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SETTORE PREVENZIONE COLLETTIVA E SANITÀ PUBBLICA  
IL RESPONSABILE  
**GIUSEPPE DIEGOLI**

REG. CFR.FILE.SEGNATURA.XLM

DEL CFR.FILE.SEGNATURA.XLM

Ai Direttori di ASPV  
Aziende UU.SS.LL.  
Regione Emilia-Romagna

Oggetto: Export Giappone – riapertura del mercato

Si trasmette in allegato la nota del Ministero della Salute prot. 0020815-17/05/2023-DGISAN-MDS-P avente per oggetto *“riapertura del mercato giapponese alle esportazioni di prodotti a base di carne suina cotti - modalità di presentazione delle manifestazioni di interesse da parte degli stabilimenti”*.

Le manifestazioni di interesse devono pervenire al Ministero della Salute entro il 5 giugno all'indirizzo pec indicato nella nota e per conoscenza allo scrivente Settore.

Cordiali saluti.

Giuseppe Diegoli  
(firmato digitalmente)

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*Ministero della Salute*

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

0020815-17/05/2023-DGISAN-MDS-P

N° prot.

Servizi Veterinari  
Regioni e Province Autonome

E p. c.

Associazioni di categoria  
(settore carni)  
Loro Sedi

**Oggetto: riapertura del mercato giapponese alle esportazioni di prodotti a base di carne suina cotti - modalità di presentazione delle manifestazioni di interesse da parte degli stabilimenti.**

Come noto, a seguito del riscontro di focolai di peste suina africana (PSA) nell'Italia continentale, il Giappone ha imposto il bando alle esportazioni dall'Italia di carni e prodotti a base di carne suina, a prescindere dall'origine delle carni dalle quali sono ottenuti questi ultimi, determinando di fatto la decadenza di tutte le autorizzazioni all'esportazione già in possesso degli stabilimenti.

Dopo intense trattative, le Autorità del Giappone (MAFF) hanno accettato di rimuovere il bando per quanto riguarda i prodotti di carne suina cotti ottenuti dalle carni di animali nati e allevati in zone non soggette a restrizioni per la PSA e riconosciuti esenti da sintomi di malattie infettive alla visita ante- e all'ispezione post-mortem.

In base all'accordo devono essere autorizzati gli stabilimenti di trasformazione che effettuano il trattamento termico dei prodotti a base di carne suina (designated heat-processing facilities). Resta in capo all'autorità centrale Italiana il riconoscimento (approved by the government of the exporting country) degli impianti che eseguono le fasi precedenti al trattamento termico (macellazione, sezionamento e/o eventuale trasformazione precedente al trattamento termico).

Si conferma pertanto che l'autorizzazione all'esportazione verrà rilasciata esclusivamente dalle Autorità del MAFF giapponese, ai soli stabilimenti che effettuano il trattamento termico del prodotto a base di carne suina (designated heat-processing facilities).

Sulla base di quanto sopra esplicitato, tutti gli stabilimenti in possesso dei requisiti previsti dalla normativa comunitaria e che **non hanno adottato un Sistema di gestione per la sicurezza alimentare (FSMS) semplificato** secondo i principi di flessibilità di cui alla [COMUNICAZIONE DELLA COMMISSIONE \(2022/C 355/01\)](#), potranno fornire le carni e i semilavorati agli stabilimenti che saranno autorizzati (designated heat-processing facilities), purché siano rispettati i requisiti di salute animale richiamati nell'accordo sanitario (Animal Health Requirements e Certificato Sanitario – Allegato 1).

L'autorizzazione del MAFF farà seguito ad un'ispezione in loco da parte di ispettori giapponesi le cui spese (trasporto, soggiorno, diaria degli ispettori, interpretariato) sono a totale carico degli stabilimenti che

manifesteranno interesse e non sarà dovuta la tariffa prevista dal D.lvo 32/21 per le autorizzazioni di competenza del Ministero della Salute.

Gli stabilimenti interessati all'autorizzazione del MAFF, in accordo con le procedure previste dalle autorità giapponesi dovranno compilare un "application form" (Allegato 2) nel quale si dà riscontro alla sussistenza dei requisiti sanitari richiesti previa verifica dell'autorità competente. Per la compilazione dell'application e per le relative verifiche effettuate dai servizi veterinari locali sono state predisposte Linee guida utili a valutare il livello di conformità (Allegato 3)

Detta procedura risponde alle modalità già previste dalla nota n. 23661 del 04/06/2018 e consentirà al Ministero della Salute di inviare alla controparte l'elenco degli stabilimenti designabili.

Pertanto, sulla base di quanto sopra, la procedura per l'individuazione della lista di stabilimenti interessati alle ispezioni autorizzative del MAFF sarà costituita secondo le seguenti azioni:

- Le aziende interessate compilano ed inviano al Servizio Veterinari territorialmente competente il questionario appositamente predisposto dalle autorità Giapponesi (Allegato 2 Application form) debitamente compilato per la corrispondenza degli specifici requisiti gestionali e strutturali tenendo conto delle Linee guida per la compilazione (Allegato3)
- il Servizio Veterinario territorialmente competente provvede alla verifica di quanto attestato dallo stabilimento tenendo conto delle Linee guida di cui all'allegato 3 e redigerà il pertinente verbale del controllo ufficiale che deve essere trasmesso al Ministero della Salute unitamente alla restante documentazione sopra citata.
- Le manifestazioni di interesse, che dovranno pervenire all'indirizzo PEC: [dgsan@postacert.sanita.it](mailto:dgsan@postacert.sanita.it) entro il 5 giugno, verranno raccolte e trasmesse al MAFF tenendo conto dei seguenti criteri di priorità:
  - livello di corrispondenza ai criteri strutturali e gestionali richiesti dalle autorità Giapponesi
  - ordine cronologico di arrivo dell'istanza (data e ora del protocollo DGISAN in ingresso)

Detti criteri sono necessari a perseguire gli obiettivi d'interesse di sistema in un rapporto non facile di comunicazione con la controparte e pertanto saranno applicati per la costruzione dell'elenco con ordine di priorità per l'organizzazione da parte giapponese delle missioni necessarie all'effettuazione delle visite autorizzative.

Tenendo conto del numero complessivo di domande raccolte si tenterà, inoltre, di concordare con la controparte le opzioni più opportune per l'espletamento logistico delle visite autorizzative.

IL DIRETTORE GENERALE  
Ugo Della Marta

#### **Allegati**

Allegato 1: Animal Health Requirements e Certificato Sanitario

Allegato 2: Application form

Allegato 3: Linee guida per la compilazione dell'application form

Referente e responsabile procedimento:

Nicola Santini: [n.santini@sanita.it](mailto:n.santini@sanita.it)

# **Animal Health Requirements for heat-processed meat and meat products derived from pigs to be exported from Italy to Japan**

Ref.No.5/shouan/831

May 10 2023

The animal health requirements for heat-processed meat and meat products derived from pigs to be exported from Italy to Japan are as follows.

## **1. Definitions**

In this document, the following definitions apply:

**(1) “pigs”**

Domestic animals of the Suidae family (limited to those which are kept under human’s supervision since birth)

**(2) “meat and meat products”**

Means meat, fat and viscera derived from pigs and meat products made from the said meat and viscera as raw materials such as sausages, ham and bacon etc.

**(3) “heat-process(ing)”**

Meat, previously deboned, and meat products derived from pigs are subjected to heat-process that results in a core temperature of at least 70 degrees Celsius for a minimum of 30 minutes.

**(4) “exporting country”**

Italy

**(5) “The animal health authorities of exporting country”**

Ministry of Health of the Italian Government

**(6) “Japanese animal health authorities”**

Animal Health Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of the Japanese Government

## **2. Requirements for raw material**

2.1. The heat-processed meat and meat products to be exported to Japan must fulfill the following requirements:

(1) In case the heat-processed meat and meat products to be exported to Japan are derived from pigs born and raised in the exporting country:

(a) the pigs were born and raised only in the exporting country;

(b) the pigs have been confirmed to be free from any animal infectious diseases as a result of ante- and post-mortem inspections conducted by official inspectors of the government of the exporting country at the slaughter facilities specified in the item 3.1.

- (2) In case the heat-processed meat and meat products to be exported to Japan are derived from pigs imported from the third countries:
- (a) the pigs were born and raised only in the third countries
  - (b) the pigs were directly imported to the exporting country from the third countries or the said pigs were kept isolated from other animals and were not mix-loaded during the transportation;
  - (c) the pigs were free from any animal infectious diseases as a result of import inspection conducted by the animal health authorities of the exporting country
  - (d) the pigs are free from any animal infectious diseases as a result of ante- and post-mortem inspections conducted by official inspectors of the government of the exporting country at the slaughter facilities specified in the item 3.1.
- (3) In case the heat-processed meat and meat products derived from pigs to be exported to Japan have been originated from meat and meat products imported from the third countries:
- (a) the pigs for the production of heat-processed meat and meat products to be exported to Japan were born and raised only in the third countries;
  - (b) the meat and meat products derived from pigs for the production of heat-processed meat and meat products to be exported to Japan were directly imported to the exporting country from the third countries or the said meat were packed in safe and sanitary boxes such as cardboard boxes and then put in a closed container which are not opened during the transportation.;
  - (c) the meat and meat products derived from pigs for the production of the heat-processed meat and meat products to be exported to Japan were free from any evidence of animal infectious diseases as a result of import inspection conducted by the animal health authorities of the exporting country, and after the said inspection, the meat and meat products were directly transported to the approved processing facility specified in item 3.2. or designated heat-processing facilities specified in item 3.3.

2.2 In case natural casings are used for the heat-processed meat and meat products derived from pigs to be exported to Japan, the products must meet the additional animal health requirements stipulated in Annex 3.

### **3. Requirements for facilities**

- 3.1. The slaughter facilities where the pigs for heat-processed meat and meat products to be exported to Japan are slaughtered must be approved by the government of the exporting country (hereinafter referred to as "the approved slaughter facilities").
- 3.2. The processing facilities where the meat and meat products derived from pigs for heat-processed meat and meat products to be exported to Japan are processed such as cutting and curing and stored

before the heat-processing must be approved by the government of the exporting country (hereinafter referred to as "the approved processing facilities").

3.3. Upon the application by the animal health authorities of the exporting country, the Japanese animal health authorities assess the application and designate the heat-processing facilities that meet the standards defined in Annex 1 (hereinafter referred to as "designation standard") for a period of 2 years in principle as the facilities eligible for exporting meat and meat products to Japan (hereinafter referred to as "designated heat-processing facilities").

3.4. The animal health authorities of the exporting country may apply for the extension of the designation period of designated heat-processing facilities to the Japanese animal health authorities. Upon the application, the Japanese animal health authorities will extend the designation period of the designated heat-processing facilities for another two years if the Japanese animal health authorities can confirm that the said facilities meet the designation standard by examining the results stipulated in item 3.11. and by conducting on-site inspections stipulated in item 3.6. as necessary. (This two-year extension may be repeated by the same procedure.)

3.5. The documents which include the following information in English or Japanese language must be submitted by the animal health authorities of the exporting country to the Japanese animal health authorities for the application described in item 3.3.

- (1) Name, address and registration number of the facility
- (2) Size of the facility (i.e. ground-floor area, total-floor area)
- (3) Number of workers and organization chart of the facility
- (4) Description of meat and meat products handling in the facility (including heat-processed meat and meat products derived from pigs to be exported to Japan).
  - (a) Species of animal, country of origin
  - (b) Production process including heating method, heating temperature, heating time
  - (c) How to measure the core temperature of meat and meat products derived from pigs in heat-processing
- (5) Description of structure of the facility
  - (a) Building map which shows the structure of pre-heating area and post-heating area
  - (b) Layout of major devices and equipment including heat-processing equipment
  - (c) Photographs of physical barrier (e.g. dividing walls) between pre-heating area and post-heating area
  - (d) Photographs of attachment point between heat-processing equipment and physical barrier (e.g. dividing walls)
  - (e) Kind of heat-processing equipment (e.g. batch-type steamer, tunnel-type fryer)
- (6) 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 flow
  - (e) Traffic line of workers
  - (7) List of Standard Operation Procedures (SOP)
  - (8) Map of neighborhood of the facility
  - (9) Other information that the Japanese animal health authorities consider necessary
- 3.6. The Japanese animal health authorities conduct on-site inspections of the facilities at the expense of the exporting country to confirm whether they meet the designation standard, in response to the application of item 3.5.
- 3.7. When the designated heat-processing facilities have a plan of alteration of the facility including reconstruction, enlargement (expansion) and / or other changes of the structure related to the designation standards stipulated in Annex 1, the animal health authorities of the exporting country must apply in advance to the Japanese animal health authorities for approval for such alteration according to Annex 2.
- 3.8. The animal health authorities of the exporting country must notify immediately to the Japanese animal health authorities of change in the registration number, name or address of the designated heat-processing facilities or the fact that the facilities no longer produce the heat-processed meat and meat products derived from pigs to be exported to Japan.
- 3.9. The managers of the designated heat-processing facilities must confirm the relevant preventive measures against the occurrence of sanitary hazard to ensure the appropriate treatment in the heat-processing procedure at least once per month. The results of the verification activities must be maintained in a written form for at least two years.
- 3.10. The managers of the designated heat-processing facilities must record the following information and keep them for at least 2 years. The relevant documents can be kept in an electronic form on condition that measures to prevent falsification and manipulation are taken and backup files are secured;
- (1) Date of heat processing and heating condition
  - (2) Country of origin (in case meat and meat products imported from the third countries, also include the name of the third countries), quantity of each heat-processed meat and meat products derived from pigs with the appropriate records on the heat-processing
  - (3) Shipping date, quantity and destination

- 3.11. The animal health authorities of the exporting country must visit the designated heat-processing facilities at least once every six month and verify whether the facilities maintain compliance with the requirements of the designation standard and the animal health requirements of this document, and keep written records of the results of each visit for two years. The relevant documents may be kept in an electronic form on condition that measures to prevent falsification and manipulation are taken and backup files are secured.
- 3.12. If the animal health authorities of the exporting country find that a designated heat-processing facility does not meet the designation standard or the animal health requirements of this document, the animal health authorities of the exporting country must immediately suspend all exports of the heat-processed meat and meat products derived from pigs from the facilities concerned and provide the Japanese animal health authorities with relevant information of the case without undue delay.
- 3.13. In the case of a suspension under item 3.12, if appropriate corrective actions have been taken for the concerned designated heat-processing facility, the animal health authorities of the exporting country must report the relevant information, and upon request, the copy of the written record of the result of the visit to the Japanese animal health authorities and resume the exports from the facility with the permission of the Japanese animal health authorities.
- 3.14. The Japanese animal health authorities may conduct on-site inspections of the designated heat-processing facilities when deemed necessary to confirm whether the facilities meet the designation standard and the animal health requirements of this document.
- 3.15. In any of the following cases, the Japanese animal health authorities may revoke the designation of facilities and immediately suspend the import of heat-processed meat and meat products derived from pigs produced from such facilities.
- (1) When the designated heat-processing facilities do not meet the designation standards.
  - (2) When it is found that the designated heat-processing facilities were designated through a fraudulent or illicit means.
  - (3) When it is found that the designated heat-processing facilities has committed a wrongful or unfaithful act in relation to the operation of the designated heat-processing facilities.
  - (4) When the designated heat-processing facilities do not comply with an order of the Japanese animal health authorities relevant to corrective measures against violations without any justifiable reasons.
  - (5) When the designated heat-processing facilities do not export heat-processed meat and meat products derived from pigs to Japan for more than two years since the designation without any justifiable reasons.

- (6) When the designated heat-processing facilities are found to be in violation of the animal health requirements and such violation has caused or are likely to cause severe harm to animal health.

#### **4. Others**

- 4.1. The animal health authorities of the exporting country must ensure that heat-processed meat and meat products are packed in safe and sanitary materials at the designated heat-processing facility, and the packed products are contained in clean boxes with the name and the registration number of the designated heat-processing facility on the surface of the boxes, and the boxes are not opened prior to shipment.
- 4.2. The animal health authorities of the exporting country must ensure that heat-processed meat and meat products are stored and handled in a way to prevent contamination with pathogens of any animal infectious diseases at the designated heat-processing facility prior to shipment.
- 4.3. In case the heat-processed meat and meat products derived from pigs to be exported to Japan are transported to Japan through other countries, The said products must fulfill the following requirements:
- (1) the heat-processed meat and meat products derived from pigs to be exported to Japan must be packed in a closed container.
  - (2) the container must be sealed by the animal health authorities of the exporting country.
  - (3) The seal must be differentiated from that of other countries by a unique number which is recorded on the inspection certificate accompanying the consignment to enable cross-check upon arrival in Japan.
- 4.4. If the seal specified in item 4.3. is found to have been intentionally broken or removed etc. at the time of inspection after arrival in Japan, the exported heat-processed meat and meat products derived from pigs may be prohibited to be imported into Japan.

#### **5. Issue of inspection certificate**

- 5.1. The animal health authorities of the exporting country must issue inspection certificates for heat-processed meat and meat products derived from pigs to be exported to Japan, stating the following information in detail in English:
- (1) Compliance with each requirement of items 2.1, 3.1., 3.2., 4.1., and 4.2.
  - (2) Name, address and approved numbers of the approved slaughter facilities, and approved processing facilities.
  - (3) Name, address and registration numbers of the designated heat-processing facilities.
  - (4) Country of origin
  - (5) Date of slaughter, processing, heat-processing and condition of heat-process.

- (6) Method of heat-processing
- (7) Identification number of the seal of the container (for shipments through third countries).
- (8) Date and name of the port of shipment.
- (9) Date and place of issuance of the inspection certificate, and name and title of the signer.

**Designation Standard**

1. The designated facilities must handle only meat and meat products derived from pigs and the said meat and meat products must be processed in accordance with the relevant requirement described in this document.
2. The designated heat-processing facilities must have pre-heating area which is exclusively for raw materials and furnished with necessary equipment dedicated for process before heat-processing, and post-heating area which is exclusively for handling products after heat-processing (hereinafter heat-processed products) and furnished with necessary equipment dedicated for process after heat-processing.
3. The post-heating area must be isolated from the pre-heating area except for penetration structure of heat-processing equipment.
4. The pre-heating area must have facilities for storage, processing and inspection.
5. The post-heating area must be walled off from other area and once the products enter the post-heating area through the heat-processing equipment, they must not be brought to the outside of the post-heating area until they are packed in containers and loaded onto vehicles for shipment in order to prevent the recontamination. To this end, post-heating area must be furnished with equipment necessary for process after heat-processing such as cooling, inspection, packing and storage. In addition, post-heating area must have instruments or devices for inspection such as temperature recorders and equipment for cooling, packing and storage.
6. The pre-heating area and post-heating area must have dedicated workers to each area and the traffic line of the workers of pre- and post-heating areas must be completely separated. To this end, the pre-heating area and the post-heating area must have separate facilities for workers in each area, such as entrance, exit, locker room etc., in order to prevent cross-contamination.
7. Floors, walls and ceilings must be smooth and easy to clean; floors must be made of impermeable material, sloped properly, provided with appropriate drainage system and be readily disinfected.
8. The designated heat-processing facilities must have facilities for decontamination as well as water supply for cleaning.

9. The designated heat-processing facilities must have relevant Standard Operating Procedures (SOP) in place to prevent occurrence of sanitary hazards and to ensure an appropriate quality management throughout the entire process of the production.
10. Qualified staff who can supervise compliance with the procedures described in item 9 must be stationed in the designated heat-processing facilities.

**The approval procedures for the alterations  
of the designated heat-processing facilities**

1. If the designated heat-processing facilities intend to make “alterations”, the animal health authorities of the exporting country must submit the detailed information of the alteration plan including construction period to the Japanese animal health authorities at least one month before starting the construction, and obtain approval from the Japanese animal health authorities.
2. The “alteration” means that reconstruction, enlargement and/or other changes of the designated heat-processing facilities which concern the designation standard. Some of the examples of “alteration” are shown below. Even the case where temporary changes related to the designation standard are made during the alteration, process are subject to this annex.  
[Reconstruction]
  - (1) A reconstruction concerning the heat-processing equipment (increase or decrease in the number of equipment, the method of heat-processing etc.)
  - (2) A reconstruction concerning the separation between the pre-heating area and post- heating area
  - (3) A reconstruction of the inner wall (except for the wall that separate the pre-heating area and post-heating area) that is accompanied by a change of the traffic line of the workers, raw materials or products
  - (4) A reconstruction concerning the outer wall
  - (5) A reconstruction accompanied by the change in the intended use of areas in the designated heat-processing facility  
[Enlargement]
  - (1) An enlargement which involves a construction which is not independent from the designated area.
  - (2) An enlargement which involves a construction which shares a registration number, name, address etc., of designated heat-processing facility.
3. The animal health authorities of the exporting country must suspend the exportation of the heat-processed meat and meat products derived from pigs which were produced in the designated heat-processing facilities (or a part of the facilities) after the start of the construction for the alterations.
4. When the construction for alterations is finished, the animal health authorities of the exporting country must submit a completion report that includes the actual construction period, floor layout and photos of the alteration area to the Japanese animal health authorities. After receiving the report the Japanese animal health authorities may conduct an on-site inspection for the designated heat-processing

facilities at the expense of the exporting country. Based on the assessment of the on-site inspection and/or the submitted report, the Japanese animal health authorities allow the designated heat-processing facilities (or a part of the facilities) to produce the heat-processed meat and meat products derived from pigs to be exported to Japan.

**Additional animal health requirements for meat products using natural casings  
to be exported from Italy to Japan**

**In case the casings are derived from cattle, sheep and goat;**

1. The natural casings are derived from animal which was born and raised in the countries other than the countries listed in the link below.

<https://www.maff.go.jp/aqs/english/news/bse.html>

2. In case the natural casings for the production of meat products to be exported are originated in the EU, it has to be confirmed that the natural casings are derived from animals which were free from any animal infectious diseases as a consequence of ante- and post-mortem inspections conducted and/or supervised by official inspectors of national government of EU member states.

In case the casings for the production of meat products to be exported are imported from outside the EU, the natural casings must have been free from any evidence of animal infectious diseases as a result of import inspection conducted and/or supervised by the official inspectors of national government of EU member states or confirmation of the health certificates issued by the originating government.

3. The natural casings have been handled only at the facilities approved (hereinafter referred to as “approved casing facilities”) by the national government of the exporting country as the ones which handle only casings prescribed in item 1 and 2. (In case the casings are imported from the third countries, this provision must apply to the casing facilities in the exporting countries.)
4. The animal health authorities of the exporting country must inform the Japanese animal health authorities of the name, address, approval number of the approved natural casing facilities in advance.
5. The animal health authorities of the exporting country must issue health certificates for the meat products using casing to be exported to Japan, stating the following items in English:
  - (1) Item 1 and 2
  - (2) The kind of casings (natural), country of origin (the name of the country where animals from which casings are derived were born and raised in) and animal species of origin
  - (3) Name, address and approval number of approved natural casing facilities

**In case the casings are derived from pig;**

1. In case the natural casings for the production of exported meat products are originated in the EU, it has to be confirmed that the natural casings are derived from animals which were free from any animal infectious diseases as a consequence of ante- and post-mortem inspections conducted by official inspectors of national government of EU member states. In case the natural casings for the production of exported meat products are imported from outside the EU, the natural casings must have been free from any evidence of animal infectious diseases as a result of import inspection conducted by the official inspectors of national government of EU member states or confirmation of the health certificates issued by the originating government.
2. The natural casings have been handled only at the facilities approved (hereinafter referred to as “approved natural casing facilities”) by the animal health authorities of the exporting country as the ones which handle only natural casings described in items 1 and 2. (In case of the natural casings imported from the third countries, this provision must apply to the casing facilities in the exporting countries.)
3. The animal health authorities of the exporting country must inform the Japanese animal health authorities of the name, address, approval number of the approved natural casing facilities in advance.
4. The animal health authorities of the exporting country must issue health certificates for the exported meat products using casing to Japan, stating the following items in English:
  - (1) Item 1 and 2
  - (2) The kind of casings (natural), country of origin (the name of the country where animals from which casings are derived were born and raised in)
  - (3) Name, address and approval number of approved natural casing facilities

# イタリアから日本国向けに輸出される加熱処理豚肉等の家畜衛生条件（仮訳）

5 消安 8 3 1 号

令和 5 年 5 月 10 日

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イタリアから日本国向けに輸出される加熱処理豚肉等の家畜衛生条件は以下によることとする。

## 1. 定義

本条件の適用において、以下の通り定義する。

### (1) 豚

イノシシ科の家畜（生後、人の監視下で飼養されたものに限る）

### (2) 豚肉等

豚由来の肉、脂肪及び臓器並びにそれらを原料とするソーセージ、ハム及びベーコン等の肉加工品。

### (3) 加熱処理

事前に脱骨された豚肉等は中心温度を30分以上摂氏70℃以上になるような加熱処理を受ける

### (4) 輸出国

イタリア

### (5) 輸出国の家畜衛生当局

イタリア保健省

### (6) 日本国の家畜衛生当局

日本国農林水産省消費・安全局動物衛生課

## 2. 原料に供される豚の条件

2.1. 日本国に輸出される加熱処理豚肉等については、次に掲げる条件を満たすものでなければならない。

(1) 日本国に輸出される加熱処理豚肉等が輸出国で出生しかつ飼養された豚に由来する場合

(a) 輸出国で出生し、かつ、飼養されたものであること。

(b) 3.1で規定すると畜施設において、輸出国の政府機関の検査官が行うと殺の前後の検査により、家畜の伝染性疾病に感染しているおそれのないことが確認されたものであること。

(2) 日本国に輸出される加熱処理豚肉等が第三国から輸入された豚に由来する場合

(a) 第三国において出生し、かつ、飼養されたものであること。

(b) 第三国から直接輸出国へ輸入されたものであること、または第三国から輸出国までの輸送中、他の動物と接触及び混載されないこと。

(c) 輸出国の家畜衛生当局の検査官が行う輸入検査により、家畜の伝染性疾病に感染しているおそれのないことが確認されたものであること。

(d) 3.1で規定すると畜施設において、輸出国の政府機関の検査官が行うと殺の前後の検査により、家畜の伝染性疾病に感染しているおそれのないことが確認されたものであること。

(3) 日本国に輸出される加熱処理豚肉等が第三国から輸入された豚肉等に由来する場合

(a) 第三国で出生、かつ、飼養されていた豚に由来するものであること。

(b) 第三国から直接輸出国へ輸入されたものであること。又は当該豚肉が安全で衛生的なダンボール等に梱包され、輸送中開かれることのないコンテナに詰められていたこと。

(c) 輸出国の家畜衛生当局の検査官が行う輸入検査により、家畜の伝染性疾病に感染しているおそれのないことが確認されたものであり、かつ、輸入検査の後、直ちに3.2で規定する認定加工施設又は3.3で規定する指定加熱処理施設に搬入されたものであること。

2.2 日本国に輸出される加熱処理豚肉等に天然ケーシングを使用する場合には、別添3に規定する追加の家畜衛生条件を満たす必要がある。

### 3. 施設の要件

3.1. 日本国に輸出される加熱処理豚肉等の原料に供される豚をと殺する施設は、輸出国の政府機関の認定を受けた施設（以下「認定食肉処理施設」という。）でなければならない。

3.2. 日本国に輸出される加熱処理豚肉等の原料に供される豚肉等を加熱処理前加工（カッティング、キューリングなど）及び保管する施設は輸出国政府機関の認定を受けた施設（以下「認定加工施設」という。）でなければならない。

3.3. 日本国に輸出するための加熱処理豚肉等について、加熱処理を行うことのできる施設（以下「指定加熱処理施設」という。）は、日本国農林水産大臣の定める別添1の基準（以下「指定基準」という。）に適合するものとして、輸出国の家畜衛生当局の申請により、日本国の家畜衛生当局は原則的に2年間に限り指定するものとする。

3.4. 輸出国の家畜衛生当局は、日本国の家畜衛生当局に対し、指定加熱処理施設の指定期間の延長を申請することができる。申請後、日本国の家畜衛生当局は、3.11.に規定する審査及び必要に応じて3.6.に規定する立入検査を行い、当該施設が指定基準を満たしていることを確認できた場合、当該指定加熱処理施設の指定期間をさらに2年間延長する。（この2年間の延長は、同様の手順で繰り返し行われる。）

3.5. 3.3の申請には、輸出国の家畜衛生当局から日本国の家畜衛生当局に、英語又は日本語で次の事項を記載した書類を提出する必要がある。

- (1) 施設の名称、住所及び施設番号
- (2) 施設の規模（敷地面積、延床面積など）
- (3) 施設の作業人数および組織図
- (4) 施設で取り扱う食肉等（日本に輸出される加熱処理豚肉等）の概要
  - (a) 動物の種類、原産国
  - (b) 加熱方法、加熱温度、加熱時間などの製造工程
  - (c) 加熱処理中の豚肉等の中心温度を測定する方法
- (5) 施設の構造の概要
  - (a) 加熱処理前部門及び加熱処理後部門の構造等を示した図面
  - (b) 加熱処理設備を含む主要設備の配置図
  - (c) 加熱処理前部門と加熱処理後部門の隔離状況（隔壁等）を示した写真
  - (d) 加熱処理設備と隔壁が接している箇所の写真
  - (e) 加熱処理設備の種類（バッチ式スチーマー、連続式フライヤー等）
- (6) 加熱処理施設における動線の概要
  - (a) 原料搬入口から製品搬出口までの豚肉等の動線
  - (b) 加熱処理施設における廃棄物及び排水の動線
  - (c) 加熱処理施設における給水の動線
  - (d) 加熱処理施設における空気の動線
  - (e) 加熱処理施設における作業者の動線
- (7) 加熱処理施設において備えられている標準作業手順書の一覧
- (8) 加熱処理施設の周辺の地図
- (9) その他日本国の家畜衛生当局が必要と認める事項

3.6. 日本国の家畜衛生当局は、3.5の申請があったときは、当該施設が指定基準に適合しているかについて確認するため、輸出国の経費負担により当該施設の立入検査を行う。

3.7. 輸出国の家畜衛生当局は、指定施設の改築または増築及びその他別添1に記載される指定基準に係る部分についての変更（以下「改築等」という）が必要な場合には、事前に日本国の家畜衛生当局に申請し、許可を受けなければならない。事前手続きの方法については別添2のとおりとする。

3.8. 輸出国の家畜衛生当局は、指定加熱処理施設の名称又は所在地名または施設番号に変更がある場合、並びに日本向け輸出加熱処理肉等の生産施設として使用されなくなった場合には、速やかに日本国の家畜衛生当局に通知すること。

- 3.9. 指定加熱処理施設の管理者は、豚肉等の加熱処理の工程において、衛生上の危害の発生の防止と適正な品質が確保されていることを少なくとも一月ごとに確認し、その結果を文書で少なくとも2年間保管しなければならない。
- 3.10. 指定加熱処理施設の管理者は、次に掲げる事項を記録原簿に記録するとともに、当該記録原簿を少なくとも2年間保管しておかなければならない。なお、改ざんや操作を防止するための措置を講じ、バックアップファイルを確保することを条件に、当該書類を電子媒体で保管することができる；
- (1) 加熱処理をした年月日
  - (2) 加熱処理豚肉等の種類別の原産国（第三国から輸入されたものを取り扱う場合に当たっては、第三国の名称）、数量及びその加熱記録
  - (3) 出荷年月日及び輸出相手先別の出荷数量
- 3.11. 輸出国の家畜衛生当局は、少なくとも半年ごとに指定加熱処理施設の巡回を行い、指定加熱処理施設について、指定基準に適合していること、その他この文書に定める家畜衛生条件が遵守されていることについて確認し、巡回の結果を2年間文書で保管するものとする。なお、改ざんや操作を防止するための措置を講じ、バックアップファイルを確保することを条件に、当該書類を電子媒体で保管することができる。
- 3.12. 輸出国の家畜衛生当局は、巡回の結果、当該指定加熱処理施設について、指定基準に適合していないこと、その他この文書に定める家畜衛生条件が遵守されていないと認める場合には、直ちに加熱処理豚肉等の輸出を停止するとともに、速やかにその旨を日本国の家畜衛生当局に報告するものとする。
- 3.13. 3.12に基づき指定加熱処理施設が停止された場合、輸出国の家畜衛生当局は、日本国の家畜衛生当局に関連情報及び必要に応じて行う調査結果の記録の写しを報告し、当該施設で適切な是正措置が講じられていることを示すことで、日本国の家畜衛生当局の許可を得て当該施設からの輸出を再開することができる。
- 3.14. 日本国の家畜衛生当局は、必要に応じて指定加熱処理施設の立入検査を行い、指定加熱処理施設について、指定基準に適合していること、その他この文書に規定する家畜衛生条件が遵守されていることについて確認することができる。
- 3.15. 次のいずれかに該当する場合、日本国の家畜衛生当局は、施設の指定を取り消し、当該施設から生産された加熱処理豚肉等の輸入を直ちに停止することができる。
- (1) 指定加熱処理施設が指定基準に適合していないとき。
  - (2) 指定加熱処理施設が不正又は違法な手段により指定されたことが判明したとき。

- (3) 指定加熱処理施設の運営に関し、不正又は不誠実な行為があったことが判明したとき。
- (4) 指定加熱処理施設が、正当な理由なく違反行為に対する是正措置に係る日本国の家畜衛生当局の命令に従わないとき。
- (5) 指定加熱処理施設が、正当な理由なく、指定後2年以上、加熱処理された豚肉等を日本に輸出しないとき。
- (6) 指定加熱処理施設が動物衛生要件に違反し、その違反が動物の健康に重大な被害を及ぼす、又は及ぼすおそれがあることが判明したとき。

#### **4. Others**

- 4.1. 輸出国の家畜衛生当局は、指定加熱処理施設において、加熱処理された豚肉等が安全かつ衛生的な材料で包装され、包装された製品が、指定加熱処理施設の名称および施設番号を表面に記載した清潔な箱に梱包され、出荷前まで開封されないことを保証する必要がある。
- 4.2. 輸出国の家畜衛生当局は、指定加熱処理施設において、加熱処理された豚肉等があらゆる家畜伝染病の病原体による汚染を防止するよう、その出荷前まで保管され取り扱われることを保証する必要がある。
- 4.3. 日本国に輸出される加熱処理豚肉等が第三国を経由して輸送される場合には、次に掲げる要件を満たすものでなければならない。
  - (1) 日本国に輸出される加熱処理豚肉等は、密封式コンテナに収容されること
  - (2) 当該コンテナは、輸出国により封印されること
  - (3) 日本に到着したときに照合できるよう、荷物に添付される検査証明書に記録のある固有番号によって、他国のものと区別された封印であること
- 4.4. 4.3.に定める封印が、日本到着後の検査時に故意に破られ、又は除去されていること等が判明した場合、輸出された加熱処理豚肉等は、日本への輸入が禁止される場合がある。

#### **5. 検査証明書について**

- 5.1. 輸出国の家畜衛生当局は、日本に輸出される加熱処理豚肉等について、次の事項を具体的に記載した英文による検査証明書を発行しなければならない。
  - (1) 2.1, 3.1., 3.2., 4.1.及び4.2.に適合している旨
  - (2) 認定食肉処理施設及び認定加工施設等の名称、住所及び認定番号
  - (3) 指定加熱処理施設の名称、住所及び指定番号
  - (4) 原産国名
  - (5) と殺年月日、加工年月日、加熱処理年月日及び加熱処理の状態
  - (6) 加熱処理方法
  - (7) コンテナの封印番号（第三国を経由する輸送の場合）
  - (8) 船積み港の名称、船積み年月日

(9) 検査証明書の発行年月日、発行場所及び発行者の氏名及び役職名

## 別添 1

### 指定基準

1. 豚肉等のみを取り扱い、取り扱われる豚肉等は本家畜衛生条件の規定に従って処理されていること。
2. 原料の取扱い専門で、加熱処理前の取扱いを行う設備を備える加熱処理前部門及び、加熱処理後の製品（以下、加熱処理製品と言う。）の取扱い専門で、加熱処理後の取扱いを行う設備を備える加熱処理後部門を有していること。
3. 加熱処理後部門は、加熱処理装置が貫通する箇所を除き、加熱処理前部門から隔離されていること。
4. 加熱処理前部門は、保管、処理及び検査を行う設備を有していること。
5. 加熱処理後部門は、外界から完全にシャ断されていること。また、加熱処理製品は、再汚染防止のため、コンテナに詰められ出荷のために車両に積み込まれるまで加熱処理後部門で取り扱われること。加熱処理後部門は、加熱処理後の温度記録計などの検査用機器や、冷却、保管及び包装を行う設備を有していること。
6. 加熱処理前部門及び加熱処理後部門は、それぞれ専用の作業者を配置し、その動線は完全に分離されていること。交差汚染防止のため、出入口、更衣室等の各部門専用の設備をそれぞれ有していること。
7. 床、壁及び天井は、平滑で清掃しやすく、床は、不浸透性材料で作られ、適当な勾配と排水設備を備えており、かつ、消毒が可能であること。
8. 汚物処理設備及び洗浄用水を十分に供給できる給水設備を有していること。
9. 加熱処理前の取扱い、加熱処理及び加熱処理後の取扱いの一連の工程において、衛生上の危害の発生の防止と適正な品質の確保を図るための手順書が設置されていること。
10. 一連の工程が 9 の手順書に従っているかについて監督する者が設置されていること。

### 指定加熱処理施設の改築等に係る事前許可について

1. 指定加熱処理施設について、改築等がある場合は、輸出国の家畜衛生当局は、日本国の家畜衛生当局に対し、改築等の施工の1か月前までに施工期間等を含む改築等の内容を添え、日本国の家畜衛生当局に申請すること。輸出国の家畜衛生当局は、改築等に関し、日本国の家畜衛生当局より許可を得なければならない
2. 改築等とは、改築、増築及びその他別添2に記載される指定基準に関わる部分についての変更であり、その例は以下の通りである。なお、これ以外の一時的な変更であっても、変更過程で下記の変更を伴う場合は、事前申請を必要とする。
  - [改築]
    - (1) 加熱処理設備に関する変更（増数、減数、加熱処理方法の変更等）
    - (2) 原料処理部門と加熱処理部門を分ける隔壁に関する変更
    - (3) 作業者及び／または原料・製品の動線の変更を伴う施設内壁（原料処理部門と加熱処理部門を分ける隔壁以外）の変更
    - (4) 施設外壁に係る変更
    - (5) 施設内エリアの用途変更
  - [増築]
    - (1) 既存の指定施設と明確に分離できない施設の増築
    - (2) 既存の指定施設と施設番号、名称、住所等を共有する施設の増築
3. 日本国の家畜衛生当局は、改築等の施工開始日以降に製造される加熱処理肉等について、当該施設（あるいは当該施設の一部）から日本向けに輸出される加熱処理肉等の輸入を一時停止する。
4. 輸出国の家畜衛生当局は、実際の施工期間、施設平面図、改築等の部分の写真を含む改築等の終了報告を日本国の家畜衛生当局に行うこと。日本国の家畜衛生当局は、改築等の終了報告を受けた後、輸出国の費用負担で、当該施設の現地調査を実施することができる。日本国の家畜衛生当局は、現地調査の結果及び／あるいは改築等の終了報告の評価をもって、当該施設（あるいは当該施設の一部）の使用を許可する。

## 日本向けに輸出される天然ケーシングを使用した食肉等の追加条件

牛、めん羊及び山羊のケーシングが使用されている場合;

1. ケーシングは、以下リンクに掲げる国以外の国で生まれ、かつ、飼養された動物に由来するものであること。

<https://www.maff.go.jp/aqs/english/news/bse.html>

2. ケーシングがEU域内で生産されたものである場合、EU加盟国政府機関の検査員が行うと畜前後の検査により、家畜伝染病に感染しているおそれのない動物に由来すると確認されていること。ケーシングがEU域外から輸入される場合、EU加盟国政府機関の検査員が行う輸入検査、又は原産国政府が発行した健康証明書の確認により、家畜伝染病に感染しているおそれのない動物に由来すると確認されていること。
3. ケーシングは、上記 1 及び 2 の要件を満たすケーシングのみを取り扱う施設として、輸出国の政府機関の認定を受けた施設（以下「認定ケーシング施設」という。）で取り扱われたものであること（第三国から輸入したケーシングを使用して食肉等を生産している場合には、その認定加工等施設に対し本規定は適用される。）
4. 輸出国の家畜衛生当局は、認定ケーシング施設の名称、所在地及び認定番号を事前 に日本国の家畜衛生当局に通知すること。
5. ケーシングを用いた食肉等の日本向け輸出に当たって、輸出国の家畜衛生当局は、 次の各事項を具体的に記載した英文による検査証明書を発行すること。
  - (1) 上記 1 及び 2 の事項
  - (2) ケーシングの種類（天然）、ケーシングの原産国名（ケーシング由来動物の出生国及び飼養国名）、動物種名
  - (3) 認定ケーシング施設の名称、所在地及び認定番号

## 豚のケーシングが使用されている場合

1. ケーシングがEU域内で生産されたものである場合、EU加盟国政府機関の検査員が行うと畜前後の検査により、家畜伝染病に感染しているおそれのない動物に由来すると確認されていること。ケーシングがEU域外から輸入される場合、EU加盟国政府機関の検査員が行う輸入検査、又は原産国政府が発行した健康証明書の確認により、家畜伝染病に感染しているおそれのない動物に由来すると確認されていること。
2. ケーシングは、上記1及び2の要件を満たすケーシングのみを取り扱う施設として、輸出国の政府機関の認定を受けた施設（以下「認定ケーシング施設」という。）で取り扱われたものであること（第三国から輸入したケーシングを使用して食肉等を生産している場合には、その認定加工等施設に対し本規定は適用される。）
3. 輸出国の家畜衛生当局は、認定ケーシング施設の名称、所在地及び認定番号を事前に日本国の家畜衛生当局に通知すること。
4. ケーシングを用いた食肉等の日本向け輸出に当たって、輸出国の家畜衛生当局は、次の各事項を具体的に記載した英文による検査証明書を発行すること。
  - (1) 上記1及び2の事項
  - (2) ケーシングの種類（天然）、ケーシングの原産国名（ケーシング由来動物の出生国及び飼養国名）、動物種名
  - (3) 認定ケーシング施設の名称、所在地及び認定番号

## Application form

# for the designation of heat-processing facilities for meat and its products derived from pigs

(Important notice)

The information required by Animal Health Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries (MAFF), for the evaluation of heat-processing facilities to export heat-processed meat and its products derived from pigs to Japan are set out below.

☐ All information should be submitted in English.

☐ Please check where applicable or fill in the blanks.

Date of application (day/month/year)

The exporting country

### ☐ A ☐ Facility Profile

(1) Facility name

Facility address

Registration number of the facility

(2) Size of the facility

Ground-floor area

Total-floor area

(3) Number of workers

total

pre heating area

post heating area

storage area

supervisor

others

※Please fulfill the numbers on average per day

(4) Year of Established

(5) Capacity of production  tons / year

### ☐ B ☐ Heat-processing

(1) Pre-heating

- a. Species of animals
- b. Country of origin of raw materials
- c. Kind of casing (if applicable) : (artificial casing / natural casing )
- d. Species and country of origin of casing (if applicable):

**(2) Heat-processing**

- a. Number of heat-processing equipment
- b. Ways of heat-processing by each heat-processing equipment 
  - Equipment 1 ☐ steam ☐ boil ☐ fry ☐ roast ☐ grill ☐ other(  )
  - Equipment 2 ☐ steam ☐ boil ☐ fry ☐ roast ☐ grill ☐ other(  )
  - Equipment 3 ☐ steam ☐ boil ☐ fry ☐ roast ☐ grill ☐ other(  )

\*If the facility has more heat-processing equipment, please add the lines as necessary.

- c. Temperature management of the meat products by the heat-processing equipment
  - Equipment 1  °C  minutes (core of the meat)
  - Equipment 2  °C  minutes (core of the meat)
  - Equipment 3  °C  minutes (core of the meat)

\*Please add the lines as necessary in accordance with the number of heat-processing equipment.

- d. Measuring method and place for core temperature for meat and meat products in heat processing

Equipment 1

Equipment 2

Equipment 3

\*Please add the lines as necessary in accordance with the number of heat-processing equipment.

- e. Kind of heat-processed products intended to be exported from the facility to Japan

- f. Kind of products other than “e”, produced in the facility

**☐ C ☐ Management**

- (1) Standard operation procedures (SOP) for the following items;

(Pre-heating and Post-heating)

- ☐ Comprehensive sanitary management ☐ equipped / not equipped
- ☐ Sanitary management for staff ☐ equipped / not equipped
- ☐ Training program for staff ☐ equipped / not equipped
- ☐ Sanitary management for water supply ☐ equipped / not equipped
- ☐ Sanitary management for draining and waste ☐ equipped / not equipped

(Pre-heating)

- ☐ Sanitary management for equipment for storage, treatment and inspection ☐  
equipped / not equipped
- ☐ Maintenance of equipment for storage, treatment and inspection ☐  
equipped / not equipped
- ☐ Sanitary handling for material ☐ equipped / not equipped
- ☐ Way of storage, treatment and inspection ☐ equipped / not equipped
- (Post-heating)
- ☐ Sanitary management for equipment for inspection, cooling, storage and packing ☐  
equipped / not equipped
- ☐ Maintenance of equipment for inspection, cooling, storage and packing ☐  
equipped / not equipped
- ☐ Sanitary handling for heat-processed products ☐ equipped / not equipped
- ☐ Way of inspection, cooling, storage and packing after heat -processing ☐  
equipped / not equipped
- ☐ Sanitary management for heat-processing equipment ☐ equipped / not equipped
- ☐ Maintenance of heat-processing equipment ☐ equipped / not equipped
- ☐ Confirmation of the heat-processing temperature and time ☐ equipped / not equipped
- ☐ Way of inspection of heat-processed products ☐ equipped / not equipped

※In case SOP is not equipped, please describe measure of management on each item.

(Title of unequipped SOP) \_\_\_\_\_

(Measure of management) \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

\*If the facility has more heat-processing equipment, please add the lines as necessary.

#### **D Additional Information**

a. Countries to which the products are exported from the facility ☐

\_\_\_\_\_

b. Actual export amount in the last twelve months (if applicable) ☐

\_\_\_\_\_ kg

**-Remarks-**

Relevant documents which need to be attached to this application□

※Please submit the documents and pictures clear enough to examine.

PDF files are the most preferable.

- ☐ Organization chart of the facility
- ☐ Building map which shows the structure of pre-heating area and post-heating area
  - Please color pre-heating area and post-heating area in different color in order to identify each area.
- ☐ Layout of major devices and equipment including heat-processing equipment
- ☐ Photographs of an physical barrier (e.g. dividing walls) between pre-heating area and post-heating area.
- ☐ Photographs of attachment point between heat-processing equipment and physical barrier (e.g. dividing walls)
- ☐ Map which shows the place where above-mentioned pictures were taken.
- ☐ Traffic line of the products from entrance to exit
- ☐ Traffic line of drainage and waste
- ☐ Traffic line of water supply
- ☐ Traffic line of air flow
- ☐ Traffic line of workers
- ☐ List of Standard Operation Procedures (SOP)
- ☐ Map of neighborhood of the facility
  - Please indicate the heat-processing facility in the map.
- ☐ Table of manufacturing process by each product

**Linee guida per la compilazione dell'application form e la valutazione dei requisiti di cui all' "Animal Health Requirements for heat-processed meat and meat products derived from pigs to be exported from Italy to Japan" del 10 maggio 2023**

Nell'accordo (AHRs) sono stabiliti i requisiti necessari per la ripresa delle esportazioni di prodotti a base di carne suina cotta dall'Italia verso il Giappone.

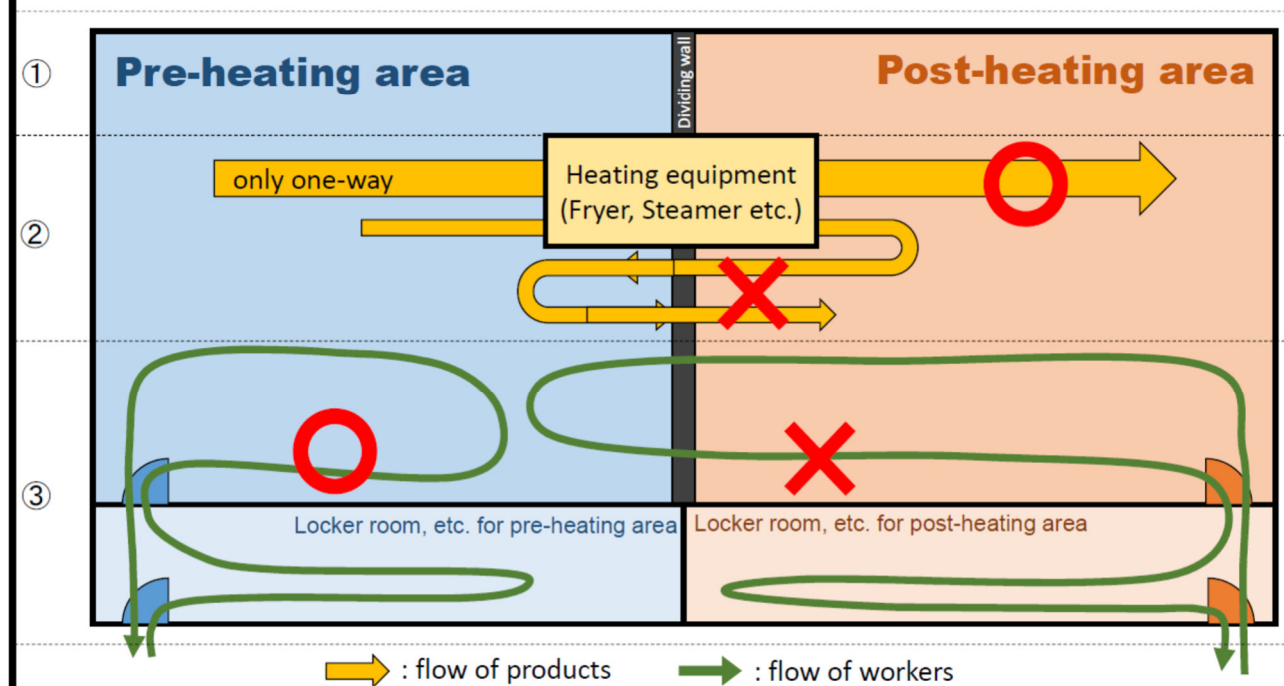
I requisiti sanitari generali per macelli, sezionamenti e stabilimenti di trasformazione sono principalmente i seguenti:

| <b>Requisito AHRs</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>(traduzione di cortesia)</b>                                                                                                                                                                                                                                                                                                                                                                                          | <b>Note comparative con lo standard nazionale/comunitario</b>                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1. The <b>slaughter facilities</b> where the pigs for heat-processed meat and meat products to be exported to Japan are slaughtered must be <b>approved</b> by the government of the exporting country (hereinafter referred to as "the approved slaughter facilities").                                                                                                                                                                                                               | gli stabilimenti dove gli animali sono macellati per le carni impiegate nella produzione di prodotti a base di carne trattati termicamente devono essere riconosciuti dall'Autorità del Paese esportatore (di seguito riferito come "I macelli riconosciuti")                                                                                                                                                            | Tutti i macelli riconosciuti ai sensi del Reg. (CE) n. 853/04 sono abilitati alla fornitura di materia prime per la produzione di pbc cotti da esportare in Giappone                                                                                                                                                                                            |
| 3.2 The <b>processing facilities</b> where the meat and meat products derived from pigs for heat-processed meat and meat products to be exported to Japan are processed such as cutting and curing and stored before the heat-processing must be <b>approved</b> by the government of the exporting country (hereinafter referred to as "the approved processing facilities").                                                                                                           | Gli stabilimenti dove le carni e i pbc suina destinati alla produzione di pbc cotti da esportare in Giappone sono lavorati (impianti di sezionamento, stagionature, depositi) prima di essere sottoposti al trattamento termico devono essere riconosciuti dall'Autorità del Paese esportatore (di seguito riferito come                                                                                                 | Tutti gli impianti di sezionamento e gli altri stabilimenti che lavorano carni e pbc destinati a essere successivamente sottoposti a trattamento termico nel rispetto dei requisiti stabiliti dal Giappone riconosciuti ai sensi del Reg. (CE) n. 853/04 sono abilitati alla fornitura di materia prime per la produzione di pbc cotti da esportare in Giappone |
| 3.3 Upon the application by the animal health authorities of the exporting country, <b>the Japanese animal health authorities assess the application and designate the heat-processing facilities</b> that meet the standards defined in Annex 1 (hereinafter referred to as "designation standard") for a period of 2 years in principle as the facilities eligible for exporting meat and meat products to Japan (hereinafter referred to as "designated heat-processing facilities"). | A seguito della domanda inoltrata dalle Autorità competenti del paese esportatore, le autorità giapponesi competenti in materia di sanità animale valutano la domanda e riconoscono gli stabilimenti di trasformazione che rispettano gli standard di cui all'allegato I (di seguito "Standard per il riconoscimento") per un periodo iniziale di 2 anni (di seguito "stabilimenti di trattamento termico riconosciuti") | Le manifestazioni di interesse da parte degli stabilimenti di pbc suina cotti sono inoltrati dal Ministero della Salute alle competenti Autorità del Giappone che decideranno, in autonomia, dell'eventuale riconoscimento degli impianti dopo avere accertato il rispetto dei requisiti di cui all'allegato I                                                  |

**Gli standard richiesti agli stabilimenti di trattamento termico sono efficacemente raffigurati nella scheda sotto riportata fornita dalle Autorità giapponesi:**

○ The main point of designation standard for heat processed livestock products

- ① Post-heating area must be walled off by physical barrier such as dividing wall.
- ② Products must be flowed only one way from pre-heating to post-heating area.
- ③ Both areas must have dedicated workers and facilities including entrance, exit, locker room etc. Both flows of workers must not be crossed to prevent cross-contamination.



I principali standard “strutturali” evidenziati nella scheda sono:

- 1) L’area post - trattamento termico deve essere fisicamente separata da una barriera come un muro divisorio
- 2) I prodotti devono fluire solo in una direzione tra zona pre e post – trattamento termico
- 3) Ogni area deve avere impianti e attrezzature per il personale, inclusi spogliatoi e servizi igienici, completamente separati per il personale che opera nelle due aree
- 4) Il personale addetto alle lavorazioni in area pre e post trattamento termico deve essere distinto e i percorsi del personale delle due aree non devono sovrapporsi.

Si tratta di requisiti strutturali non sempre riscontrabili nei nostri stabilimenti di trasformazione per prodotti cotti, ma necessari per ottenere la designazione da parte delle Autorità Giapponesi.

Tenuto conto dell’esperienza maturata con altri Paesi terzi e con le stesse Autorità sanitarie nipponiche in occasione dell’apertura del mercato giapponese all’esportazione delle carni e dei prodotti a base di carni bovine, è possibile che le autorità del MAFF possano accettare anche una segregazione nel tempo oltre che nello spazio. In questo caso

- La procedura di segregazione, adeguatamente descritta in un documento che dovrà essere allegato in lingua inglese all'*application form* unitamente alle altre procedure operative, dovrà garantire la completa separazione nel tempo di tutte le aree, i locali, gli impianti, le attrezzature e il personale impiegati in fase pre- o post-trattamento termico dei pbc destinati all'esportazione verso il Giappone
- Eventuali aree, locali, impianti, attrezzature (compresi i locali, gli impianti e le attrezzature impiegati dal personale) utilizzati in fase pre-trattamento termico, prima di essere utilizzati in fase post-trattamento termico dei pbc destinati all'esportazione verso il Giappone, devono essere disinfettati in modo accurato, completo ed efficace con l'impiego di un presidio chimico attivo nei confronti degli agenti patogeni responsabili di malattie notificabili ed in particolare nei confronti del virus della PSA. Il personale deve adottare procedure igieniche idonee a gestire il rischio di contaminazione crociata (vestiario, calzari, etc) e procedere ad accurata disinfezione delle mani prima di accedere ai locali dove il prodotto viene lavorato, stoccato, spedito. Le procedure predisposte e adottate per rispondere ai requisiti sopra riportati devono essere descritte in apposito documento allegato all'*application form*.

**Resta inteso che saranno le autorità del MAFF che, in sede di valutazione della documentazione inoltrata dai singoli stabilimenti, potranno accogliere o meno le proposte gestionali di cui sopra procedendo, quindi, alla visita in loco per l'eventuale conferma dell'effettiva sussistenza dei requisiti.**

Di seguito, alla luce delle considerazioni sopra riportate, si propone un'analisi dei "designation standard" di cui in allegato 1 agli AHR con alcune osservazioni e valutazioni per la formulazione del giudizio di conformità in situazioni operative di non completa corrispondenza ai requisiti strutturali previsti dal MAFF, ma capaci comunque di garantire in maniera equivalente i criteri di separazione e prevenzione delle contaminazioni crociate come richiesto dallo standard giapponese.

#### **Annex 1 to AHRs - analisi dei Designation Standard**

| <b>Designation Standard</b>                                                                                                                                                                                                                                                                                            | <b>Traduzione di cortesia</b>                                                                                                                                                                                                                                                                   | <b>Osservazioni</b>                                                                                                                                                                                                                                                                                                                               | <b>Valutazione di conformità</b>                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| 1. The designated facilities must handle only meat and meat products derived from pigs and the said meat and meat products must be processed in accordance with the relevant requirement described in this document.                                                                                                   | Gli stabilimenti designati devono lavorare solo carni e pbc suina e tali carni e pbc devono essere trattati nel rispetto delle disposizioni del presente documento                                                                                                                              | Laddove adottata, la segregazione temporale di carni e pbc di specie diverse dal suino deve essere documentata nel rispetto delle indicazioni sopra riportate (SSOP clean up to clean up)                                                                                                                                                         | Gestione procedurale                                                                                                  |
| 2. The designated heat-processing facilities must have pre-heating area which is exclusively for raw materials and furnished with necessary equipment dedicated for process before heat-processing, and post-heating area which is exclusively for handling products after heat-processing (hereinafter heat-processed | Gli stabilimenti designati devono disporre di aree/reparti destinati esclusivamente a materie prime pre trattamento termico forniti delle attrezzature necessarie a lavorare le carni e i pbc prima del trattamento termico, e di aree/reparti destinati esclusivamente ai prodotti che abbiano | Laddove adottata, la segregazione temporale di attrezzature e impianti per le carni e i pbc trattati e non trattati e la separazione del personale e dei relativi flussi durante la produzione di lotti di prodotti idonei all'export Giappone devono essere documentate nel rispetto delle indicazioni sopra riportate (SSOP fra le lavorazioni) | Gestione procedurale del rispetto dei "The main point of designation standard for heat processed livestock products". |

|                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| products) and furnished with necessary equipment dedicated for process after heat-processing.                                                                                                                                                                                                                           | subito il trattamento termico (di seguito prodotti trattati) forniti delle attrezzature necessarie per la lavorazione e manipolazione dei prodotti trattati                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                       |
| 3. The post-heating area must be isolated from the pre-heating area except for penetration structure of heat-processing equipment.                                                                                                                                                                                      | L'area post trattamento termico deve essere isolata dall'area Pre-trattamento fatta salva l'apertura per il passaggio delle attrezzature necessarie al processo                                                                                                                                          | Laddove adottata, la segregazione temporale di attrezzature e impianti per le carni e i pbc trattati e non trattati e la separazione del personale e dei relativi flussi durante la produzione di lotti di prodotti idonei all'export Giappone devono essere documentate nel rispetto delle indicazioni sopra riportate (SSOP fra le lavorazioni)                                                                           | Gestione procedurale del rispetto dei "The main point of designation standard for heat processed livestock products". |
| 4. The pre-heating area must have facilities for storage, processing and inspection.                                                                                                                                                                                                                                    | L'area pre-trattamento deve disporre di strutture/locali per lo stoccaggio, le lavorazioni e il controllo                                                                                                                                                                                                | Gli impianti e le attrezzature impiegate nell'area pre-trattamento non devono essere impiegate anche nell'area post-trattamento. Laddove adottata, la segregazione temporale di attrezzature e impianti per le carni e i pbc trattati e non trattati durante la produzione di lotti di prodotti idonei all'export Giappone deve essere documentata nel rispetto delle indicazioni sopra riportate (SSOP fra le lavorazioni) | Gestione procedurale                                                                                                  |
| 5. The post-heating area must be walled off from other area and once the products enter the post-heating area through the heat-processing equipment, they must not be brought to the outside of the post-heating area until they are packed in containers and loaded onto vehicles for shipment in order to prevent the | L'area post-trattamento deve essere separata da muri dall'altra porzione dello stabilimento e una volta che i prodotti entrano nell'area post-trattamento, non devono essere portati fuori fintanto che non sono confezionati e caricati in contenitori e veicoli per la spedizione così da prevenire la | Laddove adottata, la segregazione temporale di attrezzature e impianti per le carni e i pbc trattati e non trattati e la separazione del personale e dei relativi flussi durante la produzione di lotti di prodotti idonei all'export Giappone devono essere documentate nel rispetto delle indicazioni sopra riportate (SSOP fra le                                                                                        |                                                                                                                       |

|                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| recontamination. To this end, post-heating area must be furnished with equipment necessary for process after heat-processing such as cooling, inspection, packing and storage. In addition, post-heating area must have instruments or devices for inspection such as temperature recorders and equipment for cooling, packing and storage.                                                    | ricontaminazione. A tal fine l'area post-trattamento deve essere dotata con le attrezzature necessarie per le lavorazioni successive al trattamento quali il raffreddamento, il controllo, il confezionamento e lo stoccaggio. Inoltre l'area post trattamento deve disporre di strumenti o dispositivi per il controllo quali registratori di temperatura, dispositivi per il raffreddamento, il confezionamento e stoccaggio | lavorazioni). Una volta sottoposti a trattamento termico i prodotti devono rimanere segregati sino alla spedizione verso il Giappone                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                       |
| 6. The pre-heating area and post-heating area must have dedicated workers to each area and the traffic line of the workers of pre- and post-heating areas must be completely separated. To this end, the pre-heating area and the post-heating area must have separate facilities for workers in each area, such as entrance, exit, locker room etc., in order to prevent cross-contamination. | L'area pre- e post-trattamento deve impiegare personale dedicato e i flussi del personale addetto alle due aree devono essere completamente separati. A questo scopo le due aree devono disporre di strutture separate per i lavoratori di ciascuna area, quali ingressi e spogliatoi separati per prevenire contaminazioni crociate                                                                                           | Laddove adottata, la segregazione e la separazione del personale e dei relativi flussi durante la produzione di lotti di prodotti idonei all'export Giappone devono essere documentate nel rispetto delle indicazioni sopra riportate. Nel caso in cui non sia possibile dedicare del personale alle due aree, le lavorazioni e la manipolazione dei prodotti trattati termicamente, sino al momento della loro spedizione verso il Giappone devono essere condotte prima delle altre attività | Gestione procedurale del rispetto dei "The main point of designation standard for heat processed livestock products". |
| 7. Floors, walls and ceilings must be smooth and easy to clean; floors must be made of impermeable material, sloped properly, provided with appropriate drainage system and be readily disinfected.                                                                                                                                                                                            | Pavimenti, muri, soffitti devono essere lisci e facili da pulire; i pavimenti devono essere costituiti da materiali impermeabili, adeguatamente inclinati, forniti di un sistema di drenaggio delle acque e facilmente disinfettabili                                                                                                                                                                                          | Questi requisiti ricalcano quelli di cui all'allegato II al Reg. (CE) n. 852/04                                                                                                                                                                                                                                                                                                                                                                                                                | Requisito da rispettare integralmente                                                                                 |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------------------------------------|
| 8. The designated heat-processing facilities must have facilities for decontamination as well as water supply for cleaning.                                                                                                                             | Gli stabilimenti di trattamento termico designati devono disporre di stazioni di disinfezione e di una fornitura di acqua per le pulizie                                                                                                                | Questi requisiti ricalcano quelli di cui all'allegato II al Reg. (CE) n. 852/04 | Requisito da rispettare integralmente                |
| 9. The designated heat-processing facilities must have relevant Standard Operating Procedures (SOP) in place to prevent occurrence of sanitary hazards and to ensure an appropriate quality management throughout the entire process of the production. | Gli stabilimenti di trattamento termico designati devono disporre di applicare procedure operative standard (SOP) per prevenire il verificarsi di pericoli per l'igiene per assicurare una gestione della qualità lungo tutto il processo di produzione | Questi requisiti ricalcano quelli di cui al Reg. (CE) n. 852/04                 | Requisito da rispettare integralmente                |
| 10. Qualified staff who can supervise compliance with the procedures described in item 9 must be stationed in the designated heat-processing facilities.                                                                                                | Gli stabilimenti di trattamento termico designati devono disporre di personale qualificato in grado di supervisionare il rispetto delle procedure di cui al punto precedente                                                                            | Questi requisiti ricalcano quelli di cui al Reg. (CE) n. 852/04                 | Requisito da rispettare integralmente<br>Staff HACCP |

L'Amministrazione Regione Emilia Romagna [cod. r\_emiro], Area Organizzativa Omogenea Giunta [cod. AOO\_EMR], Vi invia tramite Casella Istituzionale la documentazione di cui siete destinatari e che è stata registrata in uscita come Prot. 18/05/2023.0489181.U.

con oggetto:

Export Giappone - riapertura del mercato

La verifica della firma digitale e la successiva estrazione degli oggetti firmati può essere effettuata con qualsiasi software in grado di elaborare file firmati in modo conforme alla Deliberazione CNIPA 21 maggio 2009, n. 45. Un elenco di produttori si trova a questa pagina del sito dell'Agenzia per l'Italia digitale:

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Cordiali saluti.