

# **Guidance Notes for importers (authorized by the Danish Agricultural Agency) of organic products from third countries into the European Union pursuant to Regulation (EC) No. 834/2007**

## **1 Introduction**

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, storage, marketing and import are laid down in:

- **Regulation (EC) No. 834/2007 as amended**
  - **Regulation (EC) No. 889/2008 as amended** and in
  - **Regulation (EC) No. 1235/2008 as amended**
- Organic products within the EU may be freely circulated in all EU member states, provided they have been produced, processed or imported in accordance with the provisions of the EU organic production method.
  - The European Commission has recognized that a number of third countries apply production rules and inspection systems equivalent to those applied in the EU. These countries, their equivalent production and recognized inspection bodies are listed in Annex III to Regulation (EC) No. 1235/2008. Approved products from these countries, provided they have been inspected and certified by one of the approved inspection bodies, may be brought freely into the EU and marketed as organic.
  - The European Commission will establish lists of approved inspection bodies operating in third countries according to Article 32(2) and 33(3) of Regulation (EC) No. 834/2007. The application and the approval process were started on 1 January 2009. However, no inspection body operating in third countries has been approved yet.
  - As a transitional rule, products from all other third countries, except those listed in Annex III of Regulation (EC) No. 1235/2007, can be brought into the EU and labelled as organic, provided their import has been authorized by a competent authority pursuant to Article 19 of Regulation (EC) No. 1235/2007. In Denmark, these competent authorities are the Danish Agricultural Agency for feedstuffs and seeds and the Danish Veterinary and Food Administration for food.

## **2 Step by step guide for importers of organic products from third countries into the EU**

### **Step 1:**

#### **Registration and inspection of the importer in Denmark**

Importers of organic feed and seeds from third countries have to be authorized by the Danish Agricultural Agency.

### **Step 2:**

#### **Import from a third country as set out in the list of third countries (Regulation (EC) No. 1235/2008) or from any other third country**

#### **A. Imports of organic products into the EU from third countries approved by the European Commission**

The European Commission has recognized that a number of third countries apply production rules and inspection systems equivalent to those applied in the EU. These countries, the product categories, and their inspection bodies or inspection authorities issuing the certificates of inspection required for exports are listed in Annex III of Regulation (EC) No. 1235/2008 (list of third countries).

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 products is accompanied by an inspection certificate according to Annex V of Regulation (EC) No. 1235/2008 issued by one of the approved inspection bodies or inspection authorities from the third country listed in Annex III of Regulation (EC) No. 1235/2008.

Marketing of organic products from third countries set out in the list of third countries does not require an application for marketing authorization pursuant to Articles 33 and 40 of Regulation (EC) No. 834/2007 and Article 19 of Regulation (EC) No. 1235/2008.

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

## **B. Import Authorizations: Imports from third countries that are not listed in the third country list (Annex III of Regulation (EC) No. 1235/2008)**

Until 1 January 2013, importers may market organic products from a third country not listed in the Annex III of Regulation (EC) No. 1235/2008 provided they have been authorised by the competent authority in the EU Member State. The rules for importing produce from these countries are set out in Article 19 of Regulation (EC) No. 1235/2008.

Before authorisation is granted, importers must demonstrate to their competent authority that

- The product has been produced in accordance with production rules *equivalent* to those laid down in the EU organic legislation.
- The operators have been subject to inspection measures of *equivalent effectiveness* to those referred to in the EU organic legislation and that those inspection measures have been applied *permanently and effectively*.

This procedure has not been changed yet. It is foreseen in the new legislation that the EU Commission will publish lists of recognized inspection bodies and inspection authorities that will be authorised to perform inspection to complying and equivalent production rules. Until publication of these lists and implementation of the new procedure, a transitional procedure will apply. This transitional procedure corresponds to the “old procedure” pursuant to Article 11 (6) of Regulation 2092/91. The Agricultural Agency will continue issuing authorisations up to 12 months after the publication of the lists of recognised inspection bodies.

In order to obtain an import authorisation the importer must first file an “Initial Application to market organic products from third countries in the EU according to Article 19 of Regulation (EC) 1235/2008” accompanied by relevant documentation (certificates, inspection reports etc.) to the Danish Agricultural Agency. Applications will not be backdated or granted retrospectively. It is essential to apply for authorisation before importing organic products. Imported organic products may only be marketed after a valid import authorisation has been issued by the Danish Agricultural Agency. Authorisations are usually granted for a specific shipment and valid for a period of 12 months.

### **Step 3:**

#### **Certificate of inspection for the import of agricultural products from organic production (Regulation (EC) No. 1235/2008)**

The “Certificate of inspection for import of products from organic production into the European Community” must be drawn up by the inspection body or inspection authority in the third country and shall accompany the shipment to Europe. Often it is sent electronically beforehand. However, before imported organic products from third countries may be cleared into free circulation in the EU, it must be acknowledged by the Danish Agricultural Agency and endorsed to the custom authorities in Denmark.

This applies to all imports of organic products from third countries.

### **3 How to complete the application form: “Initial Application to market organic products from third countries in the EU according to Article 19 of Regulation (EC) 1235/2008”**

#### **General considerations**

- The application form may be scanned and forwarded electronically as an Adobe Acrobat PDF file.
- All applications must bear original stamps and signatures when scanned.
- You may apply for more than one product, **BUT** a separate application must be filed in for each third country from which products are to be imported and a separate application must be filed in for each exporter.
- Please only submit the application forms when all required supporting documentation can be enclosed.
- It is the responsibility of the applicant to ensure that all information and documents are submitted.
- Applications can only be processed after all necessary information has been provided.

## Section 1 – Details on the importer

This section contains information on the company applying for authorisation to import organic products into the EU.

You must give details of the following:

- Company name
- Full postal address, including postal code
- Name of a contact person dealing with the application. We may need to ask further questions and request more information.
- Phone and fax number, including national dialling code
- Email address of the contact person (where available)
- Certification number given by the Danish Agricultural Agency

In order to import products into the EU and to market them as organic, importers *must* be registered and certified by one of the recognized inspection bodies or inspection authorities in the EU.

## Section 2 – Details on the first consignee in the EU

In this section, you can provide details of the first consignee, if it is going to be a different company or unit than the importer. It is however sufficient to hand in information about the first consignee together with the “Certificate of inspection for import of products from organic production into the European Community”.

If you already know the first consignee, you might provide the following details:

- Company name
- Full postal address, including postal code
- Name of a contact person dealing with the application. We may need to ask further questions and request more information.
- Phone and fax number, including national dialling code
- Email address of the contact person (where available)
- Certification number

Organic products may only be stored and handled by certified organic companies. If the first consignee is certified by a different the inspection body or inspection authority (not the Danish Agricultural Agency), then the following details must be provided:

- Name of the inspection body or inspection authority
- Full postal address, including postal code and country
- Name of a contact person
- Phone and fax number, including national dialling code
- Contact's email address (where available)

## Section 3 – Details on the product(s) to be imported

In this section you must provide details on the organic product or products you wish to import. Indicate the name of the third country from where the organic products are to be imported. You cannot use the same application for different third countries. A separate application form must be used for each third country.

In the column marked *English name* the products to be imported must be listed. You must give full details of the products. It is not sufficient to state “*various herbs and spices*”. The names of each herb and spice must be given (for example: basil, dill, parsley). If the list is going to be too long, it can also be attached to the application in a separate document. Only for unprocessed agricultural plant products, in particular in the case of herbs and spices, the scientific botanical names must also be stated in the next column.

If the product consists of more than one ingredient, or if a product has been processed, details on its composition must be given in Annex A. Please use a separate form (Annex A) for each product and attach a product label to it.

In the column marked *CN-Code*, please enter the relevant number of the customs tariff nomenclature. The latest edition of the combined nomenclature can be found her:

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 inspection body or inspection authority in the third country has certified the products as organic, please enter "O". If the products are in conversion products, please enter "C", and indicate month and year when the conversion period has started (e.g. 05/2002).

In the column marked *Annual quantity* an estimate of the quantity that is expected to be imported per year must be entered for each product. Please specify the unit of quantity you are using.

#### **Section 4 – Details on the exporter in the third country**

You must give details on the enterprise exporting the products from the third country:

- Company name
- Full postal address, including postal code
- Name of a contact person dealing with the application. We may need to ask further questions and request more information.
- Phone and fax number, including national dialling code
- Email address of the contact person (where available)
- Certification number given by the inspection body or inspection authority in the third country

The information requested must be given in full.

- Name of the inspection body or inspection authority of the exporter
- Date of the last inspection
- Full postal address, including postal code and third country
- Name of a contact person
- Phone and fax number, including national dialling code
- Contact's email address (where available)

The information requested must be given in full.

Please enclose a confirmation by an independent third party stating that the inspection body in the third country is fulfilling the requirements of ISO 65 or EN 45011 for carrying out inspections pursuant to Regulation (EC) No. 834/2007. Usually this will be a certificate of accreditation (option 1). Alternatively this may be a certificate issued by the competent authority in the third country, supervising the inspection body in the third country (option 2), or by a competent EU authority (option 3). Institutions issuing accreditations should be members of one of the international accrediting organisations, *International Accreditation Forum, (IAF)* or *European Cooperation of Accreditation (EA)*.

Please attach to your application an explanation of the exporter's inspection body or inspection authority on how equivalence of the production rules and the inspection is assessed, all the way from the primary producer (farmer) to the processor of the products. This is of particular importance where several inspection bodies or inspection authorities in the third country are involved. Please provide details of all inspection bodies or inspection authorities involved:

- Name of the inspection body or inspection authority
- Full postal address, including postal code and country
- Name of a contact person
- Phone and fax number, including national dialling code
- Contact's email address (where available)

#### **Section 5 – Details of the operator having carried out the most recent preparation in the third country**

Pursuant to Article 2 (i) of Regulation (EC) No. 834/2007 the term *preparation* means:

*Preserving and/or processing of organic products, including slaughtering and cutting in the case of animal products, packaging, labelling and/or altering of the labelling concerning the organic production method."*

The operator carrying out the most recent preparation in the third country usually also packs and

labels the products.

In this section you must provide information on this company. If it is identical with the exporter, please tick the appropriate box. In this case you do not have to complete Section 5.

- Company name
- Full postal address, including postal code
- Name of a contact person dealing with the application. We may need to ask further questions and request more information.
- Phone and fax number, including national dialling code
- Email address of the contact person (where available)
- Certification number

The information requested must be given in full.

Please tick the box, if the inspection body or inspection authority of the production or processing unit that has undertaken the most recent preparation is the same as that of the exporter. In this case it will not be necessary to fill in the name.

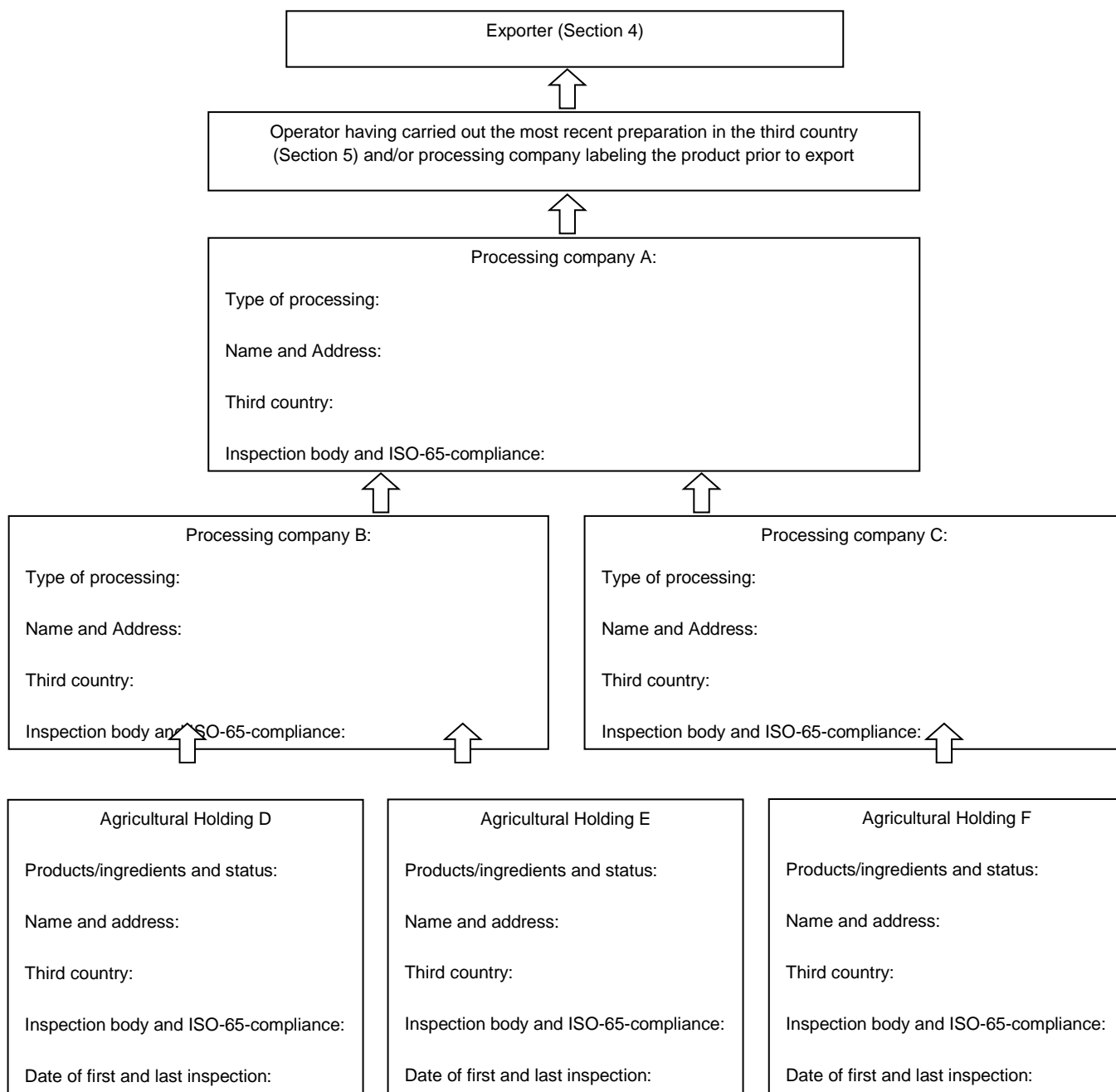
If the production or processing unit is inspected by a different inspection body or inspection authority, please enclose a confirmation by an independent third party with your application, stating that the inspection body in the third country complies with the requirements of ISO 65 or EN 45011. Usually this will be a certificate of accreditation (option 1). Alternatively this may be a certificate issued by the competent authority in the third country supervising the inspection body (option 2) or an approval by a competent EU authority (option 3).

### **Section 6 – Details of the production/processing unit(s) in the third country**

Please tick the box below and enclose a flowchart, if **more than three production or processing units** and/or **more than five agricultural holdings** in third countries have been involved in the production and/or processing of the organic products. In this case information on point 11 and 13 will not be required. Please enclose a **flowchart** giving all relevant information and indicating the product flow from agricultural production to export (see example).

Instead of giving the name and address of the units you may also state code numbers. In this case the applicant/importer will have to ensure that the certifying inspection body forwards the decoded data to the Danish Agricultural Agency without delay.

### Example of a flowchart



Instead of using the flowchart you can also choose to fill in point 11.

Please indicate:

- Name and address of the production or processing units
- Third country where the unit is located
- Type of production or processing (also packing and labelling)
- Information on the inspection body or inspection authority
- Date of last inspection

Please enclose copies of the different certificates!

By using subsections A, B and C you can provide details on more than one production or processing unit.

If the production rules (organic standards) and inspection measures applied in the third country differ from the rules laid down in EU organic legislation, please tick the appropriate box in point 12. Please enclose a detailed list stating differences in production rules and inspection measures with regard to

production or processing. You should be able to get this information from the inspection body or inspection authority of the exporter.

If you have not enclosed a flowchart, you have to fill in point 13. If you choose to fill in this section you will have to provide some information in the table on the agricultural units where the products have been produced. An agricultural unit may be a farm or a small-scale farmer grower group. This information must be provided even if you are importing a processed product.

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

- In the box marked **Name and address**, you must give details on the unit 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 complete address and the third country.
- In the box marked **Organic and conventional area**, you must give the area of the entire holding that has been certified for organic production and the area of land managed conventionally. Please indicate in **hectares**.
- In the box marked **Start of conversion period**, you must specify the date when the conversion period for the certified land started. All land used for organic production must undergo a conversion period. The usual conversion period is two years before sowing for annual crops or three years before harvest for perennial crops, with the exception of grassland. Only after the conversion period has ended, may the harvest be marketed as organic products. If the inspection body or inspection authority has granted a reduction of the conversion period, the reason for this reduction must be stated.
- In the box marked **Date of first inspection**, you must indicate when the unit was first inspected by the inspection body or inspection authority. If the first inspection was not carried out by the current inspection body, please indicate the name of the inspection body that carried out the first inspection.
- In the space marked **Date of last inspection** you must give the date when the holding was last inspected.
- In the space marked **Products produced/Status** all products produced on one holding and their status must be listed (conventional, in conversion, organic). The total range of products should be listed, not only those that you actually wish to import.
- In the space marked **Inspection body** you must indicate the inspection body responsible for inspecting this particular farm. Please tick the box, if the inspection body of the agricultural holding is the same as that of the exporter. In that case you are not required to provide further information. In any other case please state the name and address of the inspection body of the agricultural holding and proof of compliance with ISO 65/ EN 45011 (state 1 for option 1; 2 for option 2; 3 for option 3). Please also enclose the confirmation or certificate of accreditation for this body as available.

Please attach copies of the certificates issued by the third country inspection body/bodies for the different agricultural holdings.

If the products are produced by a co-operative, grower group or contract growers please tick **YES** in point 14 and complete **Annex B**.

If the production rules (organic standards) and inspection measures applied in the third country are different to those laid down in EU organic legislation, please tick the corresponding box. Please provide a list of the differences in the production rules and inspection measures concerning agricultural production. This can be done by contacting the inspection body of the exporter.

## **Section 7 – Supporting documentation**

Please indicate which inspection reports are available on request of the Danish Agricultural Agency.

## **Section 8 – Declarations**

Once you have read these guidance notes and completed the application form, please sign it in point 17 and forward it to the inspection body of the exporter. The inspection body of the exporter must sign the declaration in point 16 and stamp it. The inspection body of the exporter may scan the signed document into Adobe Acrobat PDF format and email it back to you.

You may then forward the completed application form by email to the Danish Agricultural Agency. Please enclose all available supporting documentation.

If it is not possible for you to forward the application by email, you may endorse the paper version to the Danish Agricultural Agency:

The Danish Agricultural Agency  
Customers & Production  
Area Control  
Organic Farming  
Augustenborg Slot 3  
DK – 6440 Augustenborg  
Denmark

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

### **Annex A – Only for used in case of compound products containing more than one ingredient and/or utilisation of processing aids**

**This Annex needs only to be completed, if you apply for importation of compound products containing more than one ingredient.**

A separate Annex sheet must be completed for each multi-ingredient product you wish to import.

- In the space marked **Name of the product**, please state the exact name of the product to be imported. Please do not state only the brand name of the product.
- In the box marked **Organic agricultural ingredients**, you must list the ingredients which have been grown or produced to organic standards. In the third column you must give a breakdown of ingredients by percentage of dry weight. A percentage must be indicated for each of the ingredients listed.
- In the box marked **Non-organic agricultural ingredients**, you must list the ingredients which have not been grown or produced to organic standards. In the third column, you must give a breakdown of ingredients by percentage of dry weight. A percentage must be indicated for each of the ingredients listed.
- In the box marked „**Ingredients of non-agricultural origin**“, you must list any food additives, flavourings, water, salt, micro-organism preparations and minerals used. In the fourth column, you must give a breakdown of ingredients by percentage of dry weight. A percentage must be indicated for each of the ingredients listed.
- In the box marked **Processing aids and other products used**, you must list any other substances used during processing.

### **Annex B – Producer groups**

**This Annex must only be completed if the producer groups are involved in the agricultural production. Where more than one producer group is involved, please use a separate Annex sheet for each group.**

We recommend that you contact the inspection body in the third country in order to obtain the necessary information.

Please specify the type of group. Tick the appropriate box in point 18 or provide a detailed explanation. The number of small producers in the group at the date of the last inspection must be indicated.

It is a condition for the recognition of an association of producers that either each small producer will be inspected by the external inspection body or that an internal inspection system has been introduced and implemented for the association of producers. Item 19 covers different aspects of the internal control system (ICS) that is applied where an association of producers is involved.

A typical documentation of an internal control system consists of:

- A contract between each individual farmer and the group,
- Business descriptions for each farm in the cooperative producing organic products,
- Internal inspection reports in writing,
- Documentation of internal sanctions applied to farms that do not (fully) satisfy the requirements.



All small producers must undergo internal control at least once a year. When inspecting the group the external inspection body will check documentation and the effectiveness of this system and will carry out random on-the-spot inspections of farms. The proportion of farms undergoing on the-spot inspections depends, among other things, on the quality of the internal control.

Please tick the appropriate box. If marking **Yes**, please provide a reference to the page in the last external inspection report. This report must be submitted to the Danish Agricultural Agency upon request and before taking the final decision on your application.

Please specify the number and percentage of small scale farmers inspected externally at the last inspection.

Please tick the appropriate box. If marking **Yes**, please provide a reference to the page in the last external inspection report. This report must be submitted to the Danish Agricultural Agency upon request and before taking the final decision on your application.

If requested by the Danish Agricultural Agency, the inspection body in the third country must also provide a detailed report in accordance with the *Guidance document for evaluating the equivalence of certifying systems as applied in developing countries by producer groups using organic production methods*.

#### **4 Renewal of an import authorization: How to complete the application form for a renewed permit to import organic products from a third country into the EU according to Article 19 of Regulation (EC) No. 1235/2008**

##### **Eligibility of the request:**

An import authorisation can only be renewed when all following conditions are fulfilled:

- Same operators,
- Same inspection body or inspection authority,
- Same products or a reduced list,
- Same locality of production or reduced area,
- Same units of production/processing with the same methods, and
- Continuity in time for the renewal (no time laps).

##### **Section 1 – Details of the importer**

This section should be completed with details of the company applying to import organic products into the EU. Please indicate any changes in the address or contact information given previously with the initial application. You must give the company name and any changes of the following:

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

##### **Section 2 – Details of the import authorization**

In this section, you have to provide some of the details of the import authorization that has to be renewed.

You have to provide details of the following:

- The reference number of the import authorization previously granted
- The third country where the products are to be imported from
- The exporter
- The inspection body of the exporter

You may enclose inspection reports.

##### **Section 4 – Declarations**

Once you have read these guidance notes and completed the application form, please sign it and forward it to the inspection body of the exporter. The inspection body of the exporter must sign their

declaration and stamp it. The inspection body of the exporter may scan the signed document into Adobe Acrobat PDF format and email it back to you.

You may then forward the completed application form by email to the Danish Agricultural Agency. Please enclose all available supporting documentation.

**[jordbrugskontrol@lbst.dk](mailto:jordbrugskontrol@lbst.dk)**

If it is not possible for you to forward the application by email, you may endorse the paper version to the Danish Agricultural Agency:

The Danish Agricultural Agency  
Customers & Production  
Area Control  
Organic Farming  
Augustenborg Slot 3  
DK – 6440 Augustenborg  
Denmark

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