

Attachment 2-3: Quarantine Requirements for the Importation of Fertilized Chicken Eggs for Research Purposes or Vaccine

Production from the United States

1. The fertilized chicken eggs for research purposes or vaccine production (hereinafter referred to as the “fertilized eggs”) indicated in the quarantine requirements refer to fertilized chicken eggs imported specifically to be used for research, assay or vaccine production.
2. Testing referred to in these requirements must be conducted by laboratories owned, designated or approved by the government of the exporting country using methods listed in these requirements; or prescribed, recommended or considered suitable by the World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (hereinafter the OIE Manual) for confirmation of population or individual animals being free from infection with pathogens of corresponding diseases. For diseases with no such testing methods prescribed, recommended or considered suitable in the OIE Manual, methods that have been published in international scientific journals may also be used.
3. The fertilized eggs are allowed to be imported only from zones in the United States recognized by the central competent authority of the importing country as being free from the highly pathogenic avian influenza (HPAI).
4. The application for the approval and requirements of importing fertilized eggs has to be submitted by the institution(s) of animal science (hereinafter referred to as the “institutions”) defined by the Animal Protection Act to the import/export animal quarantine authority.

The biosecurity control measures, layout, equipment and plans for the destruction of the post-entry facility pertaining to keeping, hatching, and disposing of fertilized eggs shall be provided in the aforementioned application, and the on-site audit conducted by the import/export animal quarantine authority of the importing country shall be accepted. The application for exempting the on-site audit can be submitted to the import/export animal quarantine authority for evaluation while the requirements stated below are complied with:

- 4.1 The post-entry facilities, including layout and equipment involved in keeping, hatching and disposing of fertilized eggs are the same as those in the last approval; and
- 4.2 The interval between the date of importation and the date of on-site audit of the last approval is less than 1 year.
5. The following requirements shall be complied with:
 - 5.1 Fertilized eggs shall originate from research institutes of the government and

universities, or institutes that are under the supervision of the veterinarians who are responsible for disease diagnosis and notifications and accredited by the competent authority of the United States.

- 5.2 The biosecurity measures applied on the establishment of origin shall comply with the relevant norms stipulated in the OIE Terrestrial Animal Health Code (the OIE Code).
- 5.3 Any inoculation tests involving pathogens of foot and mouth disease, classic swine fever, contagious bovine pleuropneumonia, African swine fever, African horse sickness, glanders, peste des petits ruminants (PPR), H5 and H7 subtype avian influenza, Newcastle disease or rabies are not conducted by the establishment of origin.
- 5.4 No cases have been confirmed in the establishment of origin in the corresponding time period as follows: Newcastle disease, infectious bursal disease, pullorum disease, avian infectious laryngotracheitis, and fowl cholera in the previous year; and H5 and H7 subtypes of avian influenza, avian chlamydiosis, avian encephalomyelitis, egg drop syndrome, avian infectious bronchitis, avian mycoplasmosis caused by *Mycoplasma gallisepticum*, infectious synovitis caused by *Mycoplasma synovia*, and infectious coryza in the past 6 months.
- 5.5 The breeding flocks of origin shall have been kept in the United States for at least 6 months, or since they were hatched, without coming into contact with any imported poultry or wild birds.
- 5.6 The breeding flocks of origin must not be vaccinated against avian influenza.
- 5.7 The breeding flocks of origin shall be subjected to regular testing of the following diseases and must have negative results.
 - 5.7.1 For H5 and H7 subtype avian influenza: Antibody test and causal agent identification;
 - 5.7.2 For Newcastle disease: Causal agent identification, OR exempt when the United States is recognized by the central competent authorities of the importing country as a country free from Newcastle disease; and
 - 5.7.3 For pullorum disease: Serological test.
6. Each consignment shall be accompanied by an original veterinary certificate issued by the veterinarians of the animal quarantine authority of the United States, and the certificate shall state the following information in English or Chinese:
 - 6.1 Information on the commodity:
 - 6.1.1 Name of consignment;
 - 6.1.2 Import purpose;
 - 6.1.3 Total quantity;
 - 6.1.4 The exporting country;

- 6.1.5 Name and address of the establishment of origin; and
- 6.1.6 Name and address of exporter.
- 6.2 Destination:
 - 6.2.1 Place of dispatch and exporting border port;
 - 6.2.2 Country of destination; and
 - 6.2.3 Name and address of the importer.
- 6.3 Result of the quarantine:
 - 6.3.1 The statement attesting that the breeding flocks of origin are healthy and free from clinical evidence of any communicable disease.
 - 6.3.2 The statement attesting that the fertilized eggs fulfill the requirements stipulated in Article 5. The inspection results shall specify for the name of the inspection laboratory, method, sampling inspection date and results of the recent test. For inspection methods reference international journals, the origin of data shall be specified.
- 6.4 Date of issuance, name and official stamp of the issuing authority, and name and signature of the issuing officer.
- 7. The fertilized eggs shall be transported in cargo holds with new, clean and sealed containers, which shall not transit (change vehicles) through any port in a country or zone not recognized as being free from HPAI. The means of transport and transit shall comply with the OIE Code and the Live Animal Regulations of the International Air Transport Association (IATA). When the consignment of the fertilized eggs transit through a port in a country or zone not recognized as being free from HPAI, it shall apply mutatis mutandis to the Regulations of Import Quarantine Operation for Animal Products Transported by Closed Container.
- 8. The following requirements shall be complied with for exemption of post-entry quarantine pertaining to fertilized eggs. The applicant or post-entry facility in regard to keeping, hatching and disposing of fertilized eggs have to comply with the following until fertilized eggs are destroyed.
 - 8.1 Any necessary change in import purpose, quantity of fertilized eggs, the place where the fertilized eggs are used and stocked, and the plan of destroying fertilized eggs shall be approved in advance by the import/export animal quarantine authority of the importing country.
 - 8.2 The applicant and agency in regard to keeping, hatching and disposing of fertilized eggs shall not evade, impede, or reject the on-site audit conducted by the import/export animal quarantine authority of the importing country.
 - 8.3 The disposing process and biosecurity control measures of destroying fertilized eggs shall be conducted and recorded. A copy version of related records or documents shall be submitted to the import/export animal quarantine authority of the importing

country for reference.

8.4 The original version of the abovementioned records have to be properly kept for at least 3 years in regard to the audit conducted by the import/export animal quarantine authority of the importing country.