IMPORTANT DISCLAIMER
“This English version is provided only to assist the Food Business Operators. The original Italian version has to be considered the official Standard Operative Procedure”

In force from

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<td>S. Borrello</td>
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<td>Revision 1 (one)</td>
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ISSUED BY:

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Society/authority: ____________________________ Date: ____________________________
1.0 Purpose
The purpose of the present procedure is to define the operating instructions for the notification of the establishments that export quick-frozen vegetables from Third Countries to Italy.

2.0 Scope
The present procedure applies to all the establishments that export quick-frozen vegetables from Third Countries to Italy.

3.0 Definitions
DGISAN: Directorate General for the hygiene food safety and nutrition.
USMAF: Uffici di Sanità Marittima, Aerea e di Frontiera (Italian Designated Points of Entry)
FROZEN FOODSTUFFS: Foodstuffs which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of -18 °C or lower at all points.

4.0 References
- Legislative Decree 27/1/1992, n. 110, art. 10 “Implementation of directive 89/108/CEE”
- Circular letter n. 21 del 27/4/1992 (see the website of the Ministry of Health: Sicurezza alimentare > Controlli alle frontiere > Importazioni di alimenti surgelati da Paesi terzi)
5.0 Description of the procedure

5.1 Formal procedure

In order to notify an establishment that exports quick-frozen vegetables from a Third Country to Italy, the interested company should fill in an application, with specific attachments, addressed to the following office:

**Ufficio 2 della DGISAN - Ministero della Salute - Viale G. Ribotta, 5 00144 Roma.**

The application should be sent through the Embassy of the company’s country, and, in case of need, a sworn translation into Italian should also be provided.

The requested documentation should include the following:

- Application form completed by the exporting Food Business Operator (FBO), together with a technical report concerning the main features of the production plant (**Form 2-a**);

- Statement of the local Competent Authority of the country of origin, through the Embassy in Rome, that the quick-frozen vegetables exported to Italy are produced in compliance with Council Directive 89/108/EEC, and that the legislation in force in the country of origin is equivalent to the EU legislation (**Form 2-b**).

- Receipt of 100,00 Euro payment on account postal number 11281011; account holder name  Tesoreria Provinciale dello Stato di Viterbo

The Office 2 DGISAN reviews the documentation, and has the right to ask for additional documents or call a meeting with the applicants. If the application is compliant with the provisions of this procedure, the Office 2 of the DGISAN, within thirty working days, issues an official letter to the Embassy of the country of origin and to all the USMAF, informing them of the completion of the notification procedure and acknowledging the establishment.

Any delay by the applicants in sending new data or additional documents, deemed necessary by the Ministry of Health to complete the procedure, causes the stop of the aforesaid timing.

DGISAN has the right to ask for an inspection of the establishment, carried out by qualified personnel of the Directorate, and the Food Business Operator responsible for the application shall be liable for the relevant costs for the staff involved in the official controls.

After the acknowledgment of the establishment, the Office 2 of DGISAN updates the list of notified establishments on the website of the Ministry of Health.

The list is sent every year to the Embassy of each country for revision and update.
5.2 *Roles and responsibilities*

The Director of the Office 2 DGISAN is the person in charge of the procedure for the recognition of the Third Country establishments producing quick-frozen food.

The technical managers of the Office are responsible of the examination of the technical documentation.

The administrative staff of the Office 2 DGISAN is responsible for the examination of the administrative documentation, for the final communication to the Embassy and to the USMAF, for the transmission to the website for the publication, and for the annual transmission for the update.

6.0 *Annexes and filing*

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**Access:**

A = Director of Office 2 DGISAN

B = Technical managers

C = Administrative staff

7.0 *Distribution*

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Form 2-a

APPLICATION FORM TO EXPORT QUICK-FROZEN VEGETABLES TO ITALY

The Company .................................................................................................................................
Located in (country) ......................................................................................................................
Producing ......................................................................................................................................
Has the intention to export to Italy the following quick-frozen vegetables
........................................................................................................................................................
To this effect, the main features of the production plant are summarized here below.

FOOD COMPANY

Activity __________________________________________

Name ________________________________________________

Address ______________________________________________________

.Owner or legal representative

Name/Family Name

DESCRIPTION OF THE EQUIPMENT USED FOR FOOD QUICK-FREEZING AND STORAGE

The equipment used to quick-freeze the food:
✓ Uses liquid nitrogen for quick freezing
✓ Uses a cold air flow (Air blast freezing)
✓ Uses a tunnel method
✓ Consists of vertical freezers
✓ Consists of horizontal plate freezers
✓ Consists of IQF freezers (Individual Quick Freezing)
✓ Undergoes a regular maintenance and periodic revision YES ☐ NO ☐
✓ The movement to the freezers for food storage is made through a stainless steel band belt YES ☐ NO ☐

The equipment for frozen food storage:
✓ Is controlled according to Regulation 37/2005 YES ☐ NO ☐
✓ Can guarantee a temperature constantly below -18°C (-0.4 Fahrenheit) YES ☐ NO ☐
✓ Has an easy to read thermometer or thermo-recorder, according to Regulation 37/2005 YES ☐ NO ☐
✓ The temperature of storage places and of means of conveyance is registered at regular intervals YES ☐ NO ☐
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**STRUCTURE AND EQUIPMENT**

The structures and equipment for food production and processing are kept clean, undergo regular maintenance, and are in good conditions in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs
(see Attachment 2-a)

**PROVISIONS APPLICABLE TO FOODSTUFFS**

Raw materials and finished products are accepted, processed, transformed, and stored, according to specific local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs.
(see Attachment 2-b)

**WATER SUPPLY**

The production plant has water supply procedures and systems in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs
(see Attachment 2-c)

**WASTE DISPOSAL**

All waste is eliminated in a hygienic and environmentally friendly way, in accordance with local laws and with Community legislation applicable to that effect, and in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs
(see Attachment 2-d)

**PREVENTION OF CONTAMINATION BY ANIMALS AND PESTS**

The manufacturing plant has procedures to prevent as far as possible animals and pests from causing contamination, in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs. For instance, windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production.

**GOOD HEALTH AND TRAINING OF STAFF**

The manufacturing plant ensures that staff handling foodstuffs are in good health and undergo training on health risks, in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs.
(see Attachment 2-e)
TRANSPORT

Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination, in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs.

(see Attachment 2-f)

YES ☐ NO ☐

PROVISIONS APPLICABLE TO THE WRAPPING AND PACKAGING OF FOODSTUFFS

Selection, management, and use of material used for wrapping and packaging are in compliance with local laws, equivalent to the conditions of Regulation (EC) 852/2004 on the hygiene of foodstuffs.

(see Attachment 2-g)

YES ☐ NO ☐

We hereby guarantee that the Italian Competent Health Authority has the right to organize official controls in the establishment through its qualified personnel, for the assessment of equivalence, and the applicant Food Business Operator is liable for the relevant costs.

Place, date Stamp and signature of the Legal Representative

IN CASE OF NEED, LIST OF THE ATTACHMENTS TO THE APPLICATION

(the attachments are optional and have only the aim to improve and complete the application)
Form 2-b

(HEADING OF THE COMPETENT AUTHORITY OF THE COUNTRY OF ORIGIN)

Through the Embassy of (Rome) .................................................................

The Company ................................................................. .................................................................
Producing ................................................................. .................................................................
Has declared its intention to export quick-frozen vegetables for human consumption to Italy

THIS IS TO CERTIFY

That the quick-frozen foodstuff exported to Italy is produced in compliance with the following principles of the reference EU regulations:

- Using wholesome food;
- With a deep freezing technology in compliance with Directive 89/108/CEE;
- In a manufacturing plant approved by the local competent authority;
- By personnel undergoing the necessary health controls;

and that the production of quick-frozen vegetables in the country of origin is carried out according to regulations equivalent to the EU regulations.

WE HEREBY GUARANTEE

That the Italian competent Authority has the right to organize official controls in the establishment through its qualified personnel, for the assessment of equivalence, and the applicant Food Business Operator is liable for the relevant costs.

Place, date  Stamp, signature
Attachment 2-a


(omissis)
ANNEX II
CHAPTER II

SPECIFIC REQUIREMENTS IN ROOMS WHERE FOODSTUFFS ARE PREPARED, TREATED OR PROCESSED

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
(a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;
(b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
(c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles; (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;
(e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate; and
(f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

PROVISIONS APPLICABLE TO FOODSTUFFS

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.

3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).

5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.

6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.

8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.
(omissis)
ANNEX II
CHAPTER VII
WATER SUPPLY

1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;
(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.
2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.
3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.
4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.
5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.
6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

(omissis)

ANNEX II

CHAPTER VI

FOOD WASTE

1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.
2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.
3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

(omissis)

ANNEX II

CHAPTER VIII

PERSONAL HYGIENE

1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.
2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

CHAPTER XII

TRAINING

Food business operators are to ensure:
1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and
3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.

(omission)

ANNEX II

CHAPTER IV

TRANSPORT

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked "for foodstuffs only".

5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.

6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.

7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.
(omissions)
ANNEX II
CHAPTER X

PROVISIONS APPLICABLE TO THE WRAPPING AND PACKAGING OF FOODSTUFFS

1. Material used for wrapping and packaging are not to be a source of contamination.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container’s construction and its cleanliness is to be assured.
4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

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Attachment 2-g