

Section 11 – SOPA Inspection Procedures

MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SCHEME REFERRED TO IN PROVISIONS 8 AND 9 OF ANNEX VIII

The General Provisions set out in this Annex shall apply to all operators referred to in Provision 8(1), to the extent that those provisions relate to the activities carried out by the operator concerned. In addition to the General Provisions, the Specific Provisions shall apply to those operators who carry out the activities mentioned in the title of each subsection.

11.01 General Provisions

(Annex III.1) Minimum inspection requirements

1.1 *The inspection requirements of this Annex shall apply without prejudice to the measures adopted by Defra necessary to ensure traceability of the products, as referred to in Provision 9 (12)(a) and (c), during the entire production chain, and to ensure that the provisions of Council Regulation (EEC) No. 2092/91 are satisfied.*

2. Implementation

2.1 *The operators already in activity at the date mentioned in Article 2, of Commission Regulation (EC) N° 2491/2001, shall also be subject to the provisions referred to in paragraph 3 and to the initial inspection provisions foreseen in Sections A, B, C, D, and E of the Specific Provisions of this Annex.*

3. Initial inspection

When the inspection arrangements are first implemented, the operator responsible must draw up:

- *a full description of the unit and/or premises and/or activity,*
- *all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with this Regulation, and in particular with the requirements in this Annex,*
- *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, those description and measures may be part of a quality system as set up by the operator.

The description and measures concerned must be contained in a declaration, signed by the responsible operator.

In addition, this declaration must include an undertaking by the operator:

- *to perform the operations in accordance with Articles 5, 6, 6a and, where relevant, Article 11 of this Regulation, and/or Regulation (EC) No 223/2003,*
- *to accept, in the event of infringement or irregularities, the enforcement of the measures referred to in Article 9(9) of this Regulation and, where relevant, in Article 10(3) of this Regulation, and*

- ***to accept 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.***

This declaration must be verified by the inspection body or authority that issues a report identifying the possible deficiencies and non-compliances with the provisions of this Regulation. The operator must countersign this report and take the necessary corrective measures.

5. Inspection visits

The inspection body or authority must make a full physical inspection, at least once a year, of all operators. The inspection body or authority may take samples for testing of products not authorised under this Regulation or for checking production techniques not in conformity with this Regulation. Samples may also be taken and analysed for detecting possible contamination by unauthorised products. However, such analysis must be carried out where the use of unauthorised products is suspected. An inspection report must be drawn up after each visit, countersigned by the responsible person of the unit or his representative.

Moreover, the inspection body or authority shall carry out random inspection visits, announced or not, based on a general evaluation of the risk of non-compliance with this Regulation and with Regulation (EC) No 223/2002, taking into account at least the results of previous inspections, the quantity of products concerned and the risk for exchange of products.

9. Products suspected not to satisfy the requirements of the Standard

9.2 ***Where an inspection body has a substantiated suspicion that an operator intends to place on the market a product not in compliance with these Standards but bearing a reference to the organic production method, this inspection body can require that the operator may provisionally not market the product with this reference. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the inspection body is sure that the product does not fulfil the requirements of these Standards. However if the suspicion is not confirmed, the above decision shall be cancelled not later than the time period specified by the inspection body. The operator shall co-operate fully with the inspection body in resolving the suspicion.***

10. Access to facilities

10.1 ***The operator must give the inspection body, for inspection purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents. He must provide the inspection body with any information deemed necessary for the purposes of the inspection.***

10.2 ***When requested by the inspection body, the operator shall submit the results of its own voluntary inspection and sampling programmes.***

10.3 ***In addition, importers and first consignees must submit any import authorisations under Provision 11(6) and certificates of inspection for import from third countries.***

11. Exchange of information

Where the operator and his subcontractors are inspected by different inspection bodies or authorities, the declaration referred to in paragraph 3.3 must include an agreement by the operator on his behalf and that of his subcontractors, that the different inspection bodies or authorities can exchange information on the operations under their inspection and on the way this exchange of information can be implemented.

11.02 Production of plants, plant products, livestock and/or livestock products

(Annex III A) This section applies to any unit involved in production as defined in Provision 4(2), of products referred to in Provision 1(1)(a) for its own account or for account of a third party.

Production must take place in a unit of which the production premises, land parcels, pasturage, open-air exercise areas, open air runs, livestock buildings, and, where applicable, the premises for the storage of crops, crop products, livestock products, raw materials and inputs, are clearly separate from those of any other unit not producing in accordance with the rules laid down in these Standards.

Processing, packaging and/or marketing may take place at the production unit, where these activities are limited to its own agricultural produce.

Quantities sold directly to the final consumer shall be accounted for on a daily basis.

Storage, in the unit, of input products other than those permitted by Provisions 6(1) (b), 6(1)(c) and 6(3)(a), is prohibited.

11.03 Units for preparation of plant and livestock products and foodstuffs composed of plant and livestock products

(Annex III.B) This Section applies to any unit involved in the preparation, as defined in Article 4(3), of products referred to in Article 1(1), for its own account or for account of a third party, and including in particular also:

- *units involved in packaging and/or re-packaging of such products,*
- *units involved in labelling and/or re-labelling of such products.*

1. Initial inspection

The full description of the unit referred to under point 3 of the General Provisions of this Annex must 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.

11.04 Imports of plants, plant products, livestock, livestock products and foodstuffs comprising plant and/or livestock products, animal feedingstuffs, compound feedingstuffs and feed materials from third countries.

(Annex III.C) This section 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 products referred to in Provision 1(1). For the purpose of this section:

- *the importer shall mean the natural or legal person within the European Community who presents a consignment for release for free circulation into the European Community, either on its own, or through a representative,*
- *the first consignee shall mean the natural or legal person referred to in Provision 11 (3)(a) to whom the consignment is delivered and who will receive it for further preparation and/or marketing.*

1. Initial inspection

1.1 Importers:

- *The full description of the unit referred to under paragraph 3 of the General Provisions of this Annex must include the importer's premises and 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.*
- *In addition, the declaration referred to under paragraph 3 of the General Provisions must include an undertaking by the importer to ensure that any facilities that the importer will use for storage of products are submitted to inspection, to be carried out either by the inspection body or, when these storage facilities are situated in another Member State or region, by an inspection body approved in that Member State or region.*

1.2 First consignee:

- *The full description of the unit referred to under paragraph 3 of the General Provisions must show the facilities used for the reception and storage. Where other activities, like processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well the transport of the products, take place, the relevant provisions under Section B of this Annex shall apply.*

When the importer and the first consignee are the same legal person and operating in one single unit, the reports referred to in paragraph 3 of the General Provisions can be formalised within one single report.

2. Documentary accounts

- 2.1** *When the importer and the first consignee are not operating in one single unit, both of them must keep stock and financial records.*
- 2.2** *On request of the inspection body, any details on the transport arrangements from the exporter in the third country to the first consignee and, from the first consignee's premises or storage facilities to the consignees within the EC must be provided.*

3. Information on imported consignments

- 3.1** *The importer shall, at the latest, by the time the certificate is submitted to the Port Health Authority/Local Authority in accordance with Article 4 point 1 of Commission Regulation (EC) N° 1788/2001 of 7 September 2001 laying down detailed rules for implementing the provisions concerning the certificate of inspection for imports from third countries under Article 11 of Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs¹, inform the inspection body of each consignment to be imported into the Community, giving:*

- *the name and address of the first consignee,*
- *any details the inspection body may require, such as a copy of the inspection certificate for the importation of products from organic farming. On the request of the inspection body of the importer, the latter must pass the information to the inspection body of the first consignee.*

5. Inspection visits

¹ OJ L 243, 13.9.2001, p. 3

- 5.1** *The inspection body shall inspect the stock and financial records mentioned in section C, paragraph 2 and the certificates referred to in Provision 11 (1)(b) and (3) and established by Commission Regulation (EC) N° 1788/2001.*
- 5.2** *Where the importer performs the import operations by different units or premises, he must make available on request, the reports foreseen under paragraphs 3 and 5 of the General Provisions of this Annex for each of these facilities.*

11.05 Units involved in the production, preparation or import of products referred to in Provision 1(1) and which have contracted out to third parties in part or in total the actual operations concerned.

(Annex III.D) Initial inspection

- 1.1** *With regard to the operations, which are contracted out to third parties, the full description referred to in paragraph 3 of the General Provisions shall include:*
- *a list of the subcontractors with a description of their activities and the inspection bodies to which they are subject; these subcontractors must have agreed to have their holding being subject to the inspection regime of Provision 9, in accordance with the relevant sections of Annex III;*
 - *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 their suppliers, and, where different, their sellers, as well as to their consignees and, where different, their buyers.*

11.06 Units preparing animal feedingstuffs, compound feedingstuffs and feed materials

(Annex III.E) This section applies to any unit involved in the preparation, as defined in Provision 4 paragraph 3 of products referred to in Provision 1(1)(c) on its own account or on behalf of a third party.

1. Initial inspection

- 1.1** *The full description of the unit referred to under paragraph 3 of the General Provisions of this Annex must*
- *indicate the facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them,*
 - *indicate the facilities used for the storage of other products used to prepare feedingstuffs,*
 - *indicate the facilities used to store products for cleaning and disinfection,*
 - *indicate, 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,*
 - *indicate, where necessary, the name of the feed materials that the operator intends to prepare.*

- 1.2** *The measures to be taken by operators, referred to in paragraph 3 of the General Provisions of this Annex, to guarantee compliance with these Standards must include:*
- *in particular an indication of the precautionary measures to be taken in order to reduce the risk of contamination by unauthorised substances or products, the cleaning measures implemented and the monitoring of their effectiveness,*
 - *identification of all elements of their activities crucial for guaranteeing at all times that the products referred to in Provision 1(1)(c) prepared in such units comply with these Standards and with Regulation (EC) No 223/2003,*
 - *the establishment and implementation of, compliance with and updating of appropriate procedures, based on the principles of the HACCP (Hazard Analysis and Critical Control Points) system.*
- 1.3** *The inspection body shall use these procedures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up an inspection plan. This inspection plan must provide for a minimum number of random samples depending on the potential risks.*
- 4.** *Inspection visits*
- 4.1** *In addition to the complete annual visit, the inspection body must make targeted visits based on a general evaluation of the potential risks of non-compliance with these Standards; the inspection body 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 as they should be. All the premises used by the operator for the conduct of his activities may be inspected as frequently as the attendant risks warrant.*