

## **Animal Health Requirements for beef and beef offal to be exported to Japan from Italy**

Animal health requirements for beef and beef offal to be exported to Japan from Italy are as follows:

### **1. Definitions**

For the purpose of the animal health requirements;

1-(1) "cattle" means

Bovine (*Bos taurus* and *Bos indicus* only).

1-(2) "beef and beef offal" means"

All parts of cattle and products derived therefrom, except the following tissues;

(\*Beef and beef offal for export to Japan shall be derived from cattle that is 30 months of age or less at the time of slaughter.)

- Tonsils from all cattle

- Distal ileum (two meters from connection to caecum) from all cattle

- Spinal cord from cattle over 30 months of age

- Head (except for hygienically removed tongues, cheek meat and hide) from cattle over 30 months of age

- Vertebral column (excluding vertebrae of the tail, the spinous and transverse processes of the cervical, lumbar and thoracic vertebrae, the median sacral crest and wings of the sacrum) from cattle over 30 months of age.

1-(3) "the exported beef to Japan" means"

beef and beef offal to be exported to Japan from Italy.

1-(4) “outbreak” means

detection of specific pathogen, antigen or antibody of the disease as well as appearance of animal showing clinical signs of the diseases.

1-(5) “the Japanese animal health authorities” means

Animal Health Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan.

1-(6) “the third free countries” means

countries and zones approved by the Ministry of Agriculture, Forestry and Fisheries of Japan for the export of meat etc. to Japan and that are listed in Article 1 to 3 in Annex 2.

1-(7) “the specified countries” means

countries approved by the Ministry of Agriculture, Forestry and Fisheries of Japan for the export of beef and beef offal to Japan other than third free countries as listed in Article 4 in Annex 2.

1-(8) “the designated facilities” means

the slaughterhouses, meat processing facilities and storage facilities, etc. which are designated by the Ministry of Health of Italy (or the government authorities of the third free countries or the specified countries in case of Article 5-(1)(ii)) as facilities which meet the requirements of Annex 1, 3 and 4 for the exported beef to Japan.

## **2. General requirements**

2-(1) Italy is free from Foot and mouth disease (FMD) and Rinderpest, and vaccination against FMD and Rinderpest is legally prohibited in Italy.

2-(2) Importation of cloven-hoofed animals that have been vaccinated against FMD and Rinderpest is completely prohibited in Italy.

2-(3) The Ministry of Health of Italy will continue to maintain measures to prevent introduction, control spread, and detect Bovine spongiform encephalopathy (BSE). These

measures include SRM removal, effective feed ban, and a surveillance program. In case that the Ministry of Health of Italy intends to amend or abolish the regulations or measures on BSE, the Ministry of Health of Italy should inform the Japanese animal health authorities of the fact in advance.

2-(4) The Ministry of Health of Italy annually submits copies of OIE annual status reconfirmation form for animal health controlling situations to the Japanese animal health authorities.

2-(5) The exported beef to Japan must be slaughtered, produced and stored only in the designated facilities.

### **3. Notification of the designated facilities**

3-(1) The Ministry of Health of Italy must inform the Japanese animal health authorities of the name, activities, address and establishment number of the designated facilities in advance of the shipment of the exported beef to Japan from the said facilities. The list of the designated facilities will be maintained and updated by the Ministry of Health of Italy as changes in facility status occur.

The Ministry of Health of Italy must confirm through an ordinary monitoring or periodic audit that the designated facilities are fulfilling the required conditions in Annex 1 and Articles 3 to 6 of Annex 3.

If during ordinary monitoring or periodic audits of the designated facilities, the Ministry of Health of Italy identifies a serious noncompliance with the conditions in Annex 1 and Articles 3 to 6 of Annex 3, the Ministry of Health of Italy must immediately stop certification of the exported beef to Japan from the said facilities, and must inform the Japanese animal health authorities of the name, activities, address and establishment number

of the said facilities.

Thereafter, the Ministry of Health of Italy are to revoke the designation of the said facilities.

After verifying that acceptable corrective actions have been taken and informing the Japanese animal health authorities of the corrective actions taken by the Ministry of Health of Italy, the Ministry of Health of Italy may re-designate the revoked facilities as the designated facilities.

A system-wide problem such as repeated serious noncompliance may result in the suspension of the animal health requirements.

#### **4. Requirements for shipment**

4-(1) The exported beef to Japan must have been handled at the designated facilities in such a way as to prevent contamination with any causative agents of animal infectious diseases. Clean and sanitary wrappings and/or containers such as cardboard boxes must be used to pack the exported beef to Japan.

4-(2) If an outbreak of FMD or Rinderpest is confirmed in Italy, the Ministry of Health of Italy must immediately stop certification of the exported beef to Japan.

If the exported beef to Japan has been certified and in transit to Japan at the time of the outbreak, the shipment will be prohibited entry into Japan, except where the Ministry of Health of Italy can demonstrate that the shipment definitely bears no relation (such as, time of shipment, region of origin, route of transit) to the outbreak of the said diseases.

4-(3) If a BSE case is detected in Italy and it is epidemiologically related to the exported beef to Japan, the Ministry of Health of Italy must immediately notify the Japanese animal health authorities with the relevant information.

4-(4) In the case where the exported beef to Japan is transported to Japan by way of third countries, the exported beef to Japan must be stored in an enclosed ocean/air vessel container. The Ministry of Health of Italy must close the container with an official seal, which is apparently distinguishable from those of the other countries/regions than Italy. The form of official seal must be approved in advance by the Japanese animal health authorities. In case the official seal with the container had been broken or removed prior to the time of import inspection after arrival in Japan, the exported beef to Japan in question may be prohibited to import into Japan.

## **5. Requirements for the exported beef to Japan**

5-(1) Cattle slaughtered for the production of the exported beef to Japan (hereinafter referred to as “the slaughtered cattle”) must have been born and raised only in Italy, or directly and legally imported from the third free countries or the specified countries and raised in Italy.

Beef and beef offal that are directly and legally imported from or the third free countries or the specified countries and that completely meet all the following requirements can be used for the production of the exported beef to Japan.

- (i) The imported meat etc. must be derived from cattle that were born and raised only in the third free countries or the specified countries
- (ii) The imported meat etc. must be handled only at the designated facilities in the third free countries or the specified countries and be derived from cattle that were free from any evidence of animal infectious diseases as a result of ante- and post-mortem inspections conducted by official veterinarians of the third free countries or the specified countries
- (iii) The imported meat etc. must be directly and legally imported to Italy from the third free countries or the specified countries without transiting through countries other

than the said third free countries or the specified countries, and must be accompanied by inspection certificates issued by the government authorities of the third free countries or the specified countries

or

The imported meat etc. must be directly and legally imported to Italy from third free countries or the specified countries into a sealed container and must be accompanied by inspection certificates issued by the government authorities of the third free countries or the specified countries that indicate the number of the seal.

(iv) The imported meat etc. must have been free from any evidence of animal infectious diseases as a result of import inspection conducted by the Ministry of Health of Italy, and must be directly carried into the designated facilities in Italy after the said inspection.

5-(2) The slaughtered cattle were not suspect or confirmed BSE cases, or cohorts of BSE cases, as defined in the Terrestrial Animal Health Code adopted by the World Organization for Animal Health (OIE).

5-(3) The slaughtered cattle were found to be sound and healthy as a result of ante- and post-mortem inspections conducted by veterinary inspectors of the Ministry of Health of Italy in the designated facilities at the time of slaughter.

5-(4) The exported beef to Japan has been handled at the designated facilities in such a way as to prevent contamination with any causative agents of animal infectious diseases until shipment to Japan.

## **6. Audit by the Japanese animal health authorities**

6-(1) The Japanese animal health authorities can evaluate Italy's regulatory system through a representative sample of the designated facilities etc., and may conduct on-site inspections of the designated facilities etc. and examination of the original relevant records etc. as part of a system audit of Italy's regulatory requirements and these animal health requirements.

When it is found that the animal health requirements and Italy's regulatory requirements have not been met at the designated facilities, the Ministry of Health of Italy must immediately stop certification of the exported beef to Japan from the said facilities.

If the Ministry of Health of Italy verifies corrective actions at the said facilities, the Ministry of Health of Italy may re-designate the revoked facilities as the designated facilities after informing the Japanese animal health authorities of the corrective actions verified by the Ministry of Health of Italy.

A system-wide problem such as repeated serious noncompliance may result in the suspension of the animal health requirements.

## **7. Issue of inspection certificate**

7-(1) The Ministry of Health of Italy must be responsible for issuing the inspection certificate for the exported beef to Japan, stating the following items in detail in English, after confirming the exported beef to Japan complies with the animal health requirements;

- (i) Name, activities, address and establishment number of the designated facilities (in case the relevant procedures such as slaughtering and processing were not done at the same designated facility, each of the facilities at which the exported beef to Japan has been dealt with must be described on this certificate.).
- (ii) Date of slaughter.
- (iii) Date, authorities name and place of issue of the inspection certificate, and name and title of signer
- (iv) Identification number of the seal applied to the container ( in case the container is sealed by the official seal approved by the Japanese animal health authorities

in accordance with Article 4-(4)).

(v) Each required condition of Articles 5-(1) to 5-(4).

7-(2) These Animal health requirements for beef and beef offal to be exported to Japan from Italy come into effect from 21 Oct, 2019.

### **Annex 1. Requirements for the designated facilities**

1. Cloven-hoofed animals which can be handled at the designated facilities must be born and raised only in Italy (except for cervid animals epidemiologically related to the outbreak of Chronic wasting disease (CWD), and except for pigs epidemiologically related to the outbreak of African swine fever (ASF) or Classical swine fever (CSF)), or must be directly imported to Italy from the third free countries or the specified countries listed in Annex 2 ( in the case of cloven-hoofed animals other than deer and pigs, in Article 1 or 4 of Annex 2; in the case of deer, in Article 2 of Annex 2; in the case of pigs, in Article 3 of Annex 2) and meet all of the following requirements 1-(1) to (4).

1-(1) The said animals must be born and raised only in the third free countries or the specified countries

1-(2) The said animals must be free from any evidence of animal infectious diseases as a result of export inspection conducted by the animal health authorities of the third free countries or the specified countries.

1-(3) The said animals must be directly imported to Italy from the third free countries without transiting through countries other than the said third countries or the specified countries, and must be accompanied by inspection certificates issued by the government authorities of the third free countries or the specified countries.

1-(4) The said animals must be free from any evidence of animal infectious diseases as a result of import inspection conducted by the Ministry of Health of Italy.

2. The meat etc. which can be handled at the designated facilities must originate from cloven-hoofed animals that were born and raised only in Italy (except for cervid meat and viscera epidemiologically related to the outbreak of Chronic wasting disease (CWD), and except for pig- meat and –viscera epidemiologically related to the outbreak of ASF or CSF), and be handled only at the designated facilities in Italy, or must be directly imported to Italy from the third countries and meet all of the following requirements 2-(1) to (4).

2-(1) The imported meat etc. must be derived from cloven-hoofed animals that were born in the third countries, and raised only in the same third countries above.

2-(2) The imported meat etc. must be derived from cloven-hoofed animals that were free from any evidence of animal infectious diseases as a result of ante- and post-mortem inspections conducted by official veterinarians of the third countries.

2-(3) The imported meat etc. must be directly and legally imported to Italy from the third countries without transiting through countries other than the said third countries and must be accompanied by inspection certificates issued by the government authorities of the third country. Or, the imported meat etc. must be directly and legally imported to Italy from third free countries or the specified countries into a sealed container and must be accompanied by inspection certificates issued by the government authorities of the third free countries or the specified countries that indicate the number of the seal.

2-(4) The imported meat etc. must have been free from any evidence of animal infectious diseases as a result of import inspection conducted by the Ministry of Health of Italy, and must be directly carried into the designated facilities in Italy after the said inspection.

3 In the all process, between production and the shipment, the exported beef to Japan must be completely segregated spatially, and prevented from being contaminated with meat etc. which is not eligible to be exported to Japan from Italy. If the physical segregation is not applied, the production process of the exported beef to Japan is separated temporally from other beef, and conducted cleaning and disinfection properly.

4. The processing facility can be designated as a processing facility for beef exported to Japan, if Annexes 1, 3 and 4 are completely satisfied.

5. If the designated facilities are storage facilities and satisfy the following conditions, they can be designated as storage facilities to handle the exported beef to Japan. In this case the said designated facilities may be used only for the temporary storage of final products until shipment.

5-(1) The exported beef to Japan which is handled in the storage facilities must be completely wrapped and boxed, and must be completely isolated from any meat etc. other than products which is eligible to be exported to Japan.

5-(2) The exported beef to Japan must be handled to prevent cross contamination with any

meat etc. other than products eligible to be exported to Japan.

6. The species, quantities, production areas and date of handling (and, in case of handling animals or meat imported from third countries, the name of the country/zone of origin and date of import) must be recorded on the original records at the designated facilities. The original records must be kept for at least two years at the designated facilities.

7. In case of an outbreak of FMD, Rinderpest, ASF or CSF in a third free country and the specified countries, the Ministry of Health of Italy must immediately suspend the shipment of the exported beef to Japan from all the designated facilities which handle cloven-hoofed animals and their meat etc. (for ASF and CSF, limited to pigs and pig meat) imported from the said third free country and the specified countries and inform the Japanese animal health authorities of the suspension.

The exported beef to Japan that is then en route to Japan may be prohibited from being released into Japan, except for beef that definitely has no epidemiological relation to the outbreak of the said diseases.

The shipping prohibition of the exported beef to Japan described above must be resumed either in case the Japanese animal health authorities has confirmed that the third free countries and the specified countries concerned are free from the said diseases or in case the Ministry of Health of Italy suspended the entrance of cloven-hoofed animals and their meat etc. into the designated facilities from the said third free countries and the specified countries and informed the Japanese animal health authorities of the said prohibition. (In any case, no shipment must be permitted of beef that is epidemiologically related to the outbreak of the said diseases.)

(Onsite inspections conducted by animal quarantine officer of Japan)

8. Animal quarantine officer of Japan is able to make onsite inspections of the designated facilities, etc. and to make investigation of the original records. When the said animal quarantine officer recognises the fact that it does not been met the said animal health requirements, the animal quarantine officer can suspend the importation of the exported meat, etc. from the designated facilities.

**Annex 2. The third free countries etc.**

1. The third free countries in respect of cloven-hoofed animals (excluding pigs, wild boars and deers) and their meat etc.

Update information on the MAFF official website at the following URL:

<http://www.maff.go.jp/aqs/english/news/third-free.html>

2. The third free countries in respect of cervid animals and deer meat (countries or zones approved as free from Rinderpest, FMD and Chronic wasting disease and eligible to export to Japan by the Minister of Agriculture, Forestry and Fisheries of Japan or the Japanese animal health authorities)

Update information on the MAFF official website at the following URL:

<http://www.maff.go.jp/aqs/english/news/third-free.html>

3. The third free countries in respect of pigs and pig meat (countries or zones approved as free from Rinderpest, FMD, African swine fever and Classical swine fever and eligible to export to Japan by the Minister of Agriculture, Forestry and Fisheries of Japan or the Japanese animal health authorities)

Update information on the MAFF official website at the following URL:

<http://www.maff.go.jp/aqs/english/news/third-free.html>

4. The specified countries for export beef and beef offal to Japan other than the third free countries

Update information on the MAFF official website at the following URL:

<http://www.maff.go.jp/aqs/english/news/eligible-bse-country.html>

### **Annex 3. Requirements for the designated facilities by MHLW.**

Article 3, 4, 5 and 6 of “Standards for slaughter of cattle and processing of beef and beef offal eligible for export to Japan – Export Verification Program”

#### **3. Identification and traceability records**

- 3.1 Live cattle shall be domesticated bovine animals (*Bos taurus* or *Bos indicus*) born and raised in Italy or imported to Italy from countries eligible for export beef and beef offal to Japan.
- 3.2 Live cattle shall be individually identified.
- 3.3 Live cattle shall be sent to slaughterhouse with individual document recording the exact date of birth and identification information of each animal.
- 3.4 All carcasses complying with point 4.1 shall be clearly identified with a label reporting the acronym “EJ”, meaning it eligible for export to Japan.
- 3.5 An identification mark allowing the verification that the beef and beef offal for export to Japan complies with point 4.1 is applied on the product at each level of processing.
- 3.6 Records and identification information through the process shall be sufficient to trace:
  - 3.6.1 Beef and beef offal for export to Japan to carcasses;
  - 3.6.2 Individual carcasses to individual animal;
  - 3.6.3 Individual animal to farm records.

#### **4. Specified Products Requirements**

- 4.1 Beef and beef offal for export to Japan shall be derived from cattle that is 30 months of age or less at the time of slaughter.
- 4.2 Beef and beef offal for export to Japan shall be exclusively meat, offal and their products, which the MHLW and DGHFSN recognize as eligible for export to Japan.
- 4.3 Beef and beef offal for export to Japan shall not include any Specified Risk Material (SRM) as defined by the enforced Japanese regulation, that is to say beef and beef offal for export to Japan shall not include any of the following tissues:
  - 4.3.1 Tonsils from all cattle;
  - 4.3.2 Distal ileum (two meters from connection to caecum) from all cattle;
  - 4.3.3 Spinal cord from cattle over 30 months of age;
  - 4.3.4 Head (except for hygienically removed tongues, cheek meat and hide) from cattle over 30 months of age;
  - 4.3.5 Vertebral column (excluding vertebrae of the tail, the spinous and transverse processes of the cervical, lumbar and thoracic vertebrae, the median sacral crest and wings of the

sacrum) from cattle over 30 months of age.

4.4 Beef and beef offal for export to Japan, and the carcasses and cattle from which they are derived should be traceable to production records.

## **5. Processing requirements**

5.1 Beef and beef offal for export to Japan shall be processed using procedures ensuring the compliance of point 4 and integrated into the facility HACCP/SSOP.

5.2 Verification activities for age requirements as described above in point 4.1 must be conducted at the slaughter and processing levels.

5.3 Beef and beef offal for export to Japan shall be processed in a manner to ensure the hygienic removal of the SRM as described above in point 4.3 and to prevent any cross contamination by these SRM.

5.4 The facility HACCP/SSOP shall include internal verification activities that allow to control the specified requirements of this EVP are effectively implemented and met.

## **6. Designated facilities for export to Japan**

6.1 The designated facilities for export beef and beef offal to Japan from Italy shall be facilities (slaughterhouses, cutting plants, processing plants, and cold stores) approved by the DGHFSN following an on-site inspection. The approval of the designated facilities is under the responsibility of the DGHFSN in accordance with the MHLW.

6.2 The designated facilities shall meet the specified products and processing requirements for beef and beef offal for export to Japan from Italy.

6.3 The designated facilities for export to Japan shall be listed by the DGHFSN. The DGHFSN shall provide annually to the MHLW an official listing of the designated facilities for export beef and beef offal to Japan. The DGHFSN will keep the MHLW informed of any amendments as regard additions, delisting and address or activity change at the listed facilities.

6.4 The designated facilities for export beef and beef offal to Japan from Italy are responsible for the compliance with all requirements outlined in this procedure and the Italian and EU regulations.

6.5 All necessary information to verify the enforcement of the EVP by the designated facilities shall be available to the DGHFSN for review.

28/Shouan/445  
2 May, 2016  
(Amendment: 1/Shouan/2918, 21 Oct, 2019)

**Annex 4. Segregation procedure in processing plant by the Ministry of Health of Italy.**

“Segregation procedure in Italian bovine meat processing plant authorized to export to Japan”

