

**PROTOCOL BETWEEN
THE MINISTRY OF HEALTH OF THE ITALIAN REPUBLIC AND THE
GENERAL ADMINISTRATION OF CUSTOMS OF THE PEOPLE’S REPUBLIC
OF CHINA ON INSPECTION, QUARANTINE AND VETERINARY SANITARY
REQUIREMENTS FOR FROZEN PORK TO BE EXPORTED FROM ITALY TO
CHINA**

The Ministry of Health of the Italian Republic (hereinafter referred to as “MHI”) and the General Administration of Customs of the People’s Republic of China (hereinafter referred to as “GACC”), through friendly negotiations, have reached the following understanding on inspection, quarantine and veterinary health requirements for frozen pork to be exported from the Italian Republic (hereinafter referred to as “Italy”) to the People’s Republic of China (hereinafter referred to as “China”).

Article 1

The General Directorate for Hygiene, Food Safety and Nutrition and the General Directorate of Animal Health and Veterinary Drugs are the competent authorities of the Italian Ministry of Health responsible respectively for the supervision, inspection and quarantine over food production of animal origin and for the animal diseases and management control measures, feed and veterinary drugs. The General Directorates are responsible to coordinate and supervise the activities granting that safe products are exported from Italy to China. Those activities are performed at local level by official veterinarians working at local competent authorities. The official veterinarians are appointed as the competent persons to sign the official health certification decided with China.

Article 2

MHI will provide GACC with the laws and regulations governing the plants for slaughtering, cutting-up, processing and storing frozen pork to be exported from Italy to China and the issuing of the veterinary health certificates for export and relevant inspection and quarantine programs which consist of monitoring substances or diseases, laboratory testing methods, standards and procedures applied, as well as the quarantine stamps or inspection legend/marks for export eligibility.

MHI will supply GACC with the following information every year:

1. The schedules and annual reports of the national monitoring plan of chemical residue (veterinary drugs and contaminants, etc.) and pathogenic microorganism.
2. The preventive and zoning measures applied against the diseases listed in Article 3 of this Protocol including, whenever an outbreak of diseases listed in Article 3 occurs, specific geographical location of zoning, number of swine within the zone, detail of the meat processing establishments for export and official verification information;
3. The swine epidemic situation in Italy.

MHI will cooperate with GACC to ensure that administrative systems for food safety sustainably comply with the requirements of China. When necessary, GACC may send experts to Italy, regularly or randomly, to conduct an on-site audit or review inspection. MHI will provide necessary assistance to enable the audit and inspection.

MHI will share with GACC periodically information in respect of veterinary supervision on production, exportation, hygiene and safety of the establishments intended for exportation to China. The Parties will exchange relevant information and cooperate in investigating and handling issues and taking corrective and preventive actions to ensure that the establishments satisfy the requirements of China.

Article 3

MHI confirms that the territory of Italy:

1. is free from classical swine fever (CSF) and Nipah virus encephalitis;
2. is recognized by the World Organization for Animal Health (OIE) as a country free from foot and mouth disease (FMD) where vaccination is not practiced;
3. is free from African Swine Fever (ASF) except for Sardinia island;
4. has a zone (the northern part of Italy) which is free from swine vesicular disease (SVD), having met the requirements specified in the OIE Terrestrial Animal Health Code (hereafter referred to as “the Terrestrial Code”).

Article 4

The live swine from which the frozen pork to be exported was derived should:

1. be born, reared and slaughtered in ASF and SVD free zone in Italy which has been recognized by GACC, and bear an identification mark which can be traced back to the farms of origin. Furthermore, it should never be housed together with other farmed animal.
2. originate from premises which have been free from clinical infection of anthrax, Paratuberculosis (Johne’s disease), Teschovirus encephalomyelitis, Aujeszky’s disease (Pseudorabies), Brucellosis (Brucell suis), Transmissible gastroenteritis of swine, Porcine reproductive and respiratory syndrome, Porcine circovirus within the 12 months prior to slaughter, and no infection with trichinellosis and porcine cysticercosis for 6 months prior to slaughter.
3. originate from premises on which no quarantine surveillance or movement restriction have been imposed due to other than aforementioned notifiable diseases relevant to swine listed by the OIE, China’s and Italy’s animal health regulation for the previous 6 months.

Article 5

The manufacturing establishments (including those for slaughtering, cutting-up, processing and storage) intended for exporting frozen pork to China will be located in ASF and SVD free zone as confirmed by GACC beforehand, and under the supervision of MHI in compliance with the relevant laws and regulations of Italy and China on veterinary health and public health.

The establishments for export of meat to China will be registered with China according to the Food Safety Law of the People’s Republic of China. Manufacturing establishments that have not been registered will not be allowed to import into China.

Article 6

Official veterinarians will attest, through the veterinary health certificate, that:

- 1) the pork is derived from swine that:

- a) was born, reared and slaughtered in Italy, and has an identification mark, which allows traceability to the farm of birth and rearing,
 - b) has been slaughtered, cut up, processed and stored at abattoirs, cutting-up, processing establishments and cold stores approved by China,
 - c) has never been treated with veterinary drugs or feed additives prohibited by both sides,
 - d) originates from the farms in conformity with Article 4 of this Protocol,
 - e) has been subjected to ante and post-mortem inspections in compliance with relevant China's and Italy's laws and regulations with favorable results so as to prove that the swine for slaughter is healthy and free from clinical signs of infectious disease and parasites, and that no lesions have been found on viscera and carcasses from which the major lymphatic nodes and gland tissue have been removed.
- 2) the national residue monitoring plan has been implemented and certifies that the residue level of veterinary medicinal products, pesticides, long-lasting organic pollutants contained as heavy metals, dioxin, PCB and other toxic and undesirable substances in the products is below the Maximum Residue Limits (MRLs) as per China's and Italy's laws and regulations,
 - 3) the product is free from the contamination of pathogenic agent as per China's and Italy's laws and regulations and international standards,
 - 4) the frozen pork is hygienic and safe, fit for human consumption.

Article 7

During the period of transportation (including transportation from the farm to, and the place of slaughterhouse), the swine for slaughter whose meat is to be exported to China, will not be allowed to contact with:

1. any live swine which does not comply with the requirements in Articles 3 and 4 of this Protocol; or
2. any live swine or other species of animals belonging to the establishment which does not achieve the registration in Article 5 of this Protocol.

The frozen pork for export to China will not be allowed to be processed together with:

1. animal products which are not in conformity with Article 3 and 4 of this Protocol;
2. products which are not produced by this registered establishment; or
3. other animal products of other species of origin.

A specific area within the cold store will be made available with clear identification exclusively for the storage of the frozen pork for export to China.

Article 8

The frozen pork to be exported to China will be packed with packaging materials of first use in compliance with the China's national food safety standards and the international hygienic standards.

The frozen pork for export will be labelled with the commodity name (product description), country of origin, establishment registration number and the batch numbers on the independent interior package in the Chinese language.

The country of origin, name, specifications, place of origin (specifying state/province/city), establishment registration number, batch numbers, destination (the People's Republic of China only), production date (year/month/day), shelf life and storage temperature will be labeled on the exterior package in the Chinese language. The packages will bear the official inspection and quarantine marks of Italy which have been put on file and approved by GACC.

The labels of prepackaged frozen pork will comply with the Chinese standards and regulatory requirements on pre-packaged food labeling.

Article 9

To prevent from contamination of undesirable substances, the frozen pork to be exported to China will meet the sanitary requirements of China and Italy during the package, storage and transportation.

The storage and transportation will be under suitable temperatures maintaining the core temperature of the frozen pork no warmer than minus 15 degrees Celsius.

Prior to shipment, the container should be sealed under the supervision of Italian official veterinarians. The seal number should be indicated in the veterinary health certificate. During transportation, the package of the products should not be opened or changed.

Article 10

Each container of frozen pork to be exported to China will be accompanied by at least one official and original veterinary health certificate attesting that the products are in conformity with the veterinary and public health rules and regulations of China and Italy, as well as the relevant requirements in this Protocol.

The veterinary health certificates will be written/typed in Chinese, Italian and English (the English version is compulsory when filling out the certificate). The format and content of the certificate will be mutually consented in advance by the Parties. To put on record, MHI will provide GACC with examples of the official quarantine stamp or inspection legend/marks, models of the veterinary health certificate, a list of authorized signatory veterinarians with their corresponding signatures, instructions on the anti-fraud protections and the email address through which the electronic certificates data will be delivered. If there are any modifications or changes of the above, MHI will notify GACC at least one month prior to the changes coming into effect.

To facilitate the border inspection in China, MHI will deliver the electronic data of each veterinary health certificate issued to China through official channels in a timely manner. MHI will guarantee the electronic data are correct and safe.

Article 11

If any swine infectious disease(s) stipulated in Article 3 of this Protocol break(s) out in Italy, MHI will stop the exportation of frozen pork to China, recall the affected products and the potentially affected products, inform GACC and provide it with a detailed account on the status of the disease and management control measures that have been applied.

If there are outbreaks of other infectious swine disease(s) listed in Article 4 of this Protocol or defined as list B diseases in the *List of Quarantine Diseases for the Animals Imported to*

the People's Republic of China by China's laws and regulations which could be transmitted by meat, MHI will stop the exportation of frozen pork produced in relevant containment zone/compartment immediately, recall the affected products and the potentially affected products, inform GACC and provide it with a detailed report containing information on the status of the disease and management control measures that have been applied.

If there is any issue of serious public concern in Italy on food contamination related to pork products for export, MHI will immediately stop the exportation of frozen pork produced in the relevant establishment, recall the affected products and the potentially affected products, inform GACC and provide it with a detailed report containing information on the contamination and management control measures that have been applied.

At the end of the aforementioned issue, MHI may negotiate with GACC the conditions for the resumption of exports, in accordance with international practices.

Article 12

If frozen pork exported into China is found by GACC to not be in compliance with the requirements of this Protocol, GACC will notify MHI immediately, and may take measures to return, destroy or dispose of the product. MHI will cooperate with GACC in addressing non-compliance, and taking corrective actions and rectifications to prevent the recurrence of the non-compliance.

Article 13

For the purposes of this Protocol "frozen pork" refers to the edible skeletal muscle of swine and its by-products from which the bristle, viscera/offal, head, tail and feet (below the wrist and ankle) are removed following slaughter and bleed. The ground pork, trimmings, minced meat, scraps, mechanically separated meat and other by-products are not eligible for export to China.

For the list of the edible pork by-products eligible for export from Italy to China see Annex 1.

Article 14

The sanitary processing requirements (Annex 2) should be satisfied for edible pork by-products eligible for export from Italy to China. Annex 1 and 2 are substantial parts of this Protocol and may be amended by mutual consent of GACC and MHI.

Article 15

This Protocol takes effect on the date of signature and may be amended in writing by mutual consent between the Parties.

This Protocol will remain valid for five (5) years and will be automatically renewed for further periods of five (5) years, unless one of the Parties notifies the other of its intention to terminate or amend it at least two (2) months in advance.

Article 16

Any costs regarding the implementation of the present Protocol will be borne by the Parties

in conformity with their respective national legislations and without any additional costs for the ordinary State budgets of the People's Republic of China and the Italian Republic.

Article 17

This Protocol will be implemented in accordance with the Italian and Chinese legislations, as well as applicable international law and, as for the Italian Party, the obligations arising from Italy's membership of the European Union.

Article 18

The Parties will settle any divergence arising in the implementation of this Protocol through friendly direct consultations and negotiations.

Article 19

Done at Rome on 23 March 2019, in duplicate, each in the Italian, Chinese and English languages, all texts being equally authentic. In case of divergence, the text in English will prevail.

For the Ministry of Health of the Italian
Republic

For the General Administration of Customs
of the People's Republic of China

Giulia Grillo

Li Ruiyu

Annex 1

List of the Edible Pork By-products Eligible for Export from Italy to China

1. Parts of the carcass: frozen pork cartilages, frozen unrefined pork lard (body fat only, no viscera fat), frozen pork feet, frozen pork hock;
2. Others: frozen pork knuckle, frozen pork skin, frozen pork tail.

Annex 2

Sanitary Processing Requirements of Pork Edible By-products Eligible for Export from Italy to China

1. Scope

The requirements in this Annex apply to the eligible edible pork by-products listed in Annex 1 of this Protocol.

2. General requirements

2.1 According to the laws and regulations of Italy and China, the edible pork by-products defined in this requirement are suitable for human consumption.

2.2 Italy has established a food safety and health management system especially for pork edible by-products.

2.3 The pork edible by-products for export to China will be derived from the farms, slaughterhouses and plants which have implemented an effective identification system to their place of origin.

2.4 Only plants that have been registered are allowed to export pork edible by-products into China, and their processing room exclusively for pork edible by-products should be registered as well.

2.5 The pork edible by-products for export to China will be derived from animals that were subjected to Italy's National Residue Monitoring Plan. Based on the results of this plan, it can be attested that the pork edible by-products contain no medicine, chemical residue substance, or other toxic and harmful residue substance that can be hazardous to human health.

2.6 The pork edible by-products for export to China shall be processed and handled as per the food safety requirements intended for human consumption. The HACCP based food safety management system shall be applied to ensure compliance with the relevant provisions of this Annex.

3. Edible pork by-products processing requirements

3.1 Processing sites, facilities and equipment

3.1.1 The pork edible by-products for export to China will be processed in a separate pork edible by-product processing room(s) which is relatively isolated from the inedible by-products processing room(s). The pork edible by-product processing room and its sanitary conditions will comply with the sanitary standards prescribed for edible pork by-products in Italy.

3.1.2 The size of the processing room of the pork edible by-product will be compatible with the processing ability. The equipment and facilities will meet the requirements of hygiene and sanitation prescribed for edible pork by-products. The dirty processing flow and the clean processing flow will be segregated reasonably to avoid cross contamination.

3.1.3 If the plant conducts pre-chilling of pork edible by-products, a dedicated room or area for pre-chilling procedures and a packaging room shall be available.

3.1.4 The scalding, hair removal and the cleaning machine will be installed within the processing area for feet and tails.

3.2 Sanitary requirements for personnel.

3.2.1 Plants for exporting edible pork by-products will have competent personnel that have been trained in the relevant processing procedures for pork by-product.

3.2.2 Personnel must not access processing rooms through rooms or areas where the clean status of the products is different from that in their own processing room. They must not move directly between working rooms of different status without passing through a hygiene facility, wearing protective clothing and changing visibly contaminated clothing.

3.3 Temperature requirements.

3.3.1 The temperature of the processing room(s) for pork edible by-products should be maintained at below 12 degrees Celsius, except for the room dedicated to of feet and tails scalding. The temperature of the blast freezer should be below minus 28 degrees Celsius. The chiller temperature should be below minus 18 degrees Celsius.

3.3.2 Controls on freezing of pork edible by-products will be consistent with controls prescribed for edible pork products by Italy, China and this Protocol.

3.3.3 The temperature of the hot water for equipment cleaning will be higher than 40 degrees Celsius. The temperature of the hot water for equipment sterilization will not be less than 82 degrees Celsius.

3.3.4 If the plant conducts pre-chilling of pork edible by-products, the core temperature of the edible by-products will be maintained at 3 degrees Celsius or lower after pre-chilling.

3.3.5 Pork edible by-products will be transported in refrigerated conveyance(s) which meet sanitary requirements.

3.3.6 The core temperature of the exported pork edible by-products will be not warmer than minus 15 degrees Celsius during transport.

3.4 Requirements for finished products.

3.4.1 Any visible fester, effusion, lesion, secretion, gastrointestinal contents or foreign objects (such as plastic, metal and residual feed, etc.) on the edible by-products should be removed by trimming or washing prior to packing and freezing. The finished by-products should not be processed together with inedible by-products within the same area.

3.4.2 The pork edible by-products for export must be packed in separate packaging material according to the different types of the products and stored in a specified area with identifiable mark.

3.5 Sanitary control of processing.

Each plant will implement a microbial monitoring plan depending on various pork edible by-products for export in accordance with the table below. The plant operator will collect, record and periodically analyze the microbiological results to establish a database.

Table: Sampling plans for microbiological process control monitoring*

Microorganism	Sampling plan		Limit		Sampling frequency		Stage where the sample should be collected
	n	c	m	M	Original frequency	The frequency can be reduced if the results are satisfied.	
APC	5	2	5×10 ⁵ CFU/g	5×10 ⁶ CFU/g	For each category, collect 5 samples per week, for 6 consecutive weeks	For each category, collect 5 samples every 2 weeks	End of the processing
Enterobacteriaceae			2.0LOG CFU/g (daily mean log)	3.0LOG CFU/g (daily mean log)	For each category, collect 5 samples per week, for 6 consecutive weeks	For each category, collect 5 samples every 2 weeks	Prior to chilling/freezing
E.coli	5	2	50 CFU/g	500 CFU/g	For each category, collect 5 samples per week	For each category, collect 5 samples every 2 weeks	End of the processing
Salmonella	50	5	Absence in 25 g		For each category, collect 5 samples per week, for 10 consecutive weeks, 30 weeks in total.	For each category, collect 5 samples every 2 weeks	Prior to chilling/freezing

*:n = number of units comprising the sample; c = number of sample units giving values between m and M.

Interpretation of the test results:

- satisfactory, if all the values observed are $\leq m$,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq m$,
- unsatisfactory, if one or more of the values observed are $> M$ or more than c/n values are between m and M.

3.5.1 Sampling

5 packing boxes or bulk samples should be collected randomly by cutting method. The samples shall be collected from different parts of the package, mixed thoroughly, then merged into one sample weighing at least 500 grams.

3.5.2 Storage and transportation

The samples shall be placed in the insulation containers with ice packs or ice water. The sample shall not be frozen or in direct contact with the ice pack. After sampling, the samples shall be handled in the laboratory within 1 hour, otherwise the sample should be stored between zero degree Celsius and 4 degrees Celsius for no longer than 24 hours.

3.6 Follow up steps

If result exceeds the “c” value, the following corrective actions should be applied:

3.6.1. Checking the internal quality control records (such as temperature, hygiene and other anomalies) to ascertain the reason.

3.6.2 Taking appropriate corrective actions (such as collecting more samples to verify the effectiveness of corrective actions or rectification measures).

3.6.3 Keeping records of the cause of the non-compliance and the corrective actions for at least 2 years.