

Animal health requirements for poultry meat etc. meal for pet food material to be exported to Japan from the United States
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1. This document defines animal health requirements for poultry meat etc. meal to be exported to Japan from the United States of America for pet food material.

(General requirements)

2. In this document, the definitions of terms are as follows:

- (1) **‘Poultry meat etc. meal’** means processed powder derived from poultry meat etc through processes such as spray drying or rendering.
- (2) **‘Poultry’** means chicken, quail, pheasant, emu, ostrich, guinea fowl, turkey and birds classified into order Anseriformes (such as duck and goose)
- (3) **‘Meat etc.’** means meat, bone, fat, blood, skin, tendon, and viscera.
- (4) **‘The Japanese animal health authorities’** means Animal Health Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of the Japanese government.
- (5) **‘The U.S. animal health authorities’** means Veterinary Service, Animal and Plant Health Inspection, U.S. Department of Agriculture of the U.S. government.
- (6) **‘Highly pathogenic avian influenza (HPAI)’** means an infection of poultry caused by an avian influenza virus of high pathogenicity as defined in the OIE Terrestrial Animal Health Code.
‘Low pathogenicity avian influenza (LPAI)’ means an infection of poultry caused by an avian influenza virus of H5 and H7 subtypes other than HPAI virus.
‘Notifiable Avian Influenza (referred to as NAI)’ means HPAI and LPAI as defined above.
- (7) **‘NAI-free zones’** means the areas which meet all disease-freedom zoning requirements for NAI as required for fresh poultry meat by the “Animal Health Requirements for the poultry meat etc. to be exported to Japan from the U.S.”
- (8) **‘Dairy materials’** means milk and milk products made from milk not including other animal origin products.

3. Poultry meat etc. meal to be exported to Japan must be produced in accordance with the relevant U.S. domestic regulations.
4. Live poultry, poultry meat etc. and poultry meat etc. meal must be derived from NAI-free zones. In addition, they shall be handled only in the approved slaughtering facilities, specified in the article 7(3), and/or the designated manufacturing facilities, specified in the article 9, in NAI-free zones and transported only through NAI-free zones to Japan unless in sealed containers.
5. Live poultry which poultry meat etc. and poultry meat etc. meal are derived from must have originated from counties which are free from Newcastle disease, Fowl cholera and other poultry diseases other than NAI which the animal health authorities of the U.S. recognize as serious outbreaks, for at least 90 days before shipment of the exported poultry meat.
6. The United States is free of rinderpest, foot-and-mouth disease, African swine fever, and classical swine fever.

(Requirements for the raw material)

7. The raw materials for the production of poultry meat etc. meal to be exported to Japan must fulfill the following requirements;
- (1) The raw materials must be meat etc. derived from poultry slaughtered only in the U.S.;
 - (2) The raw materials must be collected in such a way as to prevent contamination with materials derived from animals other than poultry;
 - (3) The raw materials must be supplied only from slaughtering facilities (hereinafter referred to as “the approved slaughtering facilities”) which handle only poultry and are approved by the government of U.S. in accordance with the relevant U.S. domestic regulations;
 - (4) The raw materials must be derived from poultry that is recognized to be free from animal infectious diseases as a consequence of ante-mortem and post-mortem inspections conducted by official inspectors of the government of U.S. at the approved slaughtering facilities.
 - (5) Either
 - A. The raw materials of the pig which is processed in the manufacturing facilities specified in the article 9 must be derived from pig that is recognized to be free from animal infectious diseases as a consequence of ante-mortem and post-mortem inspections conducted by official inspectors of the government of U.S. at the approved slaughtering facilities; or
 - B. The line must be thoroughly cleaned to avoid contamination with materials derived from pigs.
 - (6) Dairy materials may be added to the poultry meat etc. meal.
 - (7) The line must be thoroughly cleaned to avoid contamination with materials derived from fish and rabbit.

(Requirements for transportation of the raw materials)

8. The raw materials for the production of poultry meat etc. meal to be exported to Japan must be enclosed in new packaging material prior to transportation from the approved slaughtering facilities which meet the requirements specified in the article 7(3) to the manufacturing facilities specified in the article 9.

(Requirements for designated manufacturing facilities)

9. Poultry meat etc. meal to be exported to Japan must be manufactured (such as heat-processed), wrapped and stored at the designated manufacturing facilities which are designated by the U.S. animal health authorities through on-site inspections as the designated manufacturing facilities which meet the designation standard (Annex) and the animal health requirements stipulated in this document.
10. The U.S. animal health authorities must inform the Japanese animal health authorities in advance of the names, addresses, registration numbers of the designated manufacturing facilities, species of animals and type of products which may be handled and produced in the designated manufacturing facilities.
11. When any information described in article 10 above are modified, the U.S. animal health authorities must inform the Japanese animal health authorities of that modification immediately. When the designated manufacturing facilities are no longer used as facilities to produce, wrap and/or store the poultry meat etc. meal to be exported to Japan, the U.S. animal health authorities must immediately notify the Japanese animal health authorities.

12. The U.S. animal health authorities must confirm by an inspector stationed on a full-time basis or periodic annual on-site inspections that the designated manufacturing facilities meet the designation standard and the animal health requirements stipulated in this document. The results of these audits must be documented to ensure compliance with the requirements stipulated in this document and corrective actions taken.
13. If the U.S. animal health authorities find that the designated manufacturing facilities do not meet the designation standard and/or the animal health requirements stipulated in this document as a result of inspections of article 12, the U.S. animal health authorities must immediately suspend endorsement of certificates for the shipment of poultry meat etc. meal from the facilities. The U.S. animal health authorities also must revoke the designation of the facilities and/or take appropriate corrective actions, and then inform the Japanese animal health authorities of relevant information of the case as soon as possible.
14. If the U.S. animal health authorities confirm that the ineligible lot of poultry meat etc. meal from the designated manufacturing facilities specified in article 13 has been exported to Japan, the U.S. animal health authorities must immediately notify the Japanese animal health authorities in order to allow to identify that lot. When appropriate corrective actions have been taken for the designated manufacturing facilities specified in article 13, the U.S. animal health authorities should provide the relevant information to the Japanese animal health authorities and only resume export to Japan from the facilities with the permission of Japanese animal health authorities.
15. The U.S. animal health authorities must confirm by an inspector stationed on a full-time basis or periodic annual on-site inspections conducted by government inspectors or accredited veterinarians that the approved slaughtering facilities meet the requirements stipulated in article 7(3) of this document. The results of these audits must be documented to ensure compliance with the requirements stipulated in this documents and corrective actions taken.
16. If the U.S. animal health authorities find that the approved slaughtering facilities do not meet the requirements stipulated in this document as a result of inspections of article 15, the U.S. animal health authorities must suspend certification of product derived from the raw materials from the slaughtering facilities as soon as possible.
17. The U.S. animal health authorities must report the result of each on-site inspection stipulated in article 12 and 15 above in writing and keep the record for 8 years. The U.S. animal health authorities must provide, upon the request of the Japanese animal health authorities, a copy of the record of the result of each on-site inspection stipulated in article 12 and 15 above, whenever necessary.
18. The Japanese animal health authorities can request the relevant information on the approved slaughtering facilities and the designated manufacturing facilities (ground plan, etc.) from the U.S. animal health authorities and/or conduct systems audits including on-site inspections of designated manufacturing facilities when considered necessary to confirm whether these facilities meet the designation standards and other health requirements specified in this document.

19. When the Japanese animal health authorities recognize that the designated manufacturing facilities do not meet the designation standard or do not fulfill the animal health requirements stipulated in this document, the Japanese animal health authorities may immediately suspend the import of poultry meat etc. meal produced at such facilities.
20. The managers of the designated manufacturing facilities must keep records for at least 8 years including the following items for poultry meat etc. meal to be exported to Japan:
 - (1) names and addresses of the approved slaughtering facilities, date, quantity, and animal species of raw materials received;
 - (2) date of manufacturing;
 - (3) kind of manufactured products and their production volume, and kind of raw materials and their quantity used for production;
 - (4) date, kind and amount of products, and name and address of consignee by each shipping.
21. The managers of the designated manufacturing facilities must provide, after request from the Japanese animal health authorities to U.S. animal health authorities, a copy of the written documents in the article 20 above, whenever necessary.

(Requirements for transportation)

22. The U.S. animal health authorities must ensure that poultry meat etc. meal is transported and handled in such a way as to prevent it from being contaminated with any pathogens of any animal infectious diseases and with any other animal products between packaging/wrapping at the designated manufacturing facilities and the shipment. The containers for transportation, packaging and wrapping materials must be clean and sanitary. The packaging and wrapping must be dedicated to the poultry meat etc. meal or be thoroughly cleaned before use to prevent it from being contaminated with materials derived from ruminant animals.
23. With regard to the transportation to Japan, poultry meat etc. meal to be exported to Japan must fulfill the following requirements:
 - (1) The packages of poultry meat etc. meal must be contained in a shipping container in a fashion that prevents contamination;
 - (2) The designated manufacturing facility must have in place a Standard Operating Procedure to ensure that the poultry meat etc. meal is not contaminated prior to the shipping container being sealed. All shipping containers must be sealed by an authorized shipping company on behalf of the manufacturer prior to export.
 - (3) The export certificate must be sealed by the U.S. animal health authorities, and the certificate must note the shipping container seal number.
 - (4) The form of the USDA certificate seal must be provided Japanese animal health authorities in advance.
24. If the container seal specified in article 23(2) is found to have been broken or removed at the time of the inspection upon arrival in Japan, the import of poultry meat etc. meal in question may be prohibited into Japan.

(Issuance of inspection certificate)

25. The U.S. animal health authorities must issue certificates for the exported poultry meat etc. meal to Japan with the following items listed in detail in English:
 - (1) Compliance with each requirement of the articles from 3 to 9, and 22;

- (2) Name, address and registration number of the designated manufacturing facilities;
- (3) Identification number of the container and seal number;
- (4) Date and name of the port of shipment, and the name of the port of destination;
- (5) Date, location and inspector's name and title of export certificate;
- (6) The name and address of the consignee in Japan;
- (7) The packaging description and shipping quantity;
- (8) The use of the poultry meat etc. ("For use in pet food material only").

Designation Standard of designated manufacturing facilities

1. Manufacturing process:

- A) Poultry meat etc. meal must be manufactured on a production line in the space which is thoroughly separated physically from one where materials other than derived from poultry, pig, fish, rabbit and dairy are handled. Poultry meat etc. meal and raw materials processed in the same production line must not be contaminated with the materials other than dairy derived from ruminant animals in their manufacturing process.
- B) The designated manufacturing facilities must operate as a closed system. When the facilities are opened to the outside for the purpose of maintenance, etc., they must take measures against contamination of any other products.

2. Quality management:

- A) The facilities, equipments, machineries and environment must be cleaned, examined and inspected periodically.
- B) During facility operation, cross-contamination prevention measures must be taken such as wearing dedicated work clothes or outer coverings and other appropriate measures.
- C) The designated manufacturing facilities must conduct the periodical examination (testing shall be performed monthly for the first three months and then be validated quarterly) using one of the following methods; microscopy, ELISA or PCR to confirm that the poultry meat powder is not contaminated with the materials derived from ruminant animals other than dairy materials.
- D) A standardized procedural manual must be established across the manufacturing process to ensure sanitary hazards are prevented and proper quality maintained.
- E) The designated manufacturing facilities must have personnel to supervise that all procedures (receipt of raw materials, manufacturing of products and shipping of products) are appropriately performed in accordance with the designation standard and the animal health requirements stipulated in this document.