

Guidance Notes for imports of organic products according to Article 19 Regulation (EC) No. 1235/2008 from third countries into the European Union

All produce from third countries labelled as organic must conform to strict rules which cover all stages of production and processing. In the European Union (EU), the basic rules governing organic production, processing, export and import are laid down in Council Regulation (EC) n. 834/2007 as amended.

- Organic products from within the EU can be circulated freely in all EU-member states, provided they were produced, processed or imported in conformity with Regulation (EEC) n. 834/2007 as amended.
- The European Commission has recognised that a number of third countries operate production rules and inspection systems which are equivalent to those operating within the EU according to Article 32 (2) of Regulation (EC) n. 834/2007. These countries and products are listed in Annex III of Regulation (EC) n. 1235/2008. Approved products from these countries, provided they have been inspected and certified by one of the approved control bodies, may be brought freely into the EU and marketed as organic.
- The European Commission will establish lists of approved control bodies operating in third countries according to Article 32 (2) and 33 (3) of Regulation (EC) n. 834/2007. The application and approval process was started on 1/1/2009. No control bodies operating in third countries were approved by the European Commission yet.
- As a transitional rule, products from all other third countries except those being listed in Annex III of Regulation (EC) n. 1235/2007 can be brought into the EU and labelled as organic, provided prior authorisation of your competent authority according to article 19 of Regulation (EC) n. 1235/2007 has been obtained.

Guidance for the importers of organic products from third country

Step 1 - Registration and inspection of the importer in the EU

You need to be registered with your competent EU-authority and an inspection of an approved EU control body must demonstrate your compliance with the conditions laid down in Regulation (EC) n. 834/2007 as amended. Please contact the competent authority to obtain further information (in Italy: Ministero delle Politiche Agricole Alimentari e Forestali – Ufficio Agricoltura Biologica).

Step 2 - Import from a third country listed on the third countries list (Annex III of Regulation (EC) n. 1235/2007) or from another third country?

A. Third countries list: imports from third countries recognised by the European Commission for the export of organic produce

The European Commission has recognised that a few third countries operate production rules and inspection systems equivalent to those operating within the EU. These countries, the products, and their inspection bodies or inspection authorities issuing the certificates of inspection are listed in Annex III of Regulation (EC) n. 1235/2007 as amended.

Imports of the specified organic products into the EU are permitted without prior approval from the

competent EU-authorities provided that each consignment of the imported product is accompanied by an inspection certificate according to Annex V of Regulation (EC) n. 1235/2007 issued by one of the approved control bodies or control authorities from the third country listed in the Annex III of Regulation (EC) n. 1235/2007 as amended.

You do not need to complete an “Initial Application to market in the EU organic products from third Countries according to Article 19 of Regulation (EC) n. 1235/2008”.

B. Import Authorizations: Imports from third countries which have NOT been recognised by the European Commission for the export of organic produce

Until 1 January 2013, importers may market in the EU, organic products from a third country not listed in the Annex III of Regulation (EC) n. 1235/2008 as amended provided they have been authorised by the competent authority in the Member State. The rules for importing produce from these countries are set out in Article 19 of Commission Regulation (EC) n. 1235/2008.

Before authorisation is given, importers must demonstrate to their competent EU-authority that:

- The product has been produced in accordance with production rules equivalent to those laid down in Title III and IV Council Regulation (EC) n. 834/2007 as amended; and
- The operators have been subject to control measures of equivalent effectiveness to those referred to in Title V of Council Regulation (EC) n. 834/2007 as amended and those control measures have been permanently and effectively applied.

To obtain an authorisation, you must first complete an “Initial Application to market in the EU organic products from third Countries according to Article 19 of Regulation (EC) N. 1235/2008”. The authorization validity will be maximum for 12 months.

Step 3 Certificate of inspection for import of products from organic production (Annex V of Regulation (EC) n. 1235/2008)

Before any imported organic products from third countries may be cleared into free circulation in the EU, a certificate of inspection for import of products from organic production must be endorsed by the custom authorities in the Member State. The certificate of inspection must be drawn up by the control body in the third country.

It shall accompany the goods and it must be presented before they can be cleared into free circulation. The customs authority will carry out a documentary check before they endorse the certificate. They will check that an authorisation to import organic produce has been issued. It is therefore important that you apply for an authorisation to import produce in time.

How to complete the application form to import into the EU organic products from third Countries according to Article 19 of Regulation (EC) n. 1235/2008

- The application form may be completed by computer or using block letters and black ink.
- All applications must bear an original signature.
- Faxed or emailed applications will not be accepted.
- You may apply for more than one product on an application form, BUT
 - A separate form is needed for each third country from which products are to be imported
 - A separate form is needed for each exporter used
- Applications will not be processed until all the necessary information has been supplied in writing. Applications must not be submitted until all the supporting documentation has been obtained. Incomplete applications will be returned.
- It is the responsibility of the applicant to provide all of the details and supporting documentation.

Section 1 - Details of the importer

This section should be completed with details of the company applying to import organic products into the EU.

Question 1

You must give details of the following:

- the company name
- the full postal address, including postcode
- the name of a contact (the person dealing with the application). We may need to ask further questions or request more information.
- the telephone and fax number, including national dialling code of the contact
- the contact's email address (where available)

Question 2

In order to import products into the EU and market them as organic, importers must be registered with one of the approved EU inspection bodies. You must give the following details:

- the name of your control body
- your registration number with the control body

Section 2 – Details of the product(s) to be imported

In this section, you must provide details of the organic product or products you wish to import.

Question 3

Give the name of the third country from which the organic products are to be exported. A separate form must be used for each third country from which organic products are to be exported.

Moreover, you must indicate the customs entry points through which the imported product it is intended to be put into free circulation, and the first acceptance warehouse, directly connected with the above mentioned entry point, chosen among those in Section D of the organic activity notification. In case of multiple entry points, and related acceptance warehouse, details of each of them must be indicated in an attached document. In this case it is necessary to tick the appropriate box.

Question 4

- In the column marked “Product description” you must list the product(s) to be imported. You must give full details of the products – for example, it is not sufficient to write “various herbs and spices”; you must list the name of each herb and spice (for example, basil, dill, parsley, cardamom). In addition, you should not use the name by which the product is to be marketed, but rather the description of the composition of the product. For example, “Grandma’s traditional cornflakes” should be described as toasted flaked corn.
- Only for unprocessed agricultural products from plant origin: you must give the “scientific name” of the species.
- In the column marked CN-Code you have to fill in the corresponding code. You might consult customs authorities for further assistance.
- In the column marked In conversion (C), organic (O) you should qualify the status of the product(s). If the conversion period has been undergone and the control body in the third country indicates on its certificate that the products are fully organic, please use “O”. If the product is still in conversion, please use “C”. In both cases indicate month and year when the conversion period started.

- In the column marked “Estimated annual quantity”, you must give an estimate of the quantities of each product that you expect to import each year. You must specify which SI-unit you are using. If you are importing a product that is processed and composed of more than one ingredient, you must give details of its composition. This must be done on Annex A of the form. You should use a separate Annex A for each product and attach a product label to it.

Section 3 – Details of the exporter in the third country

In this section you must give details on the company that is exporting the products.

Question 5

You must give details of the following:

- the company name
- the full postal address, including postcode and third country
- the name of a contact
- the telephone and fax number, including international dialling code of the contact
- the contact's email address (where available)

Question 6

You must give the following details:

- the name of the control body of the exporter
- the date of the last inspection of the exporter
- the full postal address, including postcode and third country
- the name of a contact
- the telephone and fax number, including international dialling code of the contact
- the contact's email address (where available)

Please enclose to your application a confirmation of a third party that the control body is fulfilling the requirements of ISO 65 / EN 45011.

Please also attach to your application an explanation of the exporter’s control body how equivalence of the production rules and inspection measures is assessed by this body for the prior preparation/processing and agricultural production of the organic product. This point is of particular relevance if different control bodies in the third country/countries are involved.

Question 7

Occasionally, a different body to that detailed in Question 6 issues the certificates for inspection. If this is the case you must provide details of:

- the company name of certification body
- the full postal address, including postcode and third country
- the name of a contact
- the telephone and fax number, including international dialling code of the contact
- the contact's email address (where available)

If the certifying body is the same as the control body (the organisation listed in Question 6), write N/A (for not applicable) in the box.

Section 4 – Details of the operator carrying out the most recent preparation operation in the third country

According to Article 2 (i) of Regulation (EC) n. 834/2007 as amended, the term “*preparation*” means the operations of preserving and/or processing of organic products, including slaughter and cutting for livestock products, and also packaging and/or alterations made to the labelling concerning the organic production method”.

The operator carrying out the most recent preparation operation in the third country usually packs the product and attaches its labels. In this section you must give details on this company. If this

company and the exporter are the same, please tick the corresponding box, in this case you do not need to complete section 4.

Question 8

You must give details of the following:

- the company name (carrying out the most recent preparation/operation in the third country)
- the full postal address, including postcode and third country
- the name of a contact
- the telephone and fax number, including international dialling code of the contact
- the contact's email address (where available)

Question 9

You must give the following details:

- the name of the control body of the operator indicated in the question 8
- always the date of the last inspection of the operator

Please tick the corresponding box if the control body for the processing/preparation unit carrying out the most recent preparation operation is the same as for the exporter. You do not need to fill in the name. Please enclose to your application a confirmation of a third party that this control body is fulfilling the requirements of ISO 65 / EN 45011.

Section 5 – Details of the preparation/processing and agricultural production unit(s) in the third country

Please check if more than three preparation/processing companies and/or five agricultural holdings in third countries have been involved to the production and/or processing of the organic product you wish to import into the EU. If this is the case, you do not have to answer the questions 10 and 12. Please attach a flowchart containing (see example below) the necessary information and indicating the product flow from agricultural production to export.

Question 10

You do not need to fill in this item if you have attached a flowchart.

If not, you must give details in this section if the products are going to be processed or prepared in any way (including packing and labelling).

This section has been divided in boxes A, B and C so that you can provide details on more than one processing/preparation unit.

- In the column marked “*Name and address*” you must give details of the plant or unit where the products are to be prepared or processed. In many cases it will be the same place as the holding where it was produced. You must give the full address.
- In the column marked “*Third country*” you must specify the third country where the plant or unit is located.
- In the column marked “*Date of last inspection*” you must specify when the holding(s) were last inspected by the third country control body.
- In the column marked “*Type of processing*” you must specify the processing process and the product in this particular plant or unit.
- In the column marked “*Control body*” you must specify the body inspecting this particular plant or unit. Please tick the corresponding box if the control body for the processing/preparation unit is the same as for the exporter. You do not need to fill in further information. In all other cases, please specify the name and address of the control body and its proof of ISO 65 / EN 45011 compliance. Please also attach the confirmations or accreditation certificates for the body as available. Please attach copies of the certificates issued by the third countries control body/bodies for the different processing/preparation unit(s).

Question 11

Please provide a list of the differences with regard to the production rules and control measures concerning processing/preparation. This might be done by contacting the control body of the exporter.

Question 12

You do not need to fill in this item if you have attached a flowchart.

If not, you must complete the table with certain information about the agricultural unit(s) where the products were produced. An agricultural unit might be a farm or a small-scale farmer grower group. The details must be completed even if you are importing a processed product.

This section has been divided so that you can provide details on more than one holding.

- In the columns marked “*Name and address*” you must give details of the units where each of the products were grown/produced. The name might be of the actual farm or holding, the company that owns it or the actual producer, depending on the circumstances. You must give the full address and the third country where the unit is located.

- In the box marked “*Organic and conventional area*” you must give the area of the land on the entire holding which is certified for organic production and which is managed conventionally. You must also indicate the areas in conversion. Please give the area in hectares.

- In the box marked “*Start of conversion period*” you must specify the date when the conversion period for land certified for organic production started. All land used for organic production must have undergone a conversion period. The length of time varies depending on the product produced and the individual circumstances; however, the usual minimum is two years before sowing for annual crops or three years before harvest for perennial crops. If a reduced conversion period has been granted by the control body, you must provide an explanation from that control body as to why they felt they were able to reduce the conversion period.

- In the box marked “*First inspection date*” you must give the date when the holding(s) were first inspected by the third country control body. If the first inspection was not carried out by the current control body, please give the name of the body that carried out the inspection.

- In the column marked “*Last inspection date*” you must give the date when the holding(s) were last inspected by the third country control body.

- In the box marked “*Products produced*” you must list **all** of the products that the holding produces including their status (conventional/in conversion/organic). You should include all of the products produced, not just those that you wish to import.

- In the column marked *Control body*, you must specify the body inspecting the particular unit. Please tick the corresponding box if the control body for the agricultural production unit is the same as for the exporter. You do not need to fill in further information. In all other cases, please specify the name and address of the control body and its proof of ISO 65 / EN 45011 compliance. Please also attach the confirmations or accreditation certificates for the body as available.

Please attach copies of the certificates issued by the third countries control body/bodies for the different agricultural production unit(s).

Question 13

If a co-operative, a grower group or contract growers produce the products, you must tick the *Yes* box and fill in Annex B.

Please provide a list of the differences with regard to the production rules and inspection measures concerning agricultural production. This might be done by contacting the control body of the exporter.

Section 6 – Supporting documentation

Question 14

Please indicate which inspection reports are available on request of your competent authority.

Section 7 – Declarations

Once you have read these guidance notes and completed your application form, please send it **unsigned** either via e-mail, fax or mail to the control body of the exporter. This control body must sign the declaration part 7.1 and stamp or sign all pages of the application form in the corresponding boxes (*stamp or signature of the control body responsible for the exporter*). Afterwards, the control body of the exporter returns an original application form (no photocopy) to you.

Finally, please sign and date the declaration part 7.2, attach all the necessary supporting documentation and send the form and supporting documentation to Competent Authority (In Italy: Ministero Politiche Agricole Alimentari e Forestali – Ufficio Agricoltura Biologica – Via XX settembre, 20 – 00187 ROMA)

We advise you to keep a copy of your application for future reference.

Completing Annex A for multi-ingredient products

This Annex should only be completed if you apply to import products containing more than one ingredient. A separate sheet must be completed for each multi-ingredient product you wish to import.

- In the box “*Name of ingredient*” you must give the names of the ingredients included in the categories indicated in the first column (“organic agricultural ingredients”, “non-organic agricultural ingredients”, “products and substances for use in production of processed organic food”).
- In the third column “% weigh” you must give the percentage by weight at time of processing referred to each one of the ingredients listed in the second column.

For each annex A you must attach the label for any multi-ingredients products.

Completing Annex B – Grower Groups

This Annex should be only completed if grower groups of smallholder producers are involved in the agricultural production. If more than one grower group is involved, please provide a sheet for each group. We recommend to contact the relevant control body in the third country to obtain the necessary information.

Question 15

Please specify the type of the smallholder group. Tick the corresponding box or give a detailed explanation. The number of small-scale farmers in the group at the date of last inspection must be indicated.

Question 16

The question covers different aspects of a so-called internal control system (ICS), if a grower group is involved. Prerequisite for this is that either all small-scale farmers have been inspected by a control body or an internal control system has been introduced and implemented in the grower group. The typical documentation of an internal control system consists of contracts between each farmer and the group, descriptions for all farms, that produce organically within the co-operative, furthermore internal inspection reports and a documentation of the internal sanctions, that are applied to farms which do not (totally) satisfy the requirements. All small scale farms must be internally controlled at least once a year. The external control body checks the documentation and effectiveness of this system and selects a spot check of farms for inspection. The quota of the inspected farms depends, among other reasons, on the quality of the internal control. Please tick the corresponding box. If “Yes” is marked, please provide a reference to the page number of the last

external inspection report. This report must be made available to your competent EU-authority on request and before taking the final decision on your application.

Question 17

Please specify the number and the percentage of small scale farmers inspected externally at the date of last inspection. Please tick the corresponding box. If “Yes” is marked, please provide a reference to the page number of the last external inspection report. This report must be made available to your competent EU-authority on request and before taking the final decision on your application.

Example of flowchart

