

Animal health requirements for heat-processed poultry meat and poultry meat products to be exported from Italy to Japan

1. This document defines the animal health requirements for heat-processed poultry meat and poultry meat products to be exported to Japan from Italy.
2. In this document, the following definitions apply:
 - (1) **Heat processing** means the heat treatments by maintaining the temperature at the center of poultry meat and poultry meat products at 70°C or higher for one minute or more, at any of the designated facilities described in Article 7-1 and 7-2.
 - (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 poultry meat products** means meat, fat, tendon and viscera of poultry and their products (excluding meat meal and MBM (meat and bone meal)).
 - (4) **Notifiable Avian influenza (NAI)** means an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus defined as highly pathogenic according to the OIE Terrestrial Animal Health Code.
 - (5) **NAI etc.** means NAI, Newcastle disease, fowl cholera and salmonellosis (caused by *Salmonella pullorum* or *Salmonella gallinarum* only).
 - (6) **Outbreak** means an appearance of clinical signs, detection of specific antigens or antibodies (for NAI only), or identification of the pathogens of the disease in domestic poultry.
 - (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.
3. In order for Italy to export heat-processed poultry meat and poultry meat products, the following requirements must have been fulfilled in Italy.
 - (1) In Italy, NAI etc. are notifiable diseases. These diseases must be brought to the attention of the animal health authorities of Italy immediately after an outbreak is detected or suspected in accordance with national regulation.
 - (2) Surveillance programs for NAI based on the OIE Code are in place, the outcomes of which are fully acknowledged by the animal health authorities of Italy.
4. The poultry to be used for the production of heat-processed poultry meat and poultry meat products to be exported to Japan must fulfill the following requirements:

- (1) They are born and raised only in Italy.
- (2) No outbreak of NAI etc. has been confirmed at a farm from which they are derived for at least 21 days before the slaughter date.
- (3) They are confirmed free from any poultry infectious diseases as a consequence of ante- and post-mortem inspections conducted by official inspectors of the Government of Italy at an approved slaughter facility (defined in Article 5).

5. The slaughter facilities (the "approved slaughter facilities") where poultry to be used for the production of heat-processed poultry meat and poultry meat products to be exported to Japan are slaughtered must be approved by the Government of Italy.

6. The processing facilities (the "approved processing facilities") where poultry meat and poultry meat products to be exported to Japan are processed (prior to heat processing) must be approved by the Government of Italy.

7-1. Upon application by the animal health authorities of Italy, the Japanese animal health authorities will designate particular processing facilities (the "designated facilities") meeting the attached standard in the Annex 1 (the "designation standard") as approved, for a period of two years in principle, to perform heat processing of poultry meat and poultry meat products to be exported to Japan.

7-2. The animal health authorities of Italy may apply for the extension of the designated period of the designated facilities to the Japanese animal health authorities. Upon the application, the Japanese animal health authorities can 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 described in Article 14-2 and by conducting on-site inspections described in Article 9-2. (The extended period of two years may be further extended by the same procedure.)

8. The documents which show following items in English or Japanese language should be submitted by the animal health authorities of Italy to the Japanese animal health authorities at the application described in Article 7-1.

- (1) Facility name, Facility address and Registration number of the facility
- (2) Scale of the facility (i.e. ground-floor area, total-floor area)
- (3) Number of workers and organization chart of the facility

- (4) General description of heat-processed poultry meat and poultry meat products to be exported to Japan
 - (a) Species of poultry (chicken, duck, goose, etc.)
 - (b) Process for production including heat method, heating temperature, heating period
 - (c) Measuring method and place of temperature of heat-processing
- (5) General description of structure of the facility
 - (a) Drawing which shows the structure of pre-heating area and post-heating area
 - (b) Arrangement plan of major equipment including heat-processing equipment
 - (c) Photographs of an isolated appearance (dividing walls etc.) between pre-heating area and post-heating area
 - (d) Photographs of attachment point between heat-processing equipment and dividing walls
 - (e) Kind of heat-processing equipment (batch-type steamer, tunnel-type fryer etc.)
- (6) General description of traffic line in the facility
 - (a) Traffic line of the products from entrance to exit
 - (b) Traffic line of drainage and waste
 - (c) Traffic line of water supply
 - (d) Traffic line of air
 - (e) Traffic line of workers
- (7) List of Standard Operation Procedures (SOP)
- (8) Map around the facility
- (9) Other information that Japanese animal health authorities consider necessary

9-1. In response to an application made under Article 7-1, the Japanese animal health authorities will conduct on-site inspections of proposed facilities at the expense of Italy to confirm whether they meet the designation standard.

9-2. In response to an application made under Article 7-2, the Japanese animal health authorities will conduct on-site inspections of the designated facilities at the expense of Italy to confirm whether they meet the designation standard, as necessary.

10. When the designated facilities are planned to make alterations including reconstruction, enlargement and/or other changes of the structure or equipment (defined in Annex 2-2.), the animal health authorities of Italy must apply in advance to the Japanese animal health authorities for permission of the alterations.

11. The animal health authorities of Italy must notify the Japanese animal health authorities immediately if any designated facilities change their names or addresses.
12. At least once per month, the manager of each designated facility must confirm that preventive measures against the occurrence of sanitary hazards are conducted and that proper quality is ensured in the heat-processing procedure, and the results of such verification must be maintained in written form for at least two years.
13. The manager of each designated facility must keep a written record at least for two years of the following items:
 - i) date of heat processing
 - ii) quantity of poultry meat and poultry meat products of each product item, with their heating records
 - iii) date and quantity of each shipment, by destination country.
- 14-1. The animal health authorities of Italy must visit the designated facilities at least once every six months and check whether the facilities maintain fulfillment of the requirements of the designation standard and the animal health requirements of this document. The animal health authorities of Italy must maintain written records of the results of each visit for two years.
- 14-2. The animal health authorities of Italy must report the results of the visit described in Article 14-1 in written form to the Japanese animal health authorities once every six months.
15. If the animal health authorities of Italy find that any designated facility does not meet the designation standard or the animal health requirements of this document as the result of the visit made under Article 14-1, the animal health authorities of Italy must immediately suspend all exports to Japan of heat-processed poultry meat and poultry meat products from the designated facility and inform the Japanese animal health authorities of relevant information of the case as soon as possible.
16. In the case of a suspension under Article 15, if appropriate remedial actions have been taken for the relevant designated facility, the animal health authorities of Italy may report the relevant information to the Japanese animal health authorities and resume the exports from the facility with the permission of the Japanese animal health authorities.

17. The animal health authorities of Italy must, upon request, provide the Japanese animal health authorities with a copy of the written record of the result of each visit made under Article 14-1.
18. The Japanese animal health authorities may conduct on-site inspections of the designated facilities if necessary to confirm whether they meet the designation standard and the animal health requirements of this document.
19. In any of the following cases, the Japanese animal health authorities may revoke the designation of the designated facilities and immediately suspend the import of heat-processed poultry meat and poultry meat products produced in the facilities.
 - (1) When the designated facilities do not meet the designation standards.
 - (2) When it is found that the designated facilities are designated by a fraudulent or other unjust means.
 - (3) When it is found that the designated facilities commit a wrongful or unfaithful act in relation to the operation of the designated facilities.
 - (4) When the designated facilities do not comply with an order of the Japanese animal health authorities relevant to corrective measures to violations without any justifiable reasons.
 - (5) When the designated facilities have not exported heat-processed poultry meat and poultry meat products to Japan for two years since the facilities were designated without any justifiable reasons.
 - (6) When the results of the visit to the designated facilities described in Article 14-2 are not reported to Japanese animal health authorities for the second time in a row without any justifiable reasons.
 - (7) Unless otherwise above items from (1) to (6), when the designated facilities are found to be in violations of the animal health requirements and such violations cause or are likely to cause severe harm to animal health.
20. The animal health authorities of Italy must ensure that heat-processed meat and poultry meat products are stored in clean and sanitary wrappings and/or containers and handled in a way to prevent contamination with pathogens of any animal infectious diseases prior to shipment.
21. In the case that heat-processed poultry meat and poultry meat products are

transported to Japan through third countries, they must be packed in a container sealed by the animal health authorities of Italy with a seal that can be obviously differentiated from that of the third countries.

22. In case of suspicion or confirmation of an outbreak of NAI etc., the animal health authorities of Italy must inform the Japanese animal health authorities of the relevant information within 24 hours.

23. The animal health authorities of Italy must issue inspection certificates for all heat-processed poultry meat and poultry meat products exported to Japan, stating the following items in detail in English:

- (1) Compliance with each requirement of Articles 3 to 6 and Article 20.
- (2) Name, address and approval number of slaughter facilities and processing facilities.
- (3) Name, address and approval number of the designated facilities.
- (4) Dates of slaughter, processing and heat-processing.
- (5) Identification number of the seal of the container (for shipments through third countries).
- (6) Date and name of the port of shipment.
- (7) Date and place of issuance of the inspection certificate, and name and title of the signatory.

24. The animal health requirements stipulated in this document must be applied to heat-processed poultry meat and poultry meat products to be exported to Japan originated from poultry slaughtered on or after 22 January 2015.

Annex 1

Designation Standard

1. The designated facilities must have a pre-heating area furnished with necessary equipment for treating raw materials, and a post-heating area furnished with necessary equipment for treating heat processed products only including heat-processing equipment.
2. The pre-heating area must be isolated from the post-heating area except for the entrance of raw materials into the heat-processing equipment.
3. If the entrance and exit of heat-processing equipment are opened, preventive measures against the backward flow of the air from the pre-heating area into the post-heating area are taken.
4. The pre-heating area must have facilities for storage, treatment and inspection.
5. The post-heating area must not connect to the outside of the designated facility and have heat-processing equipment furnished with instruments for inspection such as temperature recorders and equipment or instruments for inspection, cooling, storage and packing after heat -processing.
6. The pre-heating area and the post-heating area must have individual facilities, such as the entrance and exit, locker room, etc., for personnel of each area in order to prevent recontamination.
7. Floors, walls and ceilings must be smooth and easy to clean; floors have to be made of impermeable material, sloped properly and provided with drainage and be able to be easily disinfected.
8. The designated facilities must have equipment for decontamination as well as equipment which has enough water for cleaning.
9. The designated facilities must be equipped with a procedural manual for preventing

occurrence of sanitary hazards and ensuring proper quality in a series of pre-heat-processing, heat-processing and post-heat processing.

10. Personnel who supervise compliance with the series of procedures of the procedural manual of Article 9 are posted.

Annex 2

The permission procedures for the alterations of the designated heat-processing facilities

1. If the designated heat-processing facilities intend to make the alterations, the animal health authorities of Italy must submit the documents which show the details of the alterations including construction period of the alterations to the Japanese animal health authorities at least one month before construction starts. The animal health authorities of Italy must be permitted for the alterations by the Japanese animal health authorities.
2. The alteration means that reconstruction, enlargement and/or other changes of the structure of the designated facilities which concerned with the designation standard stipulated in Annex 1. The example of the alterations is as follows. When any modification which could involve any of the following reconstructions or enlargements is made even temporarily, the animal health authorities of Italy must obtain an in-advance approval for the modification from the Japanese animal health authorities.

[reconstruction]

- ① A reconstruction concerning the heat-processing equipment (increase or decrease of the equipment, change of the way of the heating processing etc.).
- ② A reconstruction concerning the separation between the pre-heating area and the post- heating area.
- ③ A reconstruction of the inner wall (except the dividing wall that separates the pre-heating area and the post-heating area) accompanied by the change of the traffic line of worker and/or the traffic line of raw materials and/or products.
- ④ A reconstruction concerning the outer wall.
- ⑤ A reconstruction accompanied by the change of use of the area in the designated facility.

[enlargement]

- ① An enlargement which involves a construction of facility which is not totally independent from the existing designated area.
- ② An enlargement which involves a construction of facility which shares a

registration number, name, address etc., of the existing designated facility.

3. The Japanese animal health authorities must suspend the importation of the heat-processed poultry meat and poultry meat products produced in the designated facilities (or a part of facilities) after the starting of construction of the alterations.
4. When the construction for alterations is completed, the animal health authorities of Italy must submit a completion report including the actual construction period, construction plan and photos of the alteration area to the Japanese animal health authorities. After receiving the completion reports, the Japanese animal health authorities may perform the on-site inspection for the designated facilities. Based on the on-site inspection results and/or the completion report, the Japanese animal health authorities must allow the designated facilities (or a part of the facilities) to produce the heat-processed poultry meat and poultry meat products to be exported to Japan.
5. In case of the Article 4, the Japanese animal health authorities conduct an on-site inspection of the facilities at the expense of Italy.