

Animal Health Requirements for heat-processed liquid egg products to be exported to Japan from the United States of America

1. This document defines the animal health requirements for heat-processed liquid egg products to be exported to Japan from the United States of America (USA).
2. In this document, the definitions of terms are as follows:
 - (1) "Heat processing" means pasteurization that is conducted in the designated facilities prescribed in the article 7 of this document on the following condition:
 - (a) In case of liquid whole egg (including liquid egg yolk): Heat treatment at a minimum of 60 degrees Celsius for a minimum of 3 minutes and 8 seconds.
 - (b) In case of liquid egg white: Heat treatment at a minimum of 56.7 degrees Celsius for a minimum of 3 minutes and 52 seconds.
 - (2) "Poultry" means chicken, quail, pheasant, emu, ostrich, guinea fowl, turkey and birds classified into order Anseriformes (such as duck and goose).
 - (3) "Egg" means the egg of poultry.
 - (4) "Avian influenza" (hereinafter referred to as "AI") means an infection of poultry caused by either:
 - (a) an avian influenza virus of H5 and H7 subtypes;or
 - (b) an avian influenza virus of high pathogenicity as defined in the OIE Terrestrial Animal Health Code.
 - (5) "Outbreak" means identification of the pathogens of the disease, detection of specific antigens of the disease or the detection of antibodies (AI only) with clinical symptoms in domestic poultry.
 - (6) "The Exporting country" means the United States of America.
 - (7) "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.
 - (8) "FSIS" means the Food Safety and Inspection Service of the United States Department of Agriculture (USDA).
3. When the exporting country exports pasteurized liquid egg products (hereinafter referred to as "heat-processed egg products") to Japan, the following requirements must have been fulfilled in the exporting country.
 - (1) AI and Newcastle disease are designated as notifiable diseases by the animal health authorities of the exporting country.
 - (2) The surveillance programs for AI based on the OIE code are in place and the outcomes of these programs are fully acknowledged by the animal health authorities of the exporting country.
4. The eggs for the production of the heat-processed egg products to be exported to Japan must be the ones which fulfill the following requirements:

(1) They are laid on a farm where no outbreak of AI and Newcastle disease, and no clinical outbreak of fowl cholera and salmonellosis (which is caused by *Salmonella Pullorum* or *Salmonella Galinarum* only) have been confirmed for at least 21 days.

(2) They are laid by poultry flocks which are free from any significant infectious diseases.

5. The eggs for the production of the heat-processed egg products to be exported to Japan must be inspected, washed, sanitized, heat-processed, wrapped/filled-up and stored in the designated facilities specified in the Article 7.

6. The animal health authorities of the exporting country must ensure that the heat-processed egg products are stored in clean and sanitary wrappings and/or containers and are handled in a way to prevent them from being contaminated with any pathogens of any animal infectious diseases until the shipment.

7. In response to the application by the animal health authorities of the exporting country, 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 liquid egg products may be heat-processed to be exported to Japan.

8-1. Japanese animal health authorities conduct on-site inspections of the facilities referred in the Article 7 at the expense of the national government 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 animal health authorities of exporting country, with the prior approval by the Japanese animal health authorities, may conduct the on-site inspections stipulated in the Article 8-1 instead and report the results to the Japanese animal health authorities.

8-3. In the case that there have 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.

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

10. FSIS must notify immediately to 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 preventative

measures against the occurrence of sanitary hazard are conducted in the heat-processing procedure, and if proper quality of the eggs is ensured and the results of the checkup must be kept in a written form for at least 1 year. The relevant document can be kept in electronic form on condition that manipulation preventive measures are taken and backup files are secure.

12. The managers of the designated facilities must keep the following records for at least 1 year:

- (1) date of heat processing and amount of heat-processed egg products
- (2) date and amount of each shipping.

13. FSIS officials must conduct daily inspections in the designated facilities. The officials must verify that the facilities are in compliance with USDA requirements and the requirements of this document.

14. FSIS must keep records of the result of the inspection of the article 13 in a written form for 1 year. The relevant document can be kept in electronic form on condition that manipulation preventive measures are taken and backup files are secure. FSIS must provide a copy of the written record to the Japanese animal health authorities upon request.

15. If FSIS finds that the designated facilities do not meet the designation standards or the animal health requirements of this document as the result of the inspection in the article 13, they must immediately suspend the shipment of heat-processed egg products until the issue is resolved. FSIS must inform the Japanese animal health authorities of any removal of any facility from the list stipulated in the Article 7.

16. Under the article 15, appropriate corrective actions have been taken for the removed facility, FSIS must notify the Japanese animal health authorities if the facility is re-registered in the list stipulated in the Article 7.

17. The Japanese animal health authorities may replace its on-site inspection stipulated in the item 8-1 with receiving the report of the on-site inspection conducted by FSIS if the Japanese animal health authorities regard the competency of FSIS for conducting on-site inspection as equivalent to that of the Japanese animal health authorities.

18. The Japanese animal health authorities may suspend the application of the item 17 if the Japanese animal health authorities recognize that the competency of FSIS for conducting on-site inspection is insufficient or if the Japanese animal health authority considers it inappropriate to apply the item 17.

19. In case heat-processed egg products are exported to Japan through third countries, the heat-processed egg products must fulfill the following requirements:

- (1) The heat-processed egg products to be exported to Japan must be packed in a tight container.

- (2) The said container must be sealed with a USDA seal.
- (3) The form of the seal has been approved by the Japanese animal health authorities.

20. If the seal specified in the article 19 is found to have been intentionally broken or dropped out at the time of the arrival inspection in Japan, the exported heat-processed egg products to Japan in question might be prohibited import to Japan.

21. In the case of the confirmation of an outbreak or suspicion of AI, the animal health authorities of the exporting country must inform the Japanese animal health authorities of the relevant information within 24 hours.

22. FSIS will issue inspection certificates for the exported heat-processed egg products to Japan exported from facilities referred in the Article 7, stating the following:

- (1) AI and Newcastle disease are designated as notifiable diseases by the animal health authorities of the exporting country.
- (2) Surveillance programs for AI based on the OIE code are in place in the exporting country.
- (3) The eggs for the production of the certified heat-processed egg products to be exported to Japan must be the ones which fulfill the following requirements:
 - (a) Being laid 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 Galinarum* only) has been confirmed for at least 21 days;
 - (b) Being laid by poultry flocks which are free from any significant infectious diseases;
 - (c) Being inspected, washed, sanitized, heat-processed, wrapped/filled-up and stored in facilities inspected by FSIS;
- (4) The heat-processed egg 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.
- (5) Pasteurization time and temperature, and date of heat-processing.
- (6) Name, address and official number of the designated facilities.
- (7) Identification number of the seal on the container (for exported heat-processed egg products transported to Japan through third countries).
- (8) Date and place of issuance of the inspection certificate, and name and title of the signer.

Designation Standard

1. Areas where unpasteurized products are handled (transfer rooms, breaking rooms) will be separated from areas where pasteurized products are handled (packaging rooms). In cases where unpasteurized and pasteurized products are stored in the same room, they must be kept in separate enclosed silos, without the possibility of cross contamination.
2. Pasteurized products must be kept separate and apart from unpasteurized product at all times.
3. The facility must have adequate facilities for storage, processing (breaking etc), inspection, cleaning, drying, and sanitizing.
4. The area where pasteurized products are handled must be fully segregated from the outside.
5. The facility must have adequate equipment and utensils appropriate for handling the products after the heating process to ensure the products are not contaminated with unpasteurized materials.
6. The pasteurizer system must be equipped with temperature recording devices.
7. Adequate sanitation measures must be enforced to ensure that personnel and equipment do not pose a risk of contaminating pasteurized products with unpasteurized products.
8. Floors, walls and ceilings must be smooth and easy to clean. The floors shall be made of impermeable materials, sloped properly and provided with drainage and be easily disinfected.
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 the Article 8-2

1. The Japanese animal health authorities make an audit of exporting country's system and facilities, and confirm the followings;
 - (1) The exporting country has a law or regulation prescribing a specific program to control and register the facilities applying for the designation.
 - (2) The law or regulation referred in (1) above is consistent with this Animal Health Requirements.
 - (3) Sampled facilities to be applying for the designation are confirmed to meet all the requirements under this Animal Health Requirements.
 - (4) Products 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 inspection.

2. The animal health authorities of exporting country respect and implement the following;
 - (1) In case there are any revisions or changes made in the law referred in 1 (1) above, they 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 have occurred any problems concerning food and animal safety with the products derived from the designated facilities, those products shall be immediately suspended to export to Japan and such cases be notified to the Japanese animal health authorities.
 - (4) Experts from the Japanese animal health authorities shall be accepted at any time to make an audit of the system and facilities of exporting country.