

**Japan's comments on the proposed amendment of the Terrestrial Code in the Code
Commission Report of the September 2009 meeting**

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General Comments

Japan appreciates the efforts of the Commission for compiling the report and examining a large number of comments from the Members within a short time.

Japan thanks the Code Commission for trying to provide rationales for the proposed amendments of the codes. However, Japan notes that they do not provide sufficient convincing scientific backgrounds of the proposals in the Code Commission Report of September. Japan would like to ask the Code Commission to ensure transparency by continuously providing sufficient rationale to each amendment in the report, which leads to further involvement of the OIE members in developing the code.

Japan notes that the term “must” is used in some proposed draft chapters, such as “Use of Animals in Research and Education,” “Animal Welfare and Broiler Production Systems” and “Animal Welfare and Beef Production Systems”. Japan proposes to replace the term “must” with “should” throughout the draft texts for consistency of the term in the codes, as they constitute recommendation for the Members.

2. Glossary (Annex III)

Specific Comments

(Proposed Text)

Article 10.4.1.

Quarantine Station

means an establishment under the control of the *Veterinary Authority* where *animals* are maintained in isolation with no direct or indirect contact with other *animals*, to ensure that there is no transmission of specified pathogen(s) outside the establishment while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing and treatment. The presence of *disease* or *infection* in imported *animals* in the quarantine station does not affect the animal health status of the country or *zone*.

(Rationale)

Quarantine Station may be used for export quarantine or, if necessary, isolation of domestic animals. Animals which are deemed not to affect the animal health status should be limited to imported animals because the presence of disease or infection in domestically produced animals in the quarantine station is considered to reflect the status of the county or zone.

3. Chapter 7.X – Use of Animals in Research and Education (Annex XVII)

Specific Comments

(Proposed text)

Preamble

(5th paragraph)

~~The OIE recommends that records on animal use should be maintained, as appropriate to the institution and project proposals and species used, on a regional or national basis. These records may be used to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.~~

(Rationale)

To avoid duplication. The same description is in paragraph 2 of Article 7.X.3.

(Proposed Text)

Article 7.X.1.

Definition

~~Biological safety or B~~iosafety

means the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

~~Biological containment or B~~iocontainment

means the system and procedures designed to prevent the accidental release of biological material including allergens. The objective of biocontainment is to confine biohazards and to reduce the potential exposure of the laboratory worker, *animals* on other studies, persons outside of the laboratory, and the environment to potentially infectious agents.

Genetically altered animal (~~GA animal~~)

means an *animal* that has had a random or targeted change in its nuclear or mitochondrial DNA, or the progeny of such an *animal(s)*, where they have inherited the change, achieved through a deliberate human technological intervention.

Operant (~~Instrumental~~) conditioning

means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

(Rationale)

For “Biological safety or Biosafety” and “Biological containment or Biocontainment,” terms “Biological safety” and “Biological containment” should be deleted respectively since they are not used in the draft text.

“GA animal” and “Instrumental conditioning” should be deleted since they are not used in the draft text.

(Proposed text)

Article 7.X.3.

The Oversight Framework

(1st paragraph)

The role of a *Competent Authority* is to ~~implement~~ ensure appropriate implementation of a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance may be assessed at the level of the country, the region and/or the institution.

(3rd paragraph)

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This ~~is may be~~ accomplished by an oversight body which can be a single body or distributed across different groups. ~~The oversight body Different systems of oversight~~ may involve *animal welfare* officers, regional/local committees, or national bodies. Typically each institution utilises a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee or Animal Care Committee) as the oversight body to deliver this oversight framework. Where the local committee does not perform ethical review, this may be undertaken by regional or national ethical review bodies. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

(4th paragraph)

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included in the oversight body as a minimum:

1. Project Proposal Review

(last paragraph)

Following approval of a Project Proposal, consideration should be given to implementing an oversight method to ensure that animal activities conform with those described in the approved Project Proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body ~~local oversight committee~~, *animal welfare* officer, compliance/quality assurance officer or government inspector.

3. Animal care and use programme review

The animal care and use programme reflects the policies and practices of the institution. It should include the functioning of the oversight body ~~local oversight committee~~; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly and in case of noncompliance, should be included in relevant regulations to empower the oversight body ~~Competent Authority should~~ ~~to~~ take appropriate action to ensure compliance.

(Rationale)

In order to facilitate reader’s understanding, Japan proposes to use “oversight body” as a term to collectively describe organizations which deliver oversight framework. Whether a Competent Authority is included in the oversight body or not depends on the situation of each country or region.

For modification of first paragraph of the Article 7.X.3., a Competent Authority cannot implement a system owned by non-governmental organization but can ensure the appropriate implementation of a system.

For paragraph 4 of the Article 7.X.3., Japan proposes to add words to clarify that the expertise should be included in the oversight body.

For the paragraph in “3. Animal care use program review,” Japan proposes to modify the sentence to clarify that the oversight body is responsible for taking appropriate action to correct the noncompliance found as a result of periodical review. Japan believes that the following should be taken into consideration when developing this sentence:

- i) in some cases the oversight body other than those related to Competent Authority might take action to ensure the compliance; and
- ii) the proposed draft text dose not clearly indicate what content should be included in the regulation.

(Proposed text)

Article 7.X.4.
Assurance of Training and Competency
5. Members of the oversight body ~~local oversight committee or others involved with oversight~~
Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

(Rationale)

The same as the rationale for the proposal for Article 7.X.3.

4. Draft Chapter X.X.X- Animal Welfare and Broiler Chicken Production System (Annex XVII) Draft Chapter 7.X.X- Animal Welfare and Beef Cattle Production System (Annex XVII)

General Comments

Japan requests the Code Commission to add detailed definition or explanation to each measurable in Article X.X.4. for clarification. For example, “feeding and drinking” needs to be explained since “feeding and drinking” itself is a normal behavior and reduced “feeding and drinking” may be an outcome of poor welfare.

As how the Article X.X.5. “Recommendations” relates to Article X.X.4. “Criteria or measurable for the welfare of broilers/beef cattle” is unclear, Japan would like to request the Code Commission to add some sentences to explain their relationship. For example, “Outcome based measurables may appear when recommendations were not adequately implemented. In that case implementation of recommendations related to the certain measurables should be reviewed as appropriate.”

In addition, Japan believes there should be consistent use of the terms to indicate specific measurables in Article X.X.4. and Article X.X.5. For example, “gait” is used in Article X.X.4. while “lameness” is used in Article X.X.5. and “poor performance” described in Article X.X.5. is not listed in Article X.X.4.

Japan supports the conclusion of the *Ad hoc* group that it would be impractical to assign numeric values to measurables. Japan requests the Code Commission not to include specific numeric values to the recommendations.

*These comments apply both draft chapters for broiler and beef cattle.

5. Chapter 8.5 – Foot and Mouth Disease (Annex XX)

General Comments

The concept of FMD free compartment should not be included in Chapter 8.5. unless the OIE develop a concrete official checklist of an effective biosecurity management system against FMDV. This is because FMD spreads by airborne infection among other routs, and cattle and swine are usually raised in the field or open premises.

6. Chapter 8.10 –Paratuberculosis

General Comments

Japan would like to propose to maintain this chapter. Considering the global spread of paratuberculosis, Japan believes that the lack of adequate diagnostic tests would not be a sufficient reason for removing the chapter from the Codes.

Japan will be ready to contribute in developing technical guide on control and eradication of the disease when an ad hoc group to deal with this task is established.

7. Chapter 10.4 – Avian Influenza (Annex XXIII)

Specific Comments

(Proposed text)

Article 10.4.20

Recommendations for importation from either a NAI or a HPNAI free country, zone or compartment

for fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*:

1. which have been kept in a country, zone or compartment free from either NAI or HPNAI since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an approved abattoir in a country, zone or compartment free from either NAI or HPNAI and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2 and have been found free of any signs suggestive of NAI.

(Rationale)

If Article 10.4.19 and Article 10.4.20 are merged, descriptions regarding NAI should be put into the merged article in order to avoid any omission.

8. Chapter 15.3 - Classical Swine Fever (Annex XXXII)

Specific Comments

(Proposed text)

Article 15.3.3

CSF free country, zone or compartment

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.3.23 to 15.3.28 has been in place for at least 12 months, and when:

1. there has been no *outbreak* of CSF in domestic pigs during the past 12 months;
2. no evidence of CSFV infection has been found in domestic pigs during the past 12 months;
3. no vaccination against CSF has been carried out in domestic pigs during the past 12 months ~~unless there are means, validated to OIE standards (Chapter 2.8.3 of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;~~
4. imported domestic pigs comply with the requirements in Article 15.3.5 or Article 15.3.6.

(Rationale)

Japan requests to exclude the mentioned clause because Chapter 2.8.3. of the Manual does not contain validated diagnostic approach to distinguish whether antibody is derived from vaccine or not. Japan believes that Members should discuss inclusion of this sentence in the future when specific protocol is presented.

9. Proposed Chapter on Communication (Annex III)

General Comments

Japan notes that the previous comments of Japan on the definition of communication terms were not reflected in the draft code without any reasons. Japan would like to reiterate the importance of the Code Commission to provide its responses to the comments of Members in its report, especially when comments of Members are not reflected in the draft Codes.

Japan requests the Code Commission to restore the definitions to those proposed by the *Ad hoc* group.

Specific Comments

(Proposed text)

Proposed Chapter on Communication

Definition

Communication

means the discipline of interactively informing, influencing, and motivating individual, institutional and public audiences, ~~preferably on the basis of interactive exchanges~~ about animal health, animal welfare and related public health and food safety issues and any other ~~any~~ issues falling under ~~the mandate of the OIE and~~ the competence of the *Veterinary Services*.

Crisis

means a time of great danger, difficulty or uncertainty when problems related to animal health, public health and/or food safety ~~any issue falling under the mandate of the OIE and the competence of the~~ *Veterinary Services* require immediate action.

Crisis Communication

means the process of providing information of potentially incomplete nature within **extreme** time constraints that allows an individual, affected and/or interested parties, an entire community or the general public to make best possible decisions ~~and be informed of and/or~~ **accept** policy decisions and rationale behind policy decisions during a crisis.

(Rationale)

1) **Communication**

Japan believes that the “interactive” nature is essential but not optional for communication as is mentioned in Point 3a) of the Report of OIE Ad hoc Group on Communication in September 2008. Japan believes that one-way expression of opinions cannot be defined as communication. One-way expression should rather be called as “transmission.”

In order to make the Code more understandable for Members and other interested people, areas concerned should be specified rather than referring to “the mandate of OIE.”

2) **Crisis**

Some of issues falling under the mandate of the OIE may not be recognized as crisis by its nature, such as animal welfare. Crisis should be limited to issues related to animal or

human health.

3) Crisis Communication

Every communication faces time constraints, but crisis communication is made under the situation that time is even more limited. Therefore, the word “extreme” should be added to define the nature of crisis communication more precisely.

One-way information does not suffice as communication. It is essential that policy decisions and their rationale are accepted by public even under a crisis so that the public can make best decisions possible.

10. Control of Hazards of Animal and Public Health Importance in Heat Treated Pet Food (Annex XIV)

Specific Comments

(Proposed Text)

Article 1

Introduction

Pet food is often overlooked as a component of the animal feed ~~and human food~~ supply-chain that has a direct impact on animal health and *welfare* and also on ~~food safety and~~ public health. ~~The importance stems not only from the potential to affect pets and their owners, but also from the potential to affect food producing animals through the use of pet food as a protein source in compounded feeds.~~

Article 2

Objective and scope

The objective of this chapter is to complement Chapter 6.3. and to provide guidance on controlling hazards in pet food in relation to animal health and zoonoses ~~and food safety~~. The chapter aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of pet food fed to pets, including pet treats and pet chews.

For the purpose of this chapter, “pets” are limited to dogs or cats.

(Rationale)

As the definition tells, pet foods mean feeds prepared and distributed for consumption by dogs and cats. Japan believes that the scope of this chapter is to provide guidance on controlling hazard in pet foods during its production and use. Controlling hazards in pet foods when they are used in a way other than pet feeding (e.g. livestock feeding or human consumption) is outside the scope of this chapter. Therefore, Japan proposes to delete the words related to food safety or animal feed other than pet foods and add words to clarify the scope of this chapter.

(Proposed Text)

Article 3

Definitions

Wet pet food – means ~~low acid (pH greater than 4.6)~~ pet food ~~in hermetically sealed containers~~ with a moisture content ~~greater~~ not less than 65 percent.

(Rationale)

The wet pet food is compromised of two subtypes according to the Article 6. Since the proposed definition covers only one subtype, Japan proposes to delete some words which exclude the other subtype (i.e. refrigerated pet food in non-hermetically sealed containers).

Japan notes that pet foods with a moisture content of 65% is left out of the definition of soft-moist and wet pet food and needs to be added within the definition.

(Proposed Text)

~~Article 5~~

~~Groups of pet food~~

~~Pet food groups are described by the percentage of moisture in the finished product. Wet pet food is described as containing greater than 65% moisture in the finished product. Dry pet food contains less than 20% moisture in the finished product; while soft-moist products will contain between 20% and 65% moisture.~~³

(Rationale)

To avoid duplication. The same description can be found in the Article 3 “definitions”.

11. Report of the ad hoc Group on Private Standards and International Trade in Animals and Animal Products (Annex XL)

General Comments

Japan appreciates the establishment of the *ad hoc* group to work on the concerns about private standards. OIE's work plan indicates that during the OIE General Assembly in May 2010, Members will be discussing a strategy with an aim to help Members avoid or minimize current or potential negative effects of private standards. In light of this work plan, Japan would like to ask the Code Commission to take the following into consideration when drafting the strategy.

i) Japan supports the conclusion of the *ad hoc* group that private standards are a fact and it is probably beyond the power of governments to abolish them and also support the view discussed in the *ad hoc* group that the private companies and national or international organizations have the right to establish commercial conditions for trade without interference from governments. In this connection, Japan would like to ask the Code Commission not to place any additional obligation on Members regarding private standards.

ii) Japan requests the working definition on private standards be refined because the provisional definition covers too broad range of requirements, i.e. it covers all commercial requirements on animal and animal products including individual conditions between a buyer and a seller, while as long as Japan sees the disciplines generally agreed by the *ad hoc* group indicated on the agenda item 3 of the report, such as "private standards should be published" or "private standards should be regularly reviewed", major international schemes such as GLOBALGAP, ISO or SQF seems to be the scope of the discussion. In addition, it also covers commercial requirements which are not fallen in the mandate of OIE such as products size.

iii) Japan considers it is not necessary to differentiate approaches to deal with private standards between sanitary safety and animal welfare at this moment since the legal interpretation of private standards in the SPS Agreement remains unsolved in the WTO/SPS Committee.

12. Comments on paragraph 2 of A. MEETING WITH THE DIRECTOR GENERAL of the report of the meeting of the OIE Terrestrial Animal Health Standards Commission (standards, guidelines and recommendations)

General Comments

The texts such as standards, guidelines and recommendations developed under auspices of OIE are primary reference for the OIE members. At the same time, WTO members shall base their SPS measures on the standards, guidelines and recommendations developed by the OIE under the SPS Agreement¹.

In this regard, Japan believes that careful consideration should be given when using these terms which are used in the SPS Agreement.

Japan believes that the OIE does not intend to pose any additional obligation to WTO members by its proposal to consider texts found outside the Codes and Manuals (for example, on the OIE internet site) as guidelines or recommendations, because:

- 1) this proposal is just to categorize the name of existing texts and does not change obligations of Members; and
- 2) the Code Commission clarified in the 75th OIE Assembly that the Checklist of Avian Influenza, example of “recommendation” of the OIE proposal, would not have any legal weight.

The proposal may give impression to WTO members that they owe extensive obligations and cause Members’ confusion, because terms “standards,” “guidelines” and “recommendations” are clearly indicated in the SPS Agreement. Japan considers that difference of the liability of the term “guidelines and recommendations” should be clarified between the texts in OIE and those in the SPS Agreement.

With this purpose Japan would like OIE to ask WTO to clarify that “guidelines and recommendations” categorized in OIE are not equal to those used in the SPS Agreement

¹ Japan notes that in 1998 Dr. Tiermann, the chairperson of the SPS Committee at that time, expressed his observation in response to request of Codex (see CX/EXE 98/45/9) that how a text is applied to the SPS Agreement depend on its substantive content rather than the category of the text.

13. Comments on Item 38. Trade in animal products ('commodities') of the report of meeting of the OIE Terrestrial Animal Health Standards Commission

General Comments

Japan again would like to emphasize the importance of maintaining motivation of Members for disease eradication.

Japan recognises positive implication of “commodity approach” to the international trade of animal products by preventing unnecessary trade disruption, which is the same implication as the zoning and compartment have. However, Japan considers such approach should not undermine final objectives of Members to allocate sufficient resources including staff and establishments to eradicate animal diseases.