



*Ministero della Salute*

DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA  
DEGLI ALIMENTI E LA NUTRIZIONE  
UFFICIO 2

*Trasmissione elettronica  
N. prot. DGISAN in Docspa/PEC*

Regioni e Province Autonome  
di Trento e Bolzano  
Assessorati alla Salute (Servizi Veterinari)

E p.c.

SEGGEN, Ufficio 3

Consigliere Diplomatico  
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Ambasciata d'Italia a Tokyo  
c.a. Ufficio Economico e Commerciale

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ANMVI-FNOVI

Associazioni di Categoria  
(Settore carni)

Oggetto: Esportazione di carni bovine e prodotti a base di carni bovine dall'Italia verso il Giappone.

Con la presente si informa che, a seguito del favorevole esito delle negoziazioni condotte con le autorità competenti giapponesi dallo scrivente Ministero nonché grazie al contributo dell'Ambasciata d'Italia a Tokyo, le Parti hanno concordato la revisione dei requisiti utili all'esportazione di carni bovine e prodotti a base di carni bovine verso il Giappone.

In allegato alla presente si forniscono i nuovi requisiti di salute animale (AHRs annex 1) alla luce dei quali è stato possibile concordare i nuovi certificati sanitari che sono entrate in vigore a partire dal 21 ottobre 2019:

- "Official health certificate for beef and beef offal intended to be exported to japan from Italy" (Annex2); e
- "Official health certificate for bovine meat products intended to be exported from Italy to Japan" (Annex3).

Si conferma che i vecchi certificati continueranno ad essere ritenuti validi dalle autorità giapponesi solo se la data di emissione non supera il termine del 30 novembre 2019.

Per opportuna informazione si riportano di seguito **i punti che si discostano in maniera significativa rispetto ai requisiti sanitari previsti dai precedenti accordi:**

- La Regione Sardegna è stata inclusa nel territorio italiano riconosciuto dalle autorità giapponesi come origine degli animali eleggibile all'export verso il Giappone;

- L'origine degli animali e delle carni destinate ad essere esportate verso il Giappone comprende, oltre a quella italiana, anche le provenienze da Paesi riconosciuti dalle autorità giapponesi come:

- The third free countries (<http://www.maff.go.jp/aqs/english/news/third-free.html>);
- The specified countries (<http://www.maff.go.jp/aqs/english/news/eligible-bse-country.html>).

In caso di introduzione di materia prima proveniente da un Paese inserito in uno dei suddetti elenchi, similmente a quanto attuato per le esportazioni di prodotti a base di carne suina verso il Giappone, la certificazione finale del prodotto deve contenere in allegato copia della certificazione sanitaria emessa dall'autorità competente del Paese da cui origina la carne nella quale è attestata la relativa eleggibilità all'export verso il Giappone.

- La regola della non presenza nello stabilimento, in ogni fase produttiva, dei prodotti a base di carne bovina destinati all'export Giappone, contemporanea a quella di carni e o prodotti non considerabili eleggibili a tale export (perché non pienamente conformi ai requisiti previsti), è stata superata dall'accettazione della proposta procedura di segregazione che consente di lavorare nello stesso impianto materia prima idonea e non idonea a tale export mantenendo separati i flussi produttivi nel tempo e nello spazio, nonché assicurando appropriata tracciabilità dei prodotti. Le citate procedure di Segregazione (Annex4) sono parte integrante dei nuovi AHRs e pertanto oggetto di controllo ufficiale relativamente all'efficace e conforme applicazione da parte dell'OSA.

Si ricorda invece che per poter esportare verso il Giappone i prodotti in oggetto, è **necessario continuare ad assicurare il rispetto dei seguenti requisiti previsti dagli accordi vigenti.**

#### **a. Gestione dei materiali a rischio BSE**

Le carni e i sottoprodotti destinati all'esportazione verso il Giappone devono derivare da animali di età inferiore ai 30 mesi al momento della macellazione.

Inoltre, è necessario rispettare la normativa Giapponese che classifica come materiale specifico a rischio i seguenti tessuti:

- Tonsille di tutti i bovini;
- L'ileo distale (due metri dalla connessione al cieco) di tutti i bovini;
- Il midollo spinale dei bovini di età superiore ai trenta (30) mesi;
- La testa (con l'esclusione della lingua, carne delle guance e pelle igienicamente rimosse) dei bovini di età superiore ai trenta (30) mesi;
- La colonna vertebrale (escluse le vertebre caudali, le apofisi spinose e i processi trasversi delle vertebre cervicali, lombari e toraciche e la cresta sacrale mediana e le ali del sacro) dei bovini di età superiore ai trenta (30) mesi.

Continuano ad essere necessariamente applicate le procedure adottate dalla statunitense FSIS per la lavorazione delle lingue dei bovini, ossia l'asportazione della lingua deve avvenire mediante un taglio trasversale appena dietro l'ultima papilla vallata.

#### **b. Tracciabilità**

Al fine di permettere l'identificazione delle carcasse bovine idonee all'esportazione in Giappone, alle stesse dovrà essere apposta un'etichetta riportante la dicitura "EJ", acronimo di "Eligible for Japan".

Si raccomanda inoltre che, negli impianti abilitati all'esportazione, le carcasse e i prodotti idonei all'esportazione in Giappone vengano stoccati in apposita area dedicata ed individuata con un cartello "EJ".

### **B. Listing stabilimenti**

Restano invariate le precedenti note DGISAN concernenti le procedure di inserimento in lista degli stabilimenti che intendono esportare carni bovine e prodotti a base di carni bovine dall'Italia verso il Giappone, fatta salva la necessità di corrispondere ai requisiti sanitari contenuti nei presenti AHRs e Certificazioni sanitarie.

Gli stabilimenti già inseriti nella lista, dovranno essere valutati ai sensi dei citati nuovi requisiti al momento della emissione dei nuovi certificati sanitari concordati, nonché nelle successive attività di controllo ufficiale, in particolare quelle utili alla ricertificazione annuale export Paesi Terzi.

Si chiede a codesti Assessorati di voler cortesemente dare massima diffusione rispetto a quanto sopra riportato in particolare informando i Servizi veterinari delle ASL territorialmente competenti, nonché gli operatori interessati.

IL DIRETTORE GENERALE

\*F.to Gaetana Ferri

Allegati:

Annex 1: Animal Health Requirements for beef and beef offal to be exported to Japan from Italy

Annex 2: Official health certificate for beef and beef offal intended to be exported to Japan from Italy

Annex 3: Official health certificate for bovine meat products intended to be exported from Italy to Japan

Annex 4: Segregation procedure in Italian bovine meat processing plant authorized to export to Japan

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## **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 of 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 is 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”



IT Segregation  
procedures bovine r

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

The scope of this document is to describe a procedure that has to be implemented in each stage of the bovine meat product processing in order to prevent any direct or indirect contact of the Italian bovine meat product eligible for the export to Japan with any meat and meat products that do not meet Japanese requirements.

### TRACEABILITY SYSTEM

According to the EU / National legislation, the bovine meat introduced into a processing plant has to be identified.

In the case of export to Japan, the eligible bovine meat comes only from authorized slaughterhouses and the introduction to the authorized processing establishments must be done registering the following information from the relative accompanying pre-export health declaration:

- country of origin;
- slaughterhouse and cutting plant (among those recognised by the Japanese MAFF);
- slaughtering date;
- delivery date of bovine meat to the processing plant;
- number of pre-export health declaration accompanying the bovine meat from the country of origin (a copy will be attached to the health veterinary certificate that will subsequently accompany the processed meat product to Japan);
- quantity of bovine meat introduced.

The local Italian Veterinary Service (Local Health Unit - ASL) supervises all registration activities (keeping registers, how to make registrations, deadlines for registrations) to check the compliance with the requirements specified above.

Each individual consignment<sup>1</sup> of eligible bovine meat introduced into the authorized processing plant is identified in one or more production batches<sup>2</sup>. The production batch labels assigned are maintained throughout all processing stages according to the conditions specified by individual production establishments under the supervision of ASL veterinarians who must check the appropriateness of the solutions applied by the establishments for the correct consignments identification.

In addition to the information kept and recorded for the traceability of the bovine raw material the following data have to be kept and recorded:

- processing start date of bovine meat eligible for export to Japan;
- production batches labels;
- obtained quantity of bovine meat product eligible for export to Japan;
- destination of the bovine meat product to be exported to Japan;
- date of shipment of the bovine meat product to be exported to Japan.
- document in which the establishment must guarantee the compliance with traceability requirements for production batches destined to Japan (so-called pre-shipment review).

The above mentioned informations are verified by the official veterinarian before the issuing of the health certificate that will accompany the product that will be shipped.

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<sup>1</sup> **Consignment** shall mean the quantity of goods accompanied by a health certificate.

<sup>2</sup> **Production batch** shall mean a set of products, transformed, processed, sliced and packed in practically identical circumstances.

## DESCRIPTION OF THE STAGES AND CONDITIONS OF ISOLATION OF THE PROCESSING LINE / SEGREGATION OF PRODUCTS

Every precaution must be taken to prevent any direct or indirect contact during all stages of the bovine meat product processing, handling, packaging with any non-eligible meat or meat products that do not meet Japanese requirements.

The list of goods for which Italy expressed interest and that can be considered eligible for the export to Japan according to the agreed protocol and certificate on bovine meat product includes product as: Cured Bovine Meat Product (Bresaola); Cooked Bovine meat product shelf stable (canned/steril); Preparation of bovine meat product as meat-based sauce or similar shelf stable (canned/steril).

Taking into account the length of the processing of the products, the cured Bovine meat product, Bresaola in particular, can be considered as the more risky product in terms of traceability requirement and possible non-compliance with the segregation condition.

For that reason, in this procedure there is the description of each phase of the Bresaola processing in the framework of the compliance with the segregation requirement. However, the same approach should be considered as equivalent for any other bovine meat product eligible for the export to Japan according to the agreed protocol and certificate.

The management measures to ensure the segregation of the processing of the product eligible for the export to Japan can be categorized as follows:

### TRACEABILITY

Traceability measures (see above) are applied in order to ensure the identification of the product (including raw material) eligible for the export to Japan. Specific records are requested to guarantee the separation /segregation of product eligible from that not eligible for Japan in each phase of the processing.

### DEDICATED AREA

Each processing steps must take place in a dedicated area. When the processing is a storing phase, the dedicated storage area must be delimited and identified with a sign bearing the inscription EJ (Eligible for Japan). When the processing is a working phase, the dedicated working area must be managed with no presence at the same time of meat with different status (not eligible for export to Japan).

### POST SSOP start of the processing phase

The processing phase must take place only after SSOP (Sanitation Standard Operating Procedures) have been performed on the food contact surfaces in order to prevent any possible direct and indirect contact with meat or product with a different status (not eligible for export to Japan)

### Air Cured Bovine Meat Product – Bresaola processing example.

In this paragraph is described each phase of the Bresaola processing.

In Annex 1 is reported the flow chart of the same process with the indication (coloured code) of the measures applied to ensure segregation.

- a) **Intake:** delivery of bovine raw material into the processing plant – traceability have to be ensured according to the measures foreseen by EU/National legislation and following the specifications foreseen in the Traceability paragraph).
- b) **Storage:** the bovine meat is stored maintaining its original packaging. It is adequately identified and kept in a dedicated area separated from meat with a different status (not eligible for export to Japan);

- c) **Cardboard removal:** takes place in a working area where no meat with different status (not eligible for export to Japan) is present at the same time. Start date of bresaola processing is the record kept for verification;
- d) **Defrosting** (if necessary): takes place in a working area where meats not eligible for export to Japan are not present at the same time. This phase must take place only after the SSOP (Sanitation Standard Operating Procedures) have been performed. Start of this processing phase is the record kept for verification. Moreover this phase must be carried out in uniform batches to ensure traceability. Batch number is the record kept for verification;
- e) **Selection / trimmings:** these operations must take place:
- in dedicated premises (processing only bovine meat eligible for export to Japan) **or**:
  - in a working area where meats not eligible for export to Japan are not present at the same time. In this case, this phase must take place only after the SSOP (Sanitation Standard Operating Procedures) have been performed. Start of this processing phase is the record kept for verification ;
- i) **Deep salting / tumbling:** the bovine meat is placed in containers, where ingredients (salt, spices, nitrate) are added, and stored in coolers for a period of about 15 days. The bovine meat may be tumbled to facilitate salt penetration. These operations must take place under conditions designed to avoid any direct or indirect contact with meats and products of different status (not eligible for export to Japan):
- The equipment is dedicated to production eligible for the export to Japan or
  - This phase must take place only after the SSOP (Sanitation Standard Operating Procedures) have been performed.
- Start of this processing phase is the record kept for verification.
- j) **Casing and binding:** the bovine meat is encased in a working area where meats not eligible for export to Japan are not present at the same time. In any case, this phase must take place only after the SSOP (Sanitation Standard Operating Procedures) have been performed. Start of this processing phase is the record kept for verification. Casing shall take place using artificial (cellulose) casing. The product is placed in the net casing and then hung on trolleys adequately identified and kept in a dedicated area separated from meat with a different status (not eligible for export to Japan).
- k) **Drying and seasoning:** these stages shall take place in:
- premises free from meat not eligible for export to Japan, or
  - in a dedicated area separated from meat with a different health-hygiene status (not eligible for export to Japan)
- This processing phase must be carried out in uniform batches to ensure traceability. Batch number is the record kept for verification;

### **Bresaola (whole piece / half pieces)**

All of the subsequent processing stages shall take place in uniform batches to ensure traceability and in compliance with the principle of segregation. Every precaution must be taken to prevent any direct or indirect contact during all stages of handling, slicing and packaging of the eligible bresaola with any non-eligible meat or any meat or animal products that do not meet Japanese requirements:

- In a working area where meats not eligible for export to Japan are not present at the same time

- The equipment is dedicated to production eligible for the export to Japan or
- Take place only after the SSOP (Sanitation Standard Operating Procedures) have been performed.

Start of those processing phase is the record kept for verification

- **Cleaning:** at the end of seasoning, the surface of the product is cleaned under fresh drinking water (not recycled).
- **Drying:** after washing the product, destined for sale as a whole piece or in half pieces or several pieces, it is rapidly dried under hot air.
- **Cutting:** the product may be cut into two or more pieces.
- **Vacuum packing:** sealing the whole bresaola or pieces of the product in appropriate materials ensuring protection and waterproofing with respect to the external environment.

### **Bresaola (sliced product)**

All of the subsequent processing stages shall take place in uniform batches to ensure traceability and in compliance with the principle of segregation. Every precaution must be taken to prevent any direct or indirect contact during all stages of handling, slicing and packaging of the eligible bresaola with any non-eligible meat or any meat or animal products that do not meet Japanese requirements:

- In a working area where meats not eligible for export to Japan are not present at the same time
- The equipment is dedicated to production eligible for the export to Japan or
- Take place only after the SSOP (Sanitation Standard Operating Procedures) have been performed.

Start of those processing phase is the record kept for verification

- **Cleaning:** at the end of seasoning, the surface of the product is cleaned under fresh drinking water (not recycled).
- **Casing removal :** removal of the artificial or collagen casing.
- **Vacuum packing:** sealing the bresaola in appropriate materials ensuring protection and waterproofing with respect to the external environment.
- **Slicing:** The Bresaola is sliced ensuring the isolation of the slicing line for bresaola eligible for export to Japan from that of non-eligible products and subsequent segregation of the relative production batches.
- **Protective atmosphere packaging:** sealing the sliced bresaola in appropriate materials ensuring protection and waterproofing with respect to the external environment. The bresaola destined for the Japanese market will be clearly labelled by marking the package with the packaging date.

If the bresaola to be exported to Japan is sliced in an establishment different from the establishment in which it was produced, the following **additional** procedures must be implemented to ensure the identification and segregation of the bresaola eligible for export to Japan from products with a different status (not eligible for export to Japan). In particular:

- a) Whenever the bresaola is transported from one official establishment to another, it must be accompanied by

- an official transfer health declaration of origin and processing issued in Italian and English by an official veterinarian responsible for the establishment where the bresaola was processed;
  - a copy of the health declaration accompanying the bovine meat from the country of origin to the bresaola production establishment.
- b) The bresaola shall be transported from the production establishment to the slicing / packaging plant in sealed containers, labelled with the identification mark of the establishment and the production batch.
- c) Registrations: the establishment slicing the bresaola to be exported to Japan shall keep a register recording the following information:
- production batch entering to the slicing area
  - date of entry;
  - official transfer declaration details;
  - slicing batch / batches number;
  - production date / dates;
  - quantity sliced;
  - number of packs.

The Italian Veterinary Service (ASL) shall supervise all registration activities (keeping registers, how to make registrations such as filling in new data, deadlines for registrations) to check on compliance with the requirements specified above.

**The following stages shall apply to the product shipped to Japan irrespective of its presentation in a “whole piece”, in “pieces” or in “sliced products” when such operations are carried out in the establishment where the bresaola to be exported to Japan was produced or in another one**

- **Temporary storage:** after packaging, the bresaola shall be stored in a cooler and kept separated from meat with a different status. Packaged bresaola must be labelled (immediate package label) to distinguish it from the bresaola not eligible for export to Japan. Labels of the immediate packaging shall bear the identification mark with the official number of the packaging establishment.
- **Packaging:** The packs of bresaola destined for export to Japan shall be placed in appropriate containers. Labels on the shipping cartons shall bear the identification mark with the official number of the packaging establishment. Awaiting shipment, the bresaola eligible for export to Japan must be placed in a dedicated area to maintain segregation from products not eligible for export to Japan.
- **Shipment and delivery:** the cartons will then be placed in pallets with identification of the country of destination (Japan). Before the shipment the establishment must check that all requirements identified as necessary for export to Japan have been satisfied, filling in a specific form (pre-shipment review).

## CONCLUSION

The above mentioned described segregation procedure will become part of the official controls applied by the Italian competent Authority to verify the Italian establishments authorized for the export of bovine meat products to Japan and complying with the requirements foreseen in the protocol and certificate agreed. In particular this procedure ensure segregation between products destined to the export to Japan with those that are produced for other destinations and do not necessarily comply with all the requirements foreseen for the export to Japan.