

Appendix 1-23

Quarantine Requirements for the Importation of Fertilized Chicken Eggs for Research Purposes or Vaccine Production from the United States

(In case of any discrepancy between the English version and the Chinese text of these Requirements, the Chinese text shall govern.)

Promulgated by the Council of Agriculture on August 5, 2013 and become effective from September 1, 2013

1. In this document, the term of “fertilized chicken eggs for research purposes or vaccine production” (hereinafter referred to as the “fertilized eggs”) refers to fertilized chicken eggs imported for (a) research; (b) assay; or (c) vaccine production.
2. Application procedure:
 - 2.1. Application for the importation of fertilized eggs has to be made by the institution(s) (hereinafter referred to as the “importer(s)”) defined by Article 16 of “Animal Protection Act”. Importers shall submit completed application form (as attachment) and relevant documents to the animal quarantine authority for application of quarantine requirements. The fertilized eggs shall not be imported until the submitted documents mentioned above being approved and relevant post-entry receiving facilities being inspected and approved.
 - 2.2 The importer may apply for exempted from the post-entry receiving facilities inspection, when the conditions are in compliance with the followings:
 - 2.2.1 The post-entry receiving facilities, including layout and equipment involved in keeping, hatching and disposing of fertilized eggs are the same as those in last approval; and
 - 2.2.2 The interval between the date of importation and the date of last approval is less than 1 year.
3. Fertilized eggs shall be imported only from the U.S. zone recognized by central competent authorities of the importing country as free from highly pathogenic avian influenza.
4. Requirements for the importation of fertilized eggs:
 - 4.1 Fertilized eggs shall originate from (a) governmental facilities/establishments of authorities; (b) research institutes of universities; or (c) an institute recognized by the authority of the

U.S. as an institute subject to regular inspections by veterinarians who are responsible for disease diagnosis and notification.

4.2 The hygiene and disease security procedures in flocks of origin and hatcheries shall be in compliance with “Terrestrial Animal Health Code” of the World Organization for Animal Health (hereinafter referred to as the “OIE”).

4.3 Fertilized eggs shall originate from facilities/establishments that do not carry out any experiment or test involving etiologic agents of foot and mouth disease, rinderpest, contagious bovine pleuropneumonia, African swine fever, glanders, H5 and H7 subtype avian influenza, Newcastle disease or rabies.

4.4 The diseases listed below have not occurred in the facilities/establishments where the fertilized eggs originate from for the time periods specified below:

4.4.1 for one year without Newcastle disease, infectious bursal disease, pullorum disease, avian infectious laryngotracheitis, or fowl cholera; and

4.4.2 for six months without H5 and H7 subtype avian influenza, avian chlamydiosis, avian encephalomyelitis, egg drop syndrome, avian infectious bronchitis, avian mycoplasmosis cause by *Mycoplasma gallisepticum*, infectious synovitis caused by *Mycoplasma synoviae*, or infectious coryza.

4.5 The flocks of origin have been kept in the U.S. for the past 6 months or since hatching and have not been in contact with any wild or imported poultry or birds.

4.6 The flocks of origin must not be vaccinated against avian influenza.

4.7 The flocks of origin shall be subject to the following tests regularly carried out by the governmental laboratory of or designated laboratory by the U.S. in compliance with “Manual of Diagnostic Tests and Vaccines for Terrestrial Animals” of the OIE, and all test results must be negative:

4.7.1 for H5 and H7 subtype avian influenza: antibody test and causal agent identification;

4.7.2 for Newcastle disease: causal agent identification; or the U.S. is recognized by central

competent authorities of the importing country as a country free from Newcastle disease; and

4.7.3 for pullorum disease: serological test.

5. Each consignment shall be accompanied by an original veterinary certificate issued by animal quarantine authority of the U.S., and the certificate shall state the following information in English:

5.1 The authority issuing the certificate

5.1.1 The exporting country: the U.S.;

5.1.2 Name of the issuing authority;

5.1.3 Name of the issuing department under the authority;

5.1.4 Place of issue: province, district and so on; and

5.1.5 Reference number of the certificate.

5.2. Identification of the commodity

5.2.1 Name of the consignment;

5.2.2 Import purpose; and

5.2.3 Total quantity.

5.3. Place of origin

5.3.1 Name and address of the exporter;

5.3.2 Place of origin of the animals: province, district and so on; and

5.3.3 Name and address of the facilities/establishments from which the fertilized eggs originate.

5.4. Destination

5.4.1 Place of dispatch and exporting border post;

5.4.2 Country of destination;

5.4.3 Means of transport;

5.4.4 Date of departure; and

5.4.5 Name and address of the importer/consignee.

5.5. Zoosanitary information

5.5.1 A statement attesting that the exporting country or zone is free from highly pathogenic avian influenza;

5.5.2 A statement attesting that the breeding flocks from which fertilized eggs originate are healthy and free from clinical evidence of any communicable disease;

5.5.3 Statements attesting that the fertilized eggs are in compliance with the Articles 4 above;

5.5.4 Names and dates of vaccines administered (if applicable) to the breeding flocks from which the fertilized eggs originate.

5.6. Official stamp and signature

5.6.1 Official stamp of the issuing authority;

5.6.2 Place and date of issue;

5.6.3 Name, official position and address of the official veterinarian; and

5.6.4 Signature of the official veterinarian.

6. Transportation regulations

6.1 The consignment shall be transported in cargo holds with new, clean and sealed containers.

The consignment shall not transit (change vehicles) through any port in a country/zone where highly pathogenic avian influenza is known to occur. No additional poultry/birds, feed, fodder or bedding can be loaded after departure en route to the destination. The means of transport and transit shall be in compliance with “Terrestrial Animal Health Code” of OIE and “Live Animal Regulations of the International Air Transport Association (IATA).”

6.2 When the consignment transit through a port in a country/zone where highly pathogenic avian influenza is known to occur, it shall be in compliance with “Rules of Import Quarantine Operation for Animal Products Transported by Closed Container.”

7. Exemption of detention for post-entry quarantine

7.1 When the fertilized eggs meet this Requirements, those will be exempted from the post-entry

quarantine detention.

7.2 The importer and owner/manager of the post-entry receiving facilities (hereinafter referred to as the “user”) shall abide by the followings until the fertilized eggs are destroyed:

7.2.1 The use of fertilized eggs shall be in compliance with the application documents. Any change in import purpose, quantity of fertilized eggs, the place where the fertilized eggs are stocked or used, and the process about how to destroy the fertilized eggs shall be approved in advance by the animal quarantine authority.

7.2.2 The importer and user shall not evade, impede, or reject the post-entry receiving facilities on-site inspection conducted by the animal quarantine authority until the fertilized eggs are destroyed.

7.2.3 The importer shall make sure that the use of fertilized eggs and the biosecurity managing performances are in compliance with the application documents, and all details shall be recorded. The importer must submit a copy of the records to animal quarantine authority after the fertilized eggs are destroyed.

7.2.4 The importer and user must well keep all the original records mentioned in the Articles 7.2 3 above for at least 3 years. The animal quarantine authority will check the records as necessary.

附表 自美國輸入供試驗研究與疫苗製造用雞受精蛋申請書

Application Form (available in Chinese language only)

填表說明： 1. 所有欄位均應以中文或英文正楷填寫。 2. 應於申請書內註明檢附之附件編號，並於附件上標明對應之編號。 3. 經查有未填欄位、未提供應檢附之附件、填寫於申請書或附件之資料錯誤、疏漏或無法以肉眼清晰辨識、塗改處未加蓋申請單位負責人印章者，輸出入動物檢疫機關將不受理本項申請。							
I.1 申請日期 (年/月/日)：							
I.2 申請單位全名：							
I.3 申請單位地址及傳真：							
I.4	姓名	職稱	電話	I.5	姓名	職稱	電話
申請單位				申請單位			
負責人				本案聯絡人			
II. 輸入目的 (以下兩者擇一勾選，並應提供對應之附件) <input type="checkbox"/> 供試驗研究用 (應提供實驗動物照護及使用委員會或小組之同意書影本) <input type="checkbox"/> 供疫苗製造用 (應提供事業主管機關核發之製造證影本)							
III.1 輸出國： 美國							
III.2 輸入機場 (以下擇一勾選) <input type="checkbox"/> 桃園 <input type="checkbox"/> 高雄 <input type="checkbox"/> 松山 <input type="checkbox"/> 其他：							
III.3 預定輸入方式 (以下兩者擇一勾選，實際與預定輸入日期勿超過 3 日) <input type="checkbox"/> 單批輸入： 輸入日期 (年/月/日) 為 _____，數量為 _____ 個。 <input type="checkbox"/> 分批輸入： (第 1 次至最後 1 次輸入日期勿超過 6 個月)							
批次	輸入日期 (年/月/日)	數量 (個)	批次	輸入日期 (年/月/日)	數量 (個)	批次	輸入日期 (年/月/日)
1			8				
2			9				
3			10				
4			11				
5			12				
6			13				
7			14				

<p>IV. 輸入後留置與操作場所相關安全管制(設施設備之基礎衛生與檢疫安全條件狀況)：以下為對該等場所基本要求，不可空白或只填列「有」等字樣，所填資料為輸出入動物檢疫機關審核本申請案之重要依據，請盡量以附件方式補充詳細資料；場所 1 為受精蛋輸入後進入之第 1 個留置或操作場所，餘依序類推。</p>			
	場所 1	場所 2	場所 3
IV.1 場所性質 (孵育場、實驗室、疫苗製造廠等)			
IV.2 場所全名			
IV.3 場所地址			
IV.4 場所負責人			
IV.5 可處理之最高蛋量	個	個	個
IV.6 消毒設備 (申請單位應自行確認符合世界動物衛生組織或動物傳染病防治條例相關法規建議之方法或達同等效力)			
IV.7 銷燬設備 (應足以銷燬整批輸入受精蛋及內外包裝材料，得以銷燬計畫取代之，輸出入動物檢疫機關係以疫病傳播風險整體評估本申請案，申請單位應自行確認銷燬設備或銷燬計畫符合廢棄物清理法相關規定)			
IV.8 門禁管制 (應足以有效防止受精蛋外流)			
IV.9 物流管制 (為受精蛋於機場與場所間、場所與場所間之移動管制，應包含移動時產生之紀錄文件及使用之運輸工具等)			

V. 是否申請免予實地查核： 是 否

勾選「是」者，應檢附輸出入動物檢疫機關前次審核通過之文件；輸出入動物檢疫機關將據以評估是否符合下列免予實地查核之要件：1. 受精蛋輸入後留置、孵育、處置之場所及其設施設備與前次經審核通過之申請案相同。及 2. 受精蛋輸入日期距離前次經審核通過之申請案實地查核日期未超過一年。

VI. 申請單位簽章：

(加蓋申請單位負責人印章及加蓋公司章或機構印信)

申請單位應注意事項：

倘申請單位違反「自美國輸入供試驗研究與疫苗製造用雞受精蛋之檢疫條件」相關規定，依動物傳染病防治條例第四十三條第八款規定，處以新臺幣三萬元以上十五萬元以下罰鍰。