivation;
  - 3) The total inactivation can not be determined by summing up the inactivation effect of individual steps; and
  - 4) For above reason, it was necessary for the authors to determine total removal/inactivation experimentally by mimicking the industrial manufacturing process.

In order to achieve acceptable level of inactivation/elimination for abnormal prion proteins, the process applied in the above report should be strictly followed. Japan is concerned whether the conditions provided in the report would be implemented by large-scale industry in every country. Especially when dealing with enormous amount of materials, we can not exclude possibility of inadequate treatment leading to insufficient inactivation.

In addition, Japan would like to seek clarification on the following points:

- 1) The experiments in the above-mentioned report used bovine bone "spiked" with BSE-carrying mouse brain. The "spiked" bone is not in the same condition as the infected bovine material. Accessibility to inactivating agents, such as alkaline, may not be the same for prions embedded in bones and those added as brain homogenates. Is there any

experiments done with vertebrae of BSE-carrying cows or mice?

- 2) The compositions may not be the same among calf vertebrae and advanced age cow and other bones, which may affect inactivation/elimination of prions.
  - 3) Is mechanism of loss of infectivity of BSE through the processes of gelatin extraction known? Is it due to elimination or inactivation?
3. At last, Japan would like to point out that EFSA Journal (2006) 312,1-28 “Quantitative assessment of the human and animal BSE risk posed by gelatine with respect to residual BSE risk” says that removing the skull and vertebral column from the source bones reduces BSE risk.

## **6. Chapter 8.10 Paratuberculosis ( Annex XXIII)**

### **General Comments**

Japan welcomes the Code Commission's approach that it asked the International Trade Department to refer to the Scientific Department for consideration in order for the OIE to develop a guidance document (not for inclusion in the Terrestrial Code) on the management of paratuberculosis.

## 7. Chapter 12.9. - Equine Rhinopneumonitis (Annex XXV)

### Specific Comments

#### (Proposed Title)

Equine Herpes virus Type 1 Infection (Equine Rhinopneumonitis)

#### (Rationale)

Disease caused by EHV-1 infection is called equine rhinopneumonitis, as well as by EHV-4 infection. However, in Article 12.9.2, EHV-4 infection is not mentioned at all, indicating that the importance of EHV-1 infection for international horse movement as described in particular in General provisions. Based on the description in Articles 12.9.1 and 2, Equine Herpes virus Type 1 Infection (Equine Rhinopneumonitis) is suitable for the title of this Chapter.

#### (Proposed Text)

##### Article 12.9.2.

1. showed no clinical sign of equine herpes virus type 1 infection (abortigenic and paralytic forms), on the day of shipment and during the 21 days prior to shipment;
2. were kept for the 21 days prior to shipment in an establishment where no case of equine herpes virus type 1 infection (abortigenic and paralytic forms), was reported during that period.

#### (Rationale)

Equine herpes virus type 1 (EHV-1) is distributed all over the world, and most horses are latently infected with the virus. Therefore, respiratory infection of EHV-1 often occurs among horses by recrudescence of virus shed from latently infected horses, and some of infected horses manifest mild fever which is indistinguishable from symptoms of EHV-4 infection. This mild cold is not a menace for the horses as well as EHV-4 infection. It may bring large economic loss, especially for international horse racing, if international movement is restricted by this mild cold. Therefore, the restriction in the code of OIE should be limited to abortigenic and paralytic forms of EHV-1 infection, as described in particular in General provisions, which are a menace for the horse industry.

## 8. Chapter 14.9. Scrapie (Annex XXVI)

### Specific Comments

#### Article 14.9.1.

##### General Provisions

Scrapie is not considered to pose a risk to human health. The recommendations in this Chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The Chapter does not cover so-called 'atypical' scrapie which is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, ~~may not be contagious and~~ may, in fact, be a spontaneous degenerative condition of older sheep.

#### (Rationale)

In light of the transmissibility of atypical Scrapie which was confirmed by ovinized transgenic mice (see reference), the last sentence should be reconsidered.

#### (References)

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

#### Article 14.9.3.

##### Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

2. one of the following conditions should be met:

~~a) the country or the zone have demonstrated historical freedom taking into account the recommendations in Articles 14.9.13. and 14.9.14.; or~~

#### Article 14.9.13.

##### Principles for declaring a country or zone historically free from scrapie

~~Delete All.~~

#### Article 14.9.14.

##### Requirements to declare a country or zone historically free from scrapie

~~Delete All.~~

#### (Rationale)

Japan proposes to delete provisions referring to historical freedom because, in Chapter 15.3. Classical Swine Fever, since the concept of historical freedom is proposed to be abandoned as maintaining free status cannot be achieved without appropriate surveillance.

## 9. Chapter 15.3 Classical Swine Fever (Annex XXVII)

### Specific Comments

#### (Proposed Text)

##### Article 15.3.1.

For the purposes of international trade, a Member should not impose ~~immediate~~ trade bans in response to a notification of infection with classical swine fever virus in wild pigs according to Article 1.2.3 of the Terrestrial Code after the Member confirms that the Article 15.3.2. is appropriately implemented.

#### (Rationale)

Transmission risk of Classical Swine Fever from wild pigs to domestic pigs should be taken into account and reliable implementation of Article 15.3.2. should be ensured.

#### (Proposed Text)

##### Article 15.3.2.

##### **Determination of the CSF status of a country, zone or compartment**

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

~~1. a risk assessment has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;~~

1. a risk assessment has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;

#### (Rationale)

This particular paragraph should be retained because risk management on the basis of risk assessment is necessary for control of Classical Swine Fever, as mentioned in Article 15.3.2.6., and 15.3.2.7.

#### (Proposed Text)

##### Article 15.3.2.

7. Based on the assessed risk of spread within the wild pig population, and according to Article 15.3.24, the domestic pig population should be separated from the wild pig population by appropriate biosecurity measures to prevent transmission of CSF from wild to domestic pigs. Veterinary Authority should conduct an assessment to demonstrate the appropriate implementation of the biosecurity measures through detailed documentation and carry out periodical review.

#### (Rationale)

It should be ensured that *Veterinary Authority* of exporting country should confirm the separation and take necessary actions such as providing information and conducting on-site

inspection when requested by importing countries.

**(Proposed Text)**

**Article 15.3.13.**

1. which have been subjected to a post-mortem inspection ~~as described in the Codex Alimentarius Code of Hygienic Practice for Meat in accordance with Chapter 6.2.~~ in an approved examination centre, and have been found free of any sign suggestive of CSF. The processing plant for wild pigs to be exported should handle only wild pigs which are confirmed CSF negative by the tests according to the following paragraph 2.:

**(Rationale)**

It is necessary to prevent exportation of meat derived from CSF infected wild pigs or cross-contamination by those infected wild pigs during the processing line.

**(Proposed Text)**

**Article 15.3.13.**

~~2. from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results. and, if the zone where the animal has been killed is adjacent to a zone with infection in wild pigs:~~

2. a sample has been collected from every animal shot killed, and showed negative in virological and serological tests for CSF.

**(Rationale)**

Japan proposes to retain the text of current paragraph 2 as item 2 of paragraph 1 to make it clear that a sample is collected from every animal shot killed.

**(Proposed text)**

**Article 15.3.19.**

**Procedures for the inactivation of the CSF virus in meat**

For the inactivation of viruses present in meat, one of the following procedures should be used:

**1. Heat treatment**

Meat shall be subjected to one of the following treatments:

- a) heat treatment in a hermetically sealed container with a  $F_0$  value of 3.00 or more;
- b) heat treatment at a minimum temperature of 70°C, which must be reached throughout the meat.

**2. Natural fermentation and maturation**

The meat should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

- a) an aw value of not more than 0.93, or
- b) a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

**3. Dry cured pork meat**

- a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.
- b) Spanish style pork meat with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

**(Comment)**

For the reasons described below, Japan finds that it is difficult to apply the current recommendations on inactivation treatment stipulated in paragraphs 2 and 3 of Article 15.3.19. to actual trade. Rather, Japan supports the comments of the ad hoc Group on Trade on Animal Products in its July 2008 meeting (the 3rd paragraph of section 5.3.2 on page 546 of the Code Commission report) and encourages the OIE to review such recommendations based on the recent scientific information and production methods widely used.

**(Rationale)**

1 . According to Australian Import Risk Analysis Report, Classical swine fever virus is stable between pH 4 and 10 (Generic Import Risk Analysis for Pig Meat, February 2004, DAFF, Australia [http://www.daff.gov.au/\\_\\_data/assets/pdf\\_file/0018/18081/2004-01b.pdf](http://www.daff.gov.au/__data/assets/pdf_file/0018/18081/2004-01b.pdf)). This contradicts the condition of 2. b) “a pH value of not more than 6.0.” This discrepancy should be clarified.

2 . Current recommendations for natural fermentation and maturation stipulate different maturation periods required for hams and for loins without any further description of the products which could justify such difference.

3 . The same concern also applies to the recommendations for dry cured pork meat. The names of ham themselves such as “Italian style hams,” and “Spanish style pork meat,” do not indicate the processing methods. Without definitions on processing methods for such named products, these recommendations are not practically applicable.

## **10. Inclusion of official disease status questionnaires in the Code (Annex XXXII to XXXV)**

### **General Comments**

Japan seeks clarification whether the questionnaires are intended to apply only for official recognition by the OIE, or also apply for bilateral consultations.

Japan believes that dossiers for the official recognition by the OIE should be promptly provided to any Member showing its desire to have them, regardless of whether the dossier is provided by the OIE Secretariat or by the applying Country.

**11. Comments on paragraph 15. of “the Report of the Meeting of  
OIE Terrestrial Animal Health Standards Commission,  
Paris, 29 September- 10 October 2008”**

**Specific Comments**

**(Proposed Text)**

**Article 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 Article 7.1.1, Introduction to the Recommendations for Animal Welfare, plays important role for explaining basic idea regarding animal welfare. This article is not necessarily the simple reproduction of the definition of “Animal Welfare” in the Glossary. Japan recalls that this article have not gone through usual call for member comments. Japan believes description of this article deserves open discussion among member countries. Japan proposes the commission to ask member countries for comments regarding the inclusion of “Animal welfare measures are normally implemented taking into account of other concurring priorities of each country.”

## **12. Comments on Report of *ad hoc* group on Animal Welfare and Livestock Production System (Annex XXXVI)**

### **General Comments**

As provided in ANNEX XXXVI, Appendix D, Appendix V, “DISCUSSION PAPER ON THE DEVELOPMENT OF ANIMAL WELFARE GUIDELINES FOR PRODUCTION SYSTEMS (TERRESTRIAL ANIMALS)” there are significant differences from country to country in the level of priority accorded to the welfare of animals. Taking this situation into account, Japan continually emphasizes that the Commission should start with developing the guidelines based on protection of the basic health and normal functioning of animals, provided as first objective in “Clarifying the objectives of animal welfare guidelines” of the above-mentioned discussion paper. Based upon this minimum standard, each country can take its own animal welfare measures according to individual priorities.

Japan supports the approach proposed in the Appendix VI that the OIE guidelines should focus on animal based criteria wherever feasible because methods for producing livestock and environmental conditions greatly differ among areas. Japan believes it is appropriate for member countries to advance efforts toward animal welfare by considering OIE guidelines developed in animal based criteria and member should introduce resource based criteria as needed by taking each country’s situation (e.g. available resources of industry, environmental factors and prevalence of certain diseases) into consideration.