Note: This is an English translation of the "Standard Operating Procedure for Approval for Import of Designated Items into Japan to be quarantined" for informational purposes only, and is not prior to the original version in Japanese.

The Food Safety and Consumer Affaires Bureau, Ministry of Agriculture, Forestry and Fisheries (MAFF), Japan has developed the "Standard Operating Procedures for Approval for Import of Designated Items into Japan to be quarantined" (SOP) in accordance with the "Standard Procedure for Approval for Import of Designated Items into Japan to be quarantined" (Official Directive No.13 of 2008) (Standard Procedure) in order that it properly responses to requests from foreign countries for import of the items.

Standard Operating Procedures for Approval for Import of Designated Items into Japan to be quarantined (SOP)

April 15, 2010

Article 1

Definitions

For the purpose of the SOP, following definitions shall apply in addition to those defined in the Domestic Animal Infectious Disease Control Law (Law No.166 of 1951) and the Standard Procedure.

(1) "Written response" means an official documents submitted by a requesting country to the Questionnaire.

(2) "Release assessment" means the process of describing the biological pathway(s) necessary for an importation of the designated item(s) to introduce specific pathogenic agents into Japan and estimating the probability of entry of pathogenic agents into Japan, either qualitatively or quantitatively.

(3) "Exposure assessment" means the process of describing the biological pathway(s) necessary for exposure of susceptible animals in Japan to the pathogenic agents released from a given risk source, and estimating the probability of exposure(s), either qualitatively or quantitatively.

(4) "Consequence assessment" means the process of estimating and

assessing the relationship between specified exposures to the pathogenic agents and the consequences of those exposures to animal health situations in Japan.

Article 2

Administration pertaining to Risk Assessment

1. The Risk Assessment Office shall be established in the Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF to carry out the administrative work pertaining to risk assessment.

2. The functions of the Risk Assessment Office shall be the followings;
   (1) Planning and coordination regarding risk assessment;
   (2) Preparation of the standard Questionnaires;
   (3) Compilation of results of risk assessment;
   (4) Clerical duties (limited to those related to risk assessment) on consultation with or reporting to the Committee of Animal Health of the Council of Food, Agriculture and Rural Area Policies; and
   (5) Administrative work on compilation and disclosure of the information on risk assessment.

Article 3

Risk Assessment Teams and the Functions

1. Risk assessment teams shall be established in the Animal Health Division to properly response to requests from foreign countries for import of the designated items and to conduct appropriate risk assessment for the extent of consequences to animal health situations in Japan by accepting the requests.

2. The team shall be established for each request.

3. The heads and members of the teams shall be assigned by the Director of the Animal Health Division, after consultation with the Director General of the Animal Quarantine Service, from officers in the animal health authorities who have knowledge and experience on animal health, epidemiology and others. The Director of the Animal Health Division may assign other external experts, if it is necessary, under the procedure of Article 4.

4. The teams shall conduct the following functions in accordance with the procedure of Article 4 and the heads of the teams shall administer the progress;
   (1) Preparation of Questionnaires;
   (2) Examination of written responses submitted by requesting countries and preparation of additional questionnaires to call upon the countries to re-submit the responses based on Paragraph 2 of Article 3 of the Standard Procedure;
   (3) Conducting on-site inspection;
   (4) Preparation of risk assessment reports; and
   (5) Preparation and publication of summaries of results of risk assessment.

Article 4
Review Procedures

1. Review procedures (Protocols) in accordance with Article 3 of the Standard Procedure shall be the followings, according to the consequences of the requests to animal health situations in Japan;
   (1) when the acceptance may cause a considerable impact on animal health situations in Japan, e.g. application of new concepts on animal health; Protocol 1;
   (2) when the acceptance may cause a moderate impact on animal health situations in Japan, e.g. application of existing systems (where fall under neither Protocol 1 nor 3); Protocol 2;
   (3) when the acceptance may cause an insignificant impact on animal health situations in Japan, e.g. addition of new animals susceptible to specific diseases in the existing animal health requirements; Protocol 3.

2. The procedures of the Protocol 1 include the followings;
   (1) Organization of a risk assessment team including external experts;
   (2) Sending Questionnaires;
   (3) Conducting on-site inspection;
   (4) Preparation of a risk assessment report;
   (5) Consultation with the Committee of Animal Health; and
   (6) Preparation and publication of a summary of a result of risk assessment.

3. The procedures of the Protocol 2 include the followings;
   (1) Organization of a risk assessment team;
   (2) Preparation of Questionnaires;
   (3) Conducting on-site inspection only if the head of the team finds it necessary;
   (4) Preparation of a risk assessment report;
   (5) Report to the Committee of Animal Health; and
   (6) Preparation and publication of a summary of a result of risk assessment.

4. The procedures of the Protocol 3 include the followings;
   (1) Organization of a risk assessment team;
   (2) Preparation of Questionnaires; and
   (3) Preparation and publication of a summary of a result of risk assessment.

Article 5

Procedure of Initiation of a Review, etc.

The Animal Health Division shall immediately confirm the type of requested items, the way of transport and storage, and other necessary information in writing, in order that it can decide which protocol should be applied.

Article 6

Postponement of a Review

1. The animal health authorities may postpone the initiation of a review for appropriate period in the following cases;
   (1) Preliminary information collection and other actions are needed because the request does not conform to the existing domestic regulations and measures of Japan;
   (2) The country has made more than one request and specified that the priority of the request is lower; or
   (3) Taking into account the number of requests, human resources and other circumstances, it is difficult to initiate the review of new requests.

2. The authorities shall notify the requesting country to that effect and

reasons if they postpone the initiation of the review in accordance with the preceding paragraph.

Article 7
Questionnaires

1. The Risk Assessment Office shall develop the standard Questionnaires including questions on the followings and make public them on the MAFF's website;
   (1) The system of veterinary services of the requesting country;
   (2) Information on commodities and specific disease situations of the requesting country including the followings;
      a) General information including population of relevant animals and the situation of production and distribution of relevant livestock products;
      b) The situation of outbreaks of relevant animal diseases; and
      c) Detailed information on the each specific disease including relevant law, regulations and diagnosis tests.
   (3) Tailored information related to the request, for example regarding regionalization.

2. Risk assessment teams shall develop the specific Questionnaires provided for in the Paragraph 1 of Article 3 of the Standard Procedure by modifying the standard Questionnaires in the preceding paragraph, taking into account the type of the items and specific diseases on the request.

Article 8
Risk Assessment

1. Risk assessment teams shall conduct release assessment and, if necessary, conduct exposure and/or consequence assessment.

2. The Animal Health Division shall coordinate on-site inspection plans of a risk assessment team with the animal health authorities of the requesting country and, in principle, notify the questions for the on-site inspection to the country in advance.

Article 9

Preparation of Risk Assessment Reports

1. Risk assessment teams shall prepare draft risk assessment reports based on results of risk assessment in accordance with Article 8.

2. The animal health authorities shall, in principle, send a draft to the requesting country for comments.

3. The risk assessment team shall develop the final risk assessment report, taking the comments into account. When the review procedure is conducted in accordance with Protocol 1 of Article 4, the team shall also reflect the opinions of the Committee of Animal Health on the report.

Article 10

Exemption from Risk Assessment

1. The animal health authorities shall not conduct the risk assessment provided for in Article 5 of the Standard Procedure in case of the followings;
   (1) It is clear that the processing process of the requested items can inactivate all specific pathogenic agents; or
   (2) The performance of veterinary services of the requesting country has been evaluated by the animal health authorities of Japan; and
      a) the requested items are such items as animal protein which have been already assessed by the Japanese authorities and may be applied general risk management measures in Japan to; or
      b) such insignificant changes as additions and deletions of laboratory tests or certification items are required, taking into account animal health situations in the requesting country.

Article 11

Review of the SOP

This SOP shall be reviewed according to such circumstances as changes of animal health situations in Japan, amendments of the international standards and appearance of practical problems.