

Animal Health Requirements for heat-processed poultry meat and covered products to be exported to Japan from the United States
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1. This document defines the animal health requirements for heat-processed poultry meat and its products (excluding those that use casing) to be exported to Japan from the United States.
2. In this document, the definitions of terms are as follows:
 - (1) "Heat processing" means the treatment that is conducted in the designated facilities in article 7 of this document on the condition of either:
 - i) To keep the temperature at the center of the poultry meat and its products at a temperature of 70°C or higher for one minute or more by boiling, exposing them to heated steam or deep- frying;OR
 - ii) To keep the temperature at the center of the poultry meat and its products at a temperature of 70°C or higher for 30 minutes or more by any ways other than those stipulated in i).
 - (2) "Poultry" means chicken, quail, pheasant, emu, ostrich, guinea fowl, turkey and birds classified into order Anseriformes (such as duck and goose).
 - (3) "Poultry meat and its products" means meat, fat, tendon and viscera of poultry and their products (excluding meat meal and meat and bone meal (MBM)).
 - (4) "Avian influenza" (hereinafter referred to as "AI") means an infection of poultry caused by either:
 - i) an influenza A virus of H5 or H7 subtype;OR
 - ii) an infection of poultry caused by avian influenza virus considered to be highly pathogenic in accordance with the WOAHP Manual of Standards for Diagnostic Tests and Vaccines.
 - (5) "Outbreak" means an appearance of clinical signs, or in the case of AI, detection of antibody or the virus.
 - (6) "The Exporting country" means the United States of America.
 - (7) "The Japanese animal health authorities" means the Animal Health Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of the Japanese government.
 - (8) "USDA" means the United States Department of Agriculture (USDA) and includes the Food Safety and Inspection Service (FSIS) and the Animal Plant and Health Inspection Service (APHIS) and the Agricultural Marketing Service (AMS).

3. When the exporting country exports heat-processed poultry meat and covered products to Japan, the following requirements must have been fulfilled in the exporting country.
 - (1) AI and Newcastle disease are designated as a notifiable disease by the USDA.
 - (2) The surveillance programs for AI based on the WOA code are in place and their outcomes are fully acknowledged by the USDA.
4. Heat-processed poultry meat and its products exported to Japan must fulfill the following requirements:
 - (1) Poultry meat and its products are derived from poultry which are born and raised only in the Continental United States, Hawaii, and/or Guam. Poultry are produced on farms where no outbreak of AI or Newcastle disease (as defined by WOA) or clinical outbreak of fowl cholera or salmonellosis (which is caused by *Salmonella pullorum* or *Salmonella gallinarum* only) has been confirmed for at least 21 days before its slaughter date.
 - (2) The poultry are free from any evidence of poultry infectious diseases on ante- and post-mortem inspections conducted by official inspectors of the FSIS at the approved slaughter facilities specified in the Article 5.
5. The slaughter facilities (hereinafter referred to as "the approved slaughter facilities") where the poultry for heat-processed poultry meat and its products to be exported to Japan is slaughtered must be approved by the USDA .
6. The processing facilities (hereinafter referred to as "the approved processing facilities") where the poultry meat and its products for heat-processing to be exported to Japan are processed must be approved by the USDA.
7. In response to the application by the USDA, the Japanese animal health authorities designate the facilities which meet the attached standard (hereinafter referred to as the "designation standard") for the term of 2 years as the facilities where the poultry meat and its products may be heat-processed to be exported to Japan.
- 8-1. Japanese animal health authorities conduct on-site inspections of the facilities referenced in the Article 7 at the expense of the exporting country to confirm whether they meet the designation standard.
- 8-2. In the case that the Japanese animal health authorities confirm the conditions in the Annex are fully met and respected, the USDA with the prior approval by the Japanese animal health authorities, may conduct the on-site inspections referenced in the Article 8-1 instead and report the results to the Japanese animal health authorities.

8-3. In the case that there occurred serious food and animal safety problems with the relevant products in the exporting country, the Japanese animal health authorities can terminate the derogation in the Article 8-2.

8-4. The USDA may submit an application on behalf of the designated facilities to the Japanese animal health authorities for the extension of the designated period of the designated heat-processing facilities. Upon receipt of the application, the Japanese animal health authorities will extend the designated period of the designated facilities for another two years when the Japanese animal health authorities confirm that the designated facilities meet the designation standard by examining the results stipulated in Item 14 and by conducting on-site inspections stipulated in Item 18 as necessary. (The extended period of two years may be further extended by the same procedure.)

9. The USDA, must verify by inspection that any structural changes at the approved facility comply with the requirements of this document, and do not pose a risk of allowing contamination of heat-processed product with raw product.

10. The USDA must notify, in a timely manner, the Japanese animal health authorities, if designated facilities change their names or addresses.

11. The managers of the designated facilities must check at least once a month if preventive measures against the occurrence of sanitary hazard are conducted in the heat-processing procedure, and proper quality is ensured and the results of the checkup must be kept in a written form for at least 2 years.

12. The managers of the designated facilities must keep the following records for at least 2 years;

- i) date of heat processing
- ii) quantity of poultry meat and its products of each product item with their heating records
- iii) date and amount of each shipping

13. The USDA must conduct inspections in official establishments whenever production is occurring. The officials must verify that the facility is in compliance with the requirements of the USDA, the requirements of the designation standard, and the animal health requirements of this document.

14. The USDA must provide a copy of the written record to verify compliance to the Japanese animal health authorities upon request, which must be kept for a period of 2 years. The relevant

document can be kept in electronic form on condition that manipulation prevention measures are taken and backup files are secured.

15. If the USDA finds that the designated facilities do not meet the designation standards or the animal health requirements of this document , they must suspend the shipment of heat-processed meat and its products in a timely manner, until the issue is resolved. The USDA must inform the Japanese animal health authorities of any removal of any facility from the list referenced in Article 7.
16. In the case that article 15 happens, and appropriate corrective actions have been taken for the removed facility, the USDA must notify the Japanese animal health authorities if the facility is returned to the list referenced in Article 7.
17. Japanese animal health authorities retain the right to conduct an inspection of the exporting country producing establishments as part of a systems audit. Such inspections would be conducted to assess the performance of the exporting country inspection system in meeting the requirements rather than to approve or disapprove individual establishments. Japanese animal health authorities will document audit findings and report them to the USDA as part of a systems audit review. The USDA will review the findings and address each item appropriately.
18. The Japanese animal health authorities can make onsite inspections of the designated facilities when they regard it as necessary to confirm whether they meet the designation standard and the animal health requirements of this document.
19. When the Japanese animal health authorities recognize that designated facilities do not meet the designation standard or do not fulfill the animal health requirements of this document, they may revoke the designation and suspend the import of heat-processed poultry meat and its products produced in the facilities in a timely manner.
20. The USDA must ensure that the heat-processed meat and its products are stored in clean and sanitary wrappings and/or containers and handled in a way to prevent it from being contaminated with any pathogens of any animal infectious diseases prior to shipment.
21. In case the heat-processed poultry meat and its products are transported to Japan through third countries, those must be packed in a sealed container. The USDA's seal number will be recorded on the export certificate.
22. In the case of the confirmation of an outbreak or suspicion of AI, the USDA must inform the

Japanese animal health authorities of the relevant information within 24 hours.

23. The USDA will issue export certificates for the exported heat-processed poultry meat and its products to Japan exported from facilities referenced in Article 7, stating the following:

- (1) AI and Newcastle disease are designated as a notifiable disease by the USDA.
- (2) Surveillance programs for AI based on the WOAHA code are in place in the exporting country.
- (3) The poultry for heat-processed poultry products to be exported to Japan is produced on a farm where no outbreak of AI or Newcastle disease or clinical outbreak of fowl cholera or salmonellosis (which is caused by *Salmonella pullorum* or *Salmonella gallinarum* only) has been confirmed for at least 21 days before its slaughter date.
- (4) The heat-processed poultry meat is derived from poultry which is free from evidence of poultry infectious diseases, as confirmed by ante- and post-mortem inspections conducted by the USDA at approved slaughter facilities.
- (5) The heat-processed poultry meat and its products are stored in clean and sanitary wrappings and/or containers and are handled in a way to prevent it from being contaminated with any pathogens of any animal infectious diseases until the shipment.
- (6) Name, address and official number of the approved slaughter facilities, and approved processing facilities.
- (7) Name, address, and official numbers of the designated facilities.
- (8) Date of slaughter and date of heat-processing.
- (9) Identification number of the USDA's seal on the container (for exported heat-processed meat products transported to Japan through third countries).
- (10) Date and place of issuance of the inspection certificate, and name and title of the signer.

Attached

Designation Standard

1. Separate pre-heating and post-heating production areas are provided to preclude cross-contamination. Separate equipment is provided, and employees are only allowed to work in one area to prevent cross-contamination.
2. The raw processing rooms (pre-heating areas) are physically separated from the post-heating areas except for conveyor openings. Separation is adequate to prevent cross-contamination of uncooked meat with cooked meat.
3. The preheating processing rooms are equipped with adequate facilities and equipment to ensure sanitary operations.
4. The designated facilities must have heat-processing equipment furnished with instruments such as temperature recorders.
5. The post-heating area must be walled off completely from the outside and have equipment or instruments for inspection, cooling, storage, and packing after heat processing.
6. Adequate sanitation must be enforced to ensure that personnel and equipment do not pose a risk of contaminating heat-processed products with raw product.
7. Floors, walls and ceilings must be smooth and easy to clean. The floors shall be made of impermeable material, sloped properly and provided with drainage and be easily disinfected.
8. The designated facilities must be equipped with adequate facilities for waste disposal as well as adequate water supply facilities which can supply sufficient water for cleaning.
9. The plant must have a Sanitary Standard Operating Procedure (SSOP) for preventing the occurrence of sanitary hazards and for ensuring proper quality.
10. Plant management must supervise the compliance with the SSOP.

Conditions to be eligible for the derogation of Item 8-2

1. The Japanese animal health authorities audit the system and facilities of the USDA and confirm the following;
 - (1) The USDA has a law prescribing a specific program to control and register the facilities applying for the designation.
 - (2) The law referenced in (1) above is consistent with this Animal Health Requirements.
 - (3) Sampled facilities that apply for the designation prove that all the requirements under this Animal Health Requirements are met.
 - (4) Products that fall under this Animal Health Requirements or their related products have been exported to Japan within last 2 years with no record of food and animal safety problems including violation at the Japanese import quarantine

2. The USDA respects and/or implements the following;
 - (1) In case the law referenced in 1 (1) above is revised/changed in anyway, it should be notified to the Japanese animal health authorities.
 - (2) Any information or data requested by the Japanese animal health authorities with regard to the relevant program or facilities shall be provided as far as possible.
 - (3) If there occurred any problems concerning food and animal safety with the products derived from the designated facilities, those products shall be suspended to export to Japan and such cases to be notified to the Japanese animal health authorities in a timely manner.
 - (4) Experts from the Japanese animal health authorities shall be accepted at any time to make an audit of the program and facilities of the exporting country.