Disclaimer

This is a provisional translation of the standard procedure. Only the original Japanese text was adopted as an authentic legal text. This translation is prepared solely for a reference material to aid in the understanding of Japanese text.

Standard Procedure for Approval for Import of Designated Items into Japan to be Quarantined

Article 1 Objectives and Scope

This procedure has been developed taking into account relevant international standards and aiming to ensure fairness and transparency. The Standard Procedure applies to the consideration by the Ministry of Agriculture, Forestry and Fisheries (MAFF) of the request for import of designated items to be quarantined (as listed in Article 37 of "Domestic Animal Infectious Diseases Control Law" (Law No. 166 of 1951, hereinafter referred to as "the Law")).

Article 2 Definitions

For the purpose of this standard procedure, following definitions shall apply in addition to those defined in the Law:

- (1) "Animal health authorities" mean the Animal Health Division and the Animal Quarantine Service of the Food Safety and Consumer Affairs Bureau of MAFF;
- (2) "Animal health requirements" mean the conditions to be maintained for import of designated items to be quarantined, laid down for animal health purpose by the Japanese Government;
- (3) "Requesting country" refers to a country which made a request for lifting an import ban on designated items to be quarantined, and/or establishing or revising the animal health requirements;
- (4) "Questionnaire" refers to a document containing questions to be answered and requests for information to be provided from requesting countries for consideration of the request;
- (5) "Risk assessment" refers to an evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within Japan;
- (6) "MAFF website" refers to the website managed by MAFF; and
- (7) "Veterinary services" refers to governmental and non-governmental organizations which implement animal health measures under the overall control and direction of the veterinary authority of the requesting country, including monitoring of occurrence of contagious animal diseases in the requesting country.

Article 3 Acknowledgement of Request

- 1. When a country requests the animal health authorities to lift import ban on designated items to be quarantined or establish or revise the animal health requirements, the animal health authorities shall ask the requesting country to provide details of the request; and give any additional explanations on the Standard Procedure. The animal health authorities shall develop and send a questionnaire to the requesting country (the Questionnaire).
- 2. The requesting country submits an official letter of request with answers to all the questions and information requested in the Questionnaire (hereinafter, referred to as "submittal package"). In the case the submittal package is incomplete when checked against the Questionnaire, the animal health authorities shall ask the requesting countries to submit the required information together with the original submission.
- 3. When the submittal package is complete, the animal health authorities shall accept the submittal package and notify its receipt to the requesting country. The animal health authorities shall without delay post the name of requesting country, the date of receipt of the submittal package, and the relevant designated items to be quarantined on the MAFF website.

Article 4 Evaluation of Veterinary Services

- 1. The animal health authorities, if necessary, evaluate veterinary services of the requesting country.
- 2. If the animal health authorities, during the evaluation mentioned in paragraph 1 of this article, have identified that certain information is missing, they should make sure to acquire the information by asking the requesting country to provide it or conducting an on-site visit.
- 3. The animal health authorities shall utilize the evaluation for further consideration of the request.

Article 5 Risk Assessment

- 1. The animal health authorities shall conduct risk assessment of hazard(s) relevant to the request unless they recognize such risk assessment is not necessary, e.g., the cases where it is obvious that relevant pathogenic agents are completely inactivated.
- 2. If the animal health authorities, during risk assessment mentioned in paragraph 1 of this article, have identified that certain information is missing, they should make sure to acquire the information by asking the requesting country to provide it or conducting an on-site visit.

Notification of Summary of Risk Assessment

When the animal health authorities complete risk assessment, they shall notify the summary of the risk assessment to the requesting country and shall publish their conclusions on the MAFF website.

Article7 Establishing Animal Health Requirements

When the animal health authorities find it appropriate to accept the request with or without modifications, based on the results of the risk assessment when conducted, they shall accordingly establish or revise the animal health requirements. For this purpose, the animal health authorities shall take necessary administrative steps, including revision of relevant MAFF ministerial ordinance if applicable. The animal health authorities shall notify the established animal health requirements to the requesting country and publish the establishment of them on the MAFF website without delay. In other cases, the animal health authorities shall notify the justifications for the decision to the requesting country.

Appendix

- 1. This Standard Procedure shall take effect on April 1, 2008.
- 2. This Standard Procedure is not applicable to the request whose submittal package has been presented prior to April 1, 2008 and/or requests regarding which an "assessment of the effect of food on health" is conducted by Food Safety Commission as defined in Article 11 of "the Food Safety Basic Law" (Law No. 48 of 2003).