I. “General definition (CHAPTER 1.1.1)” (Annex III)

Specific Comments

(Proposed text)

Article 1.1.1.1

~~Animal welfare~~

~~means the state of animal as regards its attempts to cope with its environment and includes both the extent to failure to cope and the ease or difficulty in coping.~~

Commodity

means live animals, products of animal origin, animal genetic material, biological products, straw and forage and pathological material.

~~Infected country~~

~~means a country in which the absence of the disease under consideration has not been demonstrated by the requirements specified in the Terrestrial Code being met.~~

Sanitary measure

means a measure, such as those described in various chapters of the Terrestrial Code, designed to protect animal or human health or life within the territory of the Member from risks arising from the entry, establishment or spread of a hazard. [Note: A detailed definition of sanitary measure be found in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.]

(Rationale)

Animal welfare

Japan is concerned that the proposed definition of animal welfare is too broad and involves multiple meanings. Japan is of the position that the OIE should collect information on how the term “animal welfare” is used within member countries.

Commodity

Taking into account that current definition includes products for animal feeding, and that Article 2.2.10.29 provides sanitary measures for straw and forage which are not animal origin, straw and forage must be included in the definition of “commodity”.

Infected country

Taking into account that chapters for specific diseases, such as rinderpest (Article 2.2.12.5) and bluetongue (Article 2.2.13.4), have specific definitions for “infected country”, Japan believes that the proposed definition of “infected country” for general use is confusing.

Sanitary measures

Japan believes the reference to the SPS agreement is important because the agreement has substantial implication on the relation between the OIE Code and the most OIE Member countries which are at the same time members to the WTO. The reference to the SPS agreement should be retained unless the reason for such deletion is clarified.

II. "Draft Guidelines on the design and implementation of identification systems to achieve animal traceability" (Annex XXI)

Specific Comments

(Proposed text)

Article 3

2. Scope

Scope should also be defined through consultation between the *Veterinary Administration Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; poultry in a defined compartment; cattle within a defined FMD free *zone*. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

(Rationale)

Compartment for poultry against AI or ND is one of the typical cases the member countries apply these guidelines.

(Proposed text)

Article 3

5. Design of the programme

~~j) Commercial arrangements~~

~~An animal identification system requires producers, processors and others (depending on the design of the system) to purchase equipment. There are many possible commercial arrangements that will have a variety of implications for the uptake of the animal identification system.~~

~~k~~j) Transition planning

Any transition from an existing animal identification system needs to be designed to ensure it is easy for users of the existing system to make the change and to insure that data integrity is maintained during the transition and integrated into the new animal identification system.

~~l) Use of incentives~~

~~Depending on the drivers for participation in the animal identification scheme, incentives may be useful to encourage early adoption of the system or to fill capability, capacity or technology gaps.~~

(Rationale)

The proposed item j) and item l) address economic tools for facilitation of introduction of traceability, which is not relevant to the performance of the animal identification systems. These tools should be arranged according to the economic, political financial situation of each country, but should not be prescribed by the Code as elements of "Design of the programme", such as registration and information system.

III. "Guidelines for the control of hazards animal health and public health importance in animal feed"

Specific Comments

(Proposed text)

Article 3
Definitions

For the purpose of these guidelines, the following definitions apply.

~~**Hazard**~~

~~means a biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse effect.~~

(Rationale)

The scope of the definitions should be clarified. The definition of "Hazard" should be deleted since this definition is the same as defined in the General definitions in Chapter 1.1.1.

(Proposed text)

Article 4

12. Cross contamination

It is important to avoid cross-contamination during the manufacture, storage, distribution (including transport) and use of feed and feed ingredients and relevant provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Physically separated manufacturing lines should be used to avoid cross-contamination. Procedures, such as flushing, sequencing and physical clean-out, are also effective ~~should be used~~ to avoid cross-contamination between batches of feed or feed ingredients.

(Rationale)

Physical separation of manufacturing lines should be mentioned before the other measures since the feasibility of physical separation should be explored first to avoid cross contamination completely.

IV. “Guidelines for the transport of animals by sea (Appendix 3.7.2)” (Annex XXIII)

Specific Comments

(Proposed text)

Article 3.7.2.7
Pre-journey period

1. General considerations

b) In some circumstances, animals may require pre-*journey* assembly. In these circumstances, the following points should be considered:

i) Pre-*journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

~~ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the *journey*.~~

ii)~~iii)~~ When animals are to be provided with a novel diet or unfamiliar methods of supplying feed or water, they should be preconditioned.

(Rationale)

The proposed modification on item ii) does not make sense. The Working Group on Animal Welfare recommends the whole item ii) to be deleted.

V. “Draft Guidelines on dog population control” (Annex XXIII)

Specific Comments

(Proposed text)

Article 3
Definitions

For the purpose of these guidelines, the following definitions apply.

(Rationale)

The scope of the definitions in this article should be clarified.

VI. “Devising import health measures for animal commodities” (Annex XXV)

General Comments

Japan supports the OIE started the work on the commodity-based approach. This work provides members with practical instruction for development of sanitary measures applicable to trade in major animal products.

Japan notes there also seem to be some boxes which recommend “no measures necessary for trade”, in spite that no corresponding provision exists in the Code that no sanitary measures are necessary for trade. Japan would like to encourage the OIE to review such areas and to propose appropriate revisions to the Code where necessary.

VII. "Report of the sixth meeting of the OIE Working Group on Animal Welfare" (Annex XXVIII)

Wildlife welfare (6.5 of the AWWG report)

With regard to discussion in 6.5 b) of the report of the OIE Working Group on Animal Welfare (the AWWG), Japan would like to point out that conservation of wild animal resources or biodiversity is out of the mandate of the OIE accorded by the resolution of "Animal Welfare Mandate of the OIE" (Resolution XIV of International Committee in 2002). In addition, Japan believes that many Delegates to the OIE of Member countries are not responsible for environmental protection or conservation of endangered species, but responsible for animal health and related welfare issues. Therefore, these topics would be better addressed by other international organizations with different expertise than the OIE.

Discussion paper on the development of animal welfare guidelines for production systems (terrestrial animals) (Appendix J of the report of AWWG of the Annex XXVIII)

Japan appreciates the efforts of the Commission and the AWWG to develop this paper and proceed with this issue in a transparent manner.

(Backgrounds)
Japan agrees to the AWWG's view that "animals are raised under extremely diverse conditions". It is also true that "there are also large differences from country to country in the level of priority accorded to the welfare of animal food animals". Taking into account such diversity and difference, Japan requests the OIE to develop the guidance as an advisory text, rather than the Code as an international standard, so that Members may decide whether to apply the guidance.

(Animal-based criteria)
Japan supports the AWWG to utilize animal-based criteria, especially survival rate and incidence of disease and injury, since such criteria enable Member countries to devise animal welfare measures suitable for their existing livestock industry. However, Japan is concerned that some animal-based criteria, such as the reaction of animals to their handlers, are difficult to implement nationwide because of difficulty to monitor and to evaluate compliance to such criteria objectively. Japan requests the Commission and the AWWG, in the course of development of the guidance, to consider whether member countries can implement the guidance and evaluate the performance according to such criteria.

(Clarifying the objectives of animal welfare guidelines)
Japan supports the approach proposed in the discussion paper that the guidance should focus principally on objective 1 and address objective 2 and 3 where feasible and appropriate. Japan is of the position that animal welfare guidance should be developed to balance productivity and animal welfare. Japan is also of the opinion that the sanitary status of animals and products thereof should not be sacrificed in order to improve animal welfare. With regard to "social expectations" of the cultures with high priority on animal welfare, such countries may implement higher animal welfare standards of their own, according to their social expectation and building upon the OIE guidance. Therefore, Japan believes the OIE should primarily focus "to protect the basic animal health and normal functioning of animals, for example by preventing and alleviating disease, injury, malnutrition and similar harm".

(Clarifying underlying science)
Japan supports the AWWG to start from a competent review of the relevant science in place and widely accepted for development of the guidance. Japan is of the position that the AWWG should start the work from the area where scientific reviews are clear and consistent, and that the guidance should always be elaborated on scientific grounds.

(Recommended next steps)
Japan requests the AWWG to proceed with this issue taking into account our comments above. For the guidance, Japan believes that it is critical that above-mentioned diversity and difference among Members are appropriately taken into account. For this purpose, Japan recommends the Commission and the AWWG to develop and send a questionnaire to collect views and information from Members before starting drafting.

Japan's additional comments on the Report of the September 2007 meeting of the OIE Terrestrial Animal Health Standards Commission

(List of comments)

1. 1) Chapter 1.3.5 －Zoning and compartmentalization (Annex V)

2) Appendix 3.X.X －General guidelines for the application of compartmentalization (Annex V)

2. Chapter 2.2.10 －Foot and mouth disease(Appendix VII)

3. Chapter 2.3.13 －Bovine Spongiform Encephalopathy(Annex XII)

4. Chapter 2.6.7 －Classical Swine Fever(Annex XVII)

5. Chapter 2.7.12 －Avian influenza(Annex XVIII)

(Comments previously submitted)

6. Chapter 1.1.1 －General definition (Annex III)

7. Draft Guidelines on the design and implementation of identification systems to achieve animal traceability (Annex XXI)

8. Guidelines for the control of hazards animal health and public health importance in animal feed

9. Appendix 3.7.2 －Guidelines for the transport of animals by sea (Annex XXIII)

10. Draft Guidelines on dog population control (Annex XXIII)

11. Devising import health measures for animal commodities (Annex XXV)

12. Report of the sixth meeting of the OIE Working Group on Animal Welfare (Annex XXVIII)

1. 1) CHAPTER 1.3.5

Comments on the Zoning and compartmentalization

Specific Comments

1. Article 1.3.5.1: Introduction
(Proposed text)

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.

(Comments)
The following sentence should be added: "Establishing and maintaining a disease free-status throughout the country should be the final target for OIE Member countries." after paragraph 1.

(Rationale)
Compartment can only be established and managed by a limited number of major managements with enough capital to implement biosecurity measures for the compartment. It is crucial for Member countries to eradicate the disease when an outbreak of disease is detected. Even though compartments have been established, Member countries should eradicate the disease taking into account there also are many other small and medium sized farms exist in the country. For this purpose, eradication of disease for an entire country as the final target should be clearly described.

2. Article 1.3.5.1: Introduction
(Proposed text)

(Under study) A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of a limited *outbreak* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

Article 1.3.5.3: Principles for defining a zone or compartment, including containment zone
(Proposed text)

(Under study)

2. Establishment of a *containment zone* should be based on a rapid response including appropriate standstill of movement of animals and *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreak* is contained within this *zone* through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* and likely source of the *outbreak* should be identified and all *cases* shown to be epidemiologically linked. For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.

   A *stamping-out policy* or another effective control strategy should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*. Measures to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing surveillance in the *containment zone*, should be in place.

   The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The suspension of free status of these areas could be lifted, once the *containment zone* is clearly established, irrespective of the provisions of the *disease* specific chapter.

   The recovery of the free status of the *containment zone* should follow the provisions of the *disease* specific chapter.

(Comments)
Proposed text on “containment zone” as above should be kept ‘under study’.

(Rationale)
We understand that containment zone is considered to be a particular example of zoning. However, Japan believes that adding a generic reference to containment zone in Chapter 1.3.5 is premature until Member countries share how the following issues are addressed:

1. Member countries lack practical experience and knowledge in applying containment zone for various diseases;
2. Measures necessary for containment zone should vary depending on characteristics of diseases including difference in hosts, pathogenic agents, transmission manners; and
3. There are several remaining issues which should be appropriately addressed by the Code commission, such as “stamping out policy or another effective strategy”, or “no new case in the containment zone within a minimum two incubation periods…”.

1. 2) APPENDIX 3.X.X.

Comments on the GENERAL GUIDELINES FOR THE APPLICATION OF COMPARTMENALISATION

Specific Comments

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

(Proposed text)

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.

(Comments)

The following sentence should be added: "Establishing and maintaining a disease free-status throughout the country should be the final target for OIE Member countries." after paragraph 1.

(Rationale)

Compartment can only be established and managed by a limited number of major managements with enough capital to implement biosecurity measures for the compartment. It is crucial for Member countries to eradicate the disease when an outbreak of disease is detected. Even though compartments are established, Member countries should eradicate the disease taking into account there also are many other small and medium sized farms would exist in the country. For this purpose, eradication of disease for an entire country as the final target should be clearly described.

2. Article 3.x.x.3 : Separation of a compartment from potential sources of infection
(Proposed text)

c) Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

i) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;

ii) the critical control points for each pathway;

iii) measures to mitigate exposure for each critical control point;

iv) standard operating procedures including:

- implementation, maintenance, monitoring of the measures;
- application of corrective actions;
- verification of the process;
- record keeping;

v) contingency plan in the event of a change in the level of exposure;

vi) reporting procedures to the *Veterinary ~~Administration~~ Authority*;

vii) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;

viii) the surveillance programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the biosecurity plan in accordance with the level of *risk* for each identified pathway. The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the *disease* agent into the *compartment*.

(Rationale)

In order to make the guidelines to be more practical, Japan proposes to specify a general time frame for re-assessing the biosecurity risk of a compartment. Taking into account that OIE's official recognition of disease status requires documents for verification on an annual basis, the suggested minimum time for periodical assessments is necessary to be described.

3. Article 3.x.x.8 : Supervision and control of a compartment
(Proposed text)

3. Article 3.x.x.8 : Recognition, Supervision and control of a compartment

a) Veterinary Authority
The *Veterinary ~~Administration~~ Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The Veterinary Authority should:

- evaluate the Veterinary Services in terms of their ability to recognize, supervise and control the compartments
- develop general criteria for establishing and maintaining compartment. (e.g. biosecurity management standards in the compartment, surveillance in and around the compartment)
- develop model biosecurity plans in conjunction with the industry.
- publish the general criteria and model biosecurity plans.

The *Veterinary ~~Administration~~ Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this ~~appendix~~ Appendix and ensure that all the information is readily accessible to the *importing countries*.

b) Veterinary Service
The authority, organisation, and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the OIE *Terrestrial Code*, to provide confidence in the integrity of the *compartment*. The Veterinary Service should:

- periodically re-assess the risk factors in and around the compartment in order to ensure that the biosecurity plan continues to be appropriate to the situation.
- establish the protocol for auditing the biosecurity management of the compartment.

Any significant change should be notified to the *importing country*. The exporting country should provide access to the compartment to be examined and evaluated upon request of the importing counrty.

(Comments)
Sentences should be added as above.

(Rationale)
Japan believes that these guidelines should provide concrete criteria and other necessary procedures according to which Veterinary Authority and Veterinary Services could uphold the conformance to the requirements for the compartment, through recognition, supervision and control of the compartment at the time of the establishment of the compartment or through periodical audit after the establishment.

2. CHAPTER 2.2.10

Comments on the Foot and mouth disease (FMD)

Specific comments

Article 2.2.10.7: Establishment of a containment zone within an FMD free country or zone
(Proposed text)

In the event of a limited *outbreak* within an FMD free country or *zone* with or without vaccination, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

1. the *outbreak* is limited based on the following factors:
   a) immediately on suspicion, a rapid response including notification has been made;
   b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
   c) epidemiological investigation (trace-back, trace-forward) has been completed;
   d) the *infection* has been confirmed;
   e) the primary *outbreak* and likely source of the *outbreak* has been identified;
   f) all *cases* have been shown to be epidemiologically linked;
   g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 2.2.10.1. after ~~from~~ the last ~~detected~~ *case* was detected and the control measure were completed.

~~2. surveillance in accordance with Appendix 3.8.7. demonstrates that there are no undetected *cases* in the *containment zone*;~~

~~3~~2. a *stamping-out policy* ~~or another effective control strategy~~ has been applied;

3. the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;

~~4~~. increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;

5. measures to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing surveillance in the *containment zone*, are in place.

6. Containment zone should be large enough to contain the disease and comprise both a restricted/protection zone and a larger surveillance zone

7. Establishment period of a containment zone should not exceed the period in "Article 2.2.10.8". If the recovery for FMD free status of the containment zone was not regained during the period, the containment zone status should be revoked.

(Comments)

1. On item 1 g): To clarify the meaning of the sentence. In addition, we request the scientific justification on "within a minimum of two incubation period" and otherwise it should be kept "under study".
2. On item 2: "or another effective control strategy" should be deleted.
   We believe that application of the containment zone is a temporary measure and in order to secure early eradication of FMD, stamping out policy is critical.
3. On item 3: We request the rationale for adding this sentence with example.
4. On item 6: In order to be sure of the efficacy of a containment zone, item 6 should be added.
5. On item 7: Application of the containment zone should be a temporary measure.
   Too long duration of containment zone is considered that disease control system of the country is insufficient and incomplete in containing disease.

3. CHAPTER 2.3.13

Comments on the proposed amendment on the Bovine Spongiform Encephalopathy (BSE) Chapter of the code

Specific comments

Article 2.3.13.1 g
With regard to month age requirement for deboned skeletal muscle meat, Japan reiterates its former comments:
We object to the proposal, which was suggested by some member countries during the 75th General Session, that month age requirement of cattle producing deboned skeletal muscle meat (Article 2.3.13.) should be deleted.

Article 2.3.13.15.
(Proposed text)

Veterinary Authorities of *importing countries* should require:
for gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices
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 from cattle over ~~30~~ 12 months of age at the time of *slaughter* have been excluded ;
   b) the bones have been subjected to a process which includes all of the following steps:
      i) degreasing,
      ii) acid demineralisation,
      iii) acid or alkaline treatment,
      iv) filtration,
      v) sterilisation at ≥138°C for a minimum of 4 seconds,
      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating)~~;~~.

~~OR~~

~~3. they originate from a country, *zone* or *compartment* posing an undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that~~
   ~~a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;~~
   ~~b) the bones have been subjected to a process which includes all of the following steps:~~
      ~~i) degreasing,~~
      ~~ii) acid demineralisation,~~
      ~~iii) acid or alkaline treatment,~~
      ~~iv) filtration,~~
      ~~v) sterilisation at ≥138°C for a minimum of 4 seconds,~~
      ~~or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).~~

(Comments)
Japan cannot accept the proposed draft revision to point 2 a) of Article 2.2.13.15.
The revision eases the requirements, by enabling countries posing undetermined BSE risk to use cattle vertebrae as raw ingredients of gelatin and collagen. Japan cannot accept it because the OIE has not shown any scientific evidence created after the discussion we had at the 75th General Session.
Japan strongly recommends that the OIE should carefully discuss whether to relax the requirements for raw material of collagen and gelatin, based on underlying scientific evidence published.
In addition, Japan requests that in view of transparency, the OIE publish discussion proceedings and all relevant information used, including scientific rationale on deletion of vertebrae column in undetermined BSE risk, while month of age for skulls in strengthened constricting from 30 months to 12 months in controlled BSE risk.

4. CHAPTER 2.6.7

Comments on the proposed amendment on the Classical Swine Fever (amendment) Chapter of the Code

General Comments

Japan generally supports this amendment because 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.

5. CHAPTER 2.7.12

Comments on the Avian Influenza Chapter of the Code

Specific comments

(Low Pathogenic Avian Influenza)
Article 2.7.12.19.
(Proposed text)

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.

(Comments)

1) On the basis of 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.

Therefore, Japan recommends OIE TAHSC and SCAD should re-consider Article 2.7.12.19.2 and amend it 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

Article 2.7.12.1.
(Proposed text)

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.

(Comments)
In order to be more precise, Article 2.7.12.1.5 should be modified as above.

(Rationale)

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 outbreak of LPAI, that seroconversion in sentinel birds has been observed during the course of the epidemiological investigation against 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.

6. CHAPTER 1.1.1

General definition

Specific Comments

Article 1.1.1.1
(Proposed text)

~~**Animal welfare**~~

~~means the state of animal as regards its attempts to cope with its environment and includes both the extent to failure to cope and the ease or difficulty in coping.~~

Commodity

means live animals, products of animal origin, animal genetic material, biological products~~,~~ straw and forage and pathological material.

~~**Infected country**~~

~~means a country in which the absence of the disease under consideration has not been demonstrated by the requirements specified in the Terrestrial Code being met.~~

Sanitary measure

means a measure, such as those described in various chapters of the Terrestrial Code, designed to protect animal or human health or life within the territory of the Member from risks arising from the entry, establishment or spread of a hazard. [Note: A detailed definition of sanitary measure be found in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.]

(Rationale)

Animal welfare

Japan is concerned that the proposed definition of animal welfare is too broad and involves multiple meanings. Japan is of the position that the OIE should collect information on how the term “animal welfare” is used within member countries.

Commodity

Taking into account that current definition includes products for animal feeding, and that Article 2.2.10.29 provides sanitary measures for straw and forage which are not animal origin, straw and forage must be included in the definition of “commodity”.

Infected country

Taking into account that chapters for specific diseases, such as rinderpest (Article 2.2.12.5) and bluetongue (Article 2.2.13.4), have specific definitions for “infected country”, Japan believes that the proposed definition of “infected country” for general use is confusing.

Sanitary measures

Japan believes the reference to the SPS agreement is important because the agreement has substantial implication on the relation between the OIE Code and the most OIE Member countries which are at the same time members to the WTO. The reference to the SPS agreement should be retained unless the reason for such deletion is clarified.

7. Draft Guidelines on the design and implementation of identification systems to achieve animal traceability

Specific Comments

Article 3
(Proposed text)

2. Scope

Scope should also be defined through consultation between the *Veterinary Administration Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; poultry in a defined compartment; cattle within a defined FMD free *zone*. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

(Rationale)

Compartment for poultry against AI or ND is one of the typical cases the member countries apply these guidelines.

Article 3
(Proposed text)

5. Design of the programme

~~j) Commercial arrangements~~

~~An animal identification system requires producers, processors and others (depending on the design of the system) to purchase equipment. There are many possible commercial arrangements that will have a variety of implications for the uptake of the animal identification system.~~

~~k)~~ j) Transition planning

Any transition from an existing animal identification system needs to be designed to ensure it is easy for users of the existing system to make the change and to insure that data integrity is maintained during the transition and integrated into the new animal identification system.

~~l) Use of incentives~~

~~Depending on the drivers for participation in the animal identification scheme, incentives may be useful to encourage early adoption of the system or to fill capability, capacity or technology gaps.~~

(Rationale)

The proposed item j) and item l) address economic tools for facilitation of introduction of traceability, which is not relevant to the performance of the animal identification systems. These tools should be arranged according to the economic, political financial situation of each country, but should not be prescribed by the Code as elements of “Design of the programme”, such as registration and information system.

8. Guidelines for the control of hazards animal health and public health importance in animal feed

Specific Comments

Article 3
(Proposed text)

Definitions

For the purpose of these guidelines, the following definitions apply.

~~**Hazard**~~

~~means a biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse effect.~~

(Rationale)

The scope of the definitions should be clarified. The definition of "Hazard" should be deleted since this definition is the same as defined in the General definitions in Chapter 1.1.1.

Article 4
(Proposed text)

12. Cross contamination

It is important to avoid cross-contamination during the manufacture, storage, distribution (including transport) and use of feed and feed ingredients and relevant provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Physically separated manufacturing lines should be used to avoid cross-contamination. Procedures, such as flushing, sequencing and physical clean-out, are also effective ~~should be used~~ to avoid cross-contamination between batches of feed or feed ingredients.

(Rationale)

Physical separation of manufacturing lines should be mentioned before the other measures since the feasibility of physical separation should be explored first to avoid cross contamination completely.

9. APPENDIX 3.7.2

Guidelines for the transport of animals by sea

Specific Comments

Article 3.7.2.7: Pre-journey period
(Proposed text)

1. General considerations

b) In some circumstances, animals may require pre-*journey* assembly. In these circumstances, the following points should be considered:

i) Pre-*journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

~~ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the *journey*.~~

ii)~~iii)~~ When animals are to be provided with a novel diet or unfamiliar methods of supplying feed or water, they should be preconditioned.

(Rationale)

The proposed modification on item ii) does not make sense. The Working Group on Animal Welfare recommends the whole item ii) to be deleted.

10. Draft Guidelines on dog population control

Specific Comments

Article 3: Definitions
(Proposed text)

For the purpose of these guidelines, the following definitions apply.

(Rationale)

The scope of the definitions in this article should be clarified.

11. Devising import health measures for animal commodities

General Comments

Japan supports the OIE started the work on the commodity-based approach. This work provides members with practical instruction for development of sanitary measures applicable to trade in major animal products.

Japan notes there also seem to be some boxes which recommend “no measures necessary for trade”, in spite that no corresponding provision exists in the Code that no sanitary measures are necessary for trade. Japan would like to encourage the OIE to review such areas and to propose appropriate revisions to the Code where necessary.

12. Report of the sixth meeting of the OIE Working Group on Animal Welfare

Wildlife welfare (6.5 of the AWWG report)

With regard to discussion in 6.5 b) of the report of the OIE Working Group on Animal Welfare (the AWWG), Japan would like to point out that conservation of wild animal resources or biodiversity is out of the mandate of the OIE accorded by the resolution of "Animal Welfare Mandate of the OIE" (Resolution XIV of International Committee in 2002). In addition, Japan believes that many Delegates to the OIE of Member countries are not responsible for environmental protection or conservation of endangered species, but responsible for animal health and related welfare issues. Therefore, these topics would be better addressed by other international organizations with different expertise than the OIE.

Discussion paper on the development of animal welfare guidelines for production systems (terrestrial animals) (Appendix J of the report of AWWG of the Annex XXVIII)

Japan appreciates the efforts of the Commission and the AWWG to develop this paper and proceed with this issue in a transparent manner.

(Backgrounds)
Japan agrees to the AWWG's view that "animals are raised under extremely diverse conditions". It is also true that "there are also large differences from country to country in the level of priority accorded to the welfare of animal food animals". Taking into account such diversity and difference, Japan requests the OIE to develop the guidance as an advisory text, rather than the Code as an international standard, so that Members may decide whether to apply the guidance.

(Animal-based criteria)
Japan supports the AWWG to utilize animal-based criteria, especially survival rate and incidence of disease and injury, since such criteria enable Member countries to devise animal welfare measures suitable for their existing livestock industry. However, Japan is concerned that some animal-based criteria, such as the reaction of animals to their handlers, are difficult to implement nationwide because of difficulty to monitor and to evaluate compliance to such criteria objectively. Japan requests the Commission and the AWWG, in the course of development of the guidance, to consider whether member countries can implement the guidance and evaluate the performance according to such criteria.

(Clarifying the objectives of animal welfare guidelines)
Japan supports the approach proposed in the discussion paper that the guidance should focus principally on objective 1 and address objective 2 and 3 where feasible and appropriate. Japan is of the position that animal welfare guidance should be developed to balance productivity and animal welfare. Japan is also of the opinion that the sanitary status of animals and products thereof should not be sacrificed in order to improve animal welfare. With regard to "social expectations" of the cultures with high priority on animal welfare, such countries may implement higher animal welfare standards of their own, according to their social expectation and building upon the OIE guidance. Therefore, Japan believes the OIE should primarily focus "to protect the basic animal health and normal functioning of animals, for example by preventing and alleviating disease, injury, malnutrition and similar harm".

(Clarifying underlying science)
Japan supports the AWWG to start from a competent review of the relevant science in place and widely accepted for development of the guidance. Japan is of the position that the AWWG should start the work from the area where scientific reviews are clear and consistent, and that the guidance should always be elaborated on scientific grounds.

(Recommended next steps)
Japan requests the AWWG to proceed with this issue taking into account our comments above. For the guidance, Japan believes that it is critical that above-mentioned diversity and difference among Members are appropriately taken into account. For this purpose, Japan recommends the Commission and the AWWG to develop and send a questionnaire to collect views and information from Members before starting drafting.