

## Section 11 – SOPA Inspection Procedures

### 11.1 Adherence to the control system

- 11.1.1 Any operator who produces, prepares, stores, or imports from a third country organic products or who places such products on the market shall, prior to placing on the market any products as organic or in conversion to organic:
1. Notify his activity to the competent authorities of the Member State, such as SOPA/SFQC where the activity is carried out.
  2. Submit his undertaking to the control system referred to in this section.
- 11.1.2 The first subparagraph shall apply also to exporters who export products produced in compliance with the production rules laid down in these Standards.
- 11.1.3 Where an operator contracts out any of the activities to a third party, that operator shall nonetheless be subject to the requirements referred to in points (a) and (b), and the subcontracted activities shall be subject to the control system.
- 11.1.4 Defra exempts from the application of this Article operators who sell products directly to the final consumer or user provided they do not produce, prepare or store other than in connection with the point of sale or import such products from a third country or have not contracted out such activities to a third party.
- 11.1.5 SOPA/SFQC shall keep an updated list containing the names and addresses of operators under their control. This list shall be made available to the interested parties.

### 11.2 Control arrangements and undertaking by the operator

- 11.2.1 When the control arrangements are first implemented, the operator shall draw up and subsequently maintain:
1. A full description of the unit and/or premises and/or activity.
  2. All the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules.
  3. The precautionary measures to be taken in order to reduce the risk of contamination by unauthorised products or substances and the cleaning measures to be taken in storage places and throughout the operator's production chain. Where appropriate, the description and measures provided for in the first subparagraph may be part of a quality system as set up by the operator.
- 11.2.2 The description and the measures referred to in paragraph 1 shall be contained in a declaration, signed by the responsible operator. In addition, this declaration shall include an undertaking by the operator:
1. To perform the operations in accordance with the organic production rules.
  2. To accept, in the event of infringement or irregularities, the enforcement of the measures of the organic production rules.
  3. To undertake to inform in writing the buyers of the product in order to ensure that the

indications referring to the organic production method are removed from this production.

- 11.2.3 The declaration provided for in the first subparagraph shall be verified by the control body or control authority that issues a report identifying the possible deficiencies and non-compliances with the organic production rules. The operator shall countersign this report and take the necessary corrective measures.
- 11.2.4 For the application of Article 28(1) of Regulation (EC) No 834/2007 the operator shall notify the following information to SOPA/SFQC.
1. Name and address of operator.
  2. Location of premises and, where appropriate, parcels (land register data) where operations are carried out.
  3. Nature of operations and products.
  4. Undertaking by the operator to carry out the operation in accordance with the provision laid down in Regulation (EC) No 834/2007 and this Regulation.
  5. In the case of an agricultural holding, the date on which the producer ceased to apply products not authorised for organic production on the parcels concerned.

**Modification of control arrangements**

- 11.2.5 The operator responsible shall notify any change in the description or of the measures referred to in paragraph 11.2.4 and in the initial control arrangements set out below to SOPA/SFQC in due time.

**11.3 Certificate of Compliance**

- 11.3.1 SOPA/SFQC shall provide documentary evidence in the form of a Certificate to any such operator who is subject to their controls and who in the sphere of his activities, meets the requirements laid down in these Standards. The Certificate evidence shall at least permit the identification of the operator and the type or range of products as well as the period of validity.
- 11.3.2 The operator shall verify the documentary evidence of his suppliers.

**11.4 Control visits for Processors & Importers**

- 11.4.1 SOPA/SFQC shall carry out at least once a year a physical inspection of all operators.
- 11.4.2 SOPA/SFQC may take samples for testing of products not authorised for organic production or for checking production techniques not in conformity with the organic production rules. Samples may also be taken and analysed for detecting possible contamination by products not authorised for organic production. However, such analysis shall be carried out where the use of products not authorised for organic production is suspected.
- 11.4.3 An inspection report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.
- 11.4.4 SOPA/SFQC shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.

**Control arrangements**

11.4.5 In the case of a unit involved in the preparation for its own account or for account of a third party, and including in particular units involved in packaging and/or re-packaging of such products or units involved in labelling and/or re-labelling of such products, the full description of the unit referred to in paragraph 11.2.1 shall show the facilities used for the reception, the processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well as the procedures for the transport of the products.

11.4.6 With regard to the operations, which are contracted out to third parties, the full description of the unit referred to in paragraph 11.2.1 shall include:

1. A list of the subcontractors with a description of their activities and an indication of the control bodies or authorities to which they are subject.
2. Written agreement by the subcontractors that their holding will be subject to the control regime of these Standards.
3. All the practical measures, including inter alia an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to, as appropriate, their suppliers, sellers, consignees and buyers.

**Access to facilities**

11.4.7 The operator shall:

1. Give the control authority or control body, for control purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents.
2. Provide the control authority or control body with any information reasonably necessary for the purposes of the control.
3. Submit, when requested by the control authority or control body, the results of its own quality assurance programmes.

**11.5 Additional control measures for importers**

11.5.1 This Chapter applies to any operator involved, as importer and/ or as first consignee, in the import and/or reception, for its own account or for account of another operator, of organic products.

**Control arrangements**

11.5.2 In the case of the importer, the full description of the unit referred to in paragraph 11.2.1 shall include the importer's premises and of his import activities, indicating the points of entry of the products into the Community and any other facilities the importer intends to use for the storage of the imported products pending their delivery to the first consignee.

11.5.3 In addition, the declaration referred to in paragraph 11.2.4.4 shall include an undertaking by the importer to ensure that any facilities that the importer will use for storage of products are submitted to control, to be carried out either by the control body or control authority or, when these storage facilities are situated in another Member State or region, by a control body or authority approved for control in that Member State or region.

11.5.4 In the case of the first consignee, the full description of the unit referred to in paragraph 11.2.1 shall show the facilities used for the reception and storage.

11.5.5 Where the importer and the first consignee are the same legal person and operate in one single

unit, the reports referred to in the second subparagraph of paragraph 11.2 may be formalized within one single report.

**Information on imported consignments**

11.5.6 The importer shall, in due time, inform SOPA/SFQC of each consignment to be imported into the Community, providing:

1. The name and address of the first consignee;
2. Any details SOPA/SFQC may reasonably require,
  - (a) In case of products imported in accordance with Standard 9.6, the documentary evidence referred to in that Article.
  - (b) In case of products imported in accordance with Standard 9.7, a copy of the Certificate of Inspection.

**Control visits**

11.5.7 SOPA/SFQC shall check the documentary accounts referred to in Section 10.2 of these Standards.

11.5.8 Where the importer performs the import operations at different units or premises, he shall make available on request the reports referred to in the paragraph 11.2.2 for each of these facilities.

**11.6 Additional control measures for units preparing feed**

**Control arrangements**

11.6.1 The full description of the unit referred to in paragraph 11.2.1 shall indicate:

1. The facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them.
2. The facilities used for the storage of other products used to prepare feedingstuffs.
3. The facilities used to store products for cleaning and disinfection.
4. Where necessary, the description of the compound feedingstuff that the operator intends to produce, in accordance with Article 5(1)(a) of Directive 79/373/EEC, and the livestock species or class for which the compound feedingstuff is intended;
5. Where necessary, the name of the feed materials that the operator intends to prepare.

11.6.2 The measures to be taken by operators, as referred to in paragraph 11.2.1.2 to guarantee compliance with the organic production rules shall include the indications of measures referred to in Section 8 of these Standards.

11.6.3 SOPA/SFQC shall use these measures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up a control plan. This control plan shall provide for a minimum number of random samples depending on the potential risks.

**Control visits**

11.6.4 SOPA/SFQC shall make targeted visits based on a general evaluation of the potential risks of non-compliance with the organic production rules. SOPA/SFQC shall pay particular attention to the critical control points pointed out for the operator, with a view to establishing whether the surveillance and checking operations are carried out correctly. All the premises used by the operator for the conduct of his activities may be checked as frequently as the attendant risks

warrant.

## **11.7 Exchange of information**

- 11.7.1 Upon a request duly justified by the necessity to guarantee that a product has been produced in accordance with this Regulation, the competent authorities, control authorities and the control bodies shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies. They may also exchange such information on their own initiative.
- 11.7.2 Where the operator and his subcontractors are checked by different control authorities or control bodies, the declaration referred to in paragraph 11.2.2 shall include an agreement by the operator on his behalf and that of his subcontractors, that the different control bodies or control authorities can exchange information on the operations under their control and on the way this exchange of information can be implemented.