

COMMISSION REGULATION (EC) No 1336/2005

of 12 August 2005

amending Annex III to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs⁽¹⁾, and in particular the second indent of Article 13 thereof,

Whereas:

- (1) As a result of Article 8 of Regulation (EEC) No 2092/91 as amended by Council Regulation (EC) No 392/2004⁽²⁾, the scope of operators' activities subject to the inspection system provided for in Article 9 of Regulation (EEC) No 2092/91 covers all operators throughout the production, preparation and marketing process.
- (2) To cover adequately all the categories of operators referred to in Article 8(1) of Regulation (EEC) No 2092/91, it is necessary to extend the application of the general provisions set out in Annex III to that Regulation.

- (3) It is appropriate to relate the frequency of random inspections to the risks of non-compliance with Regulation (EEC) No 2092/91.

- (4) Annex III to Regulation (EEC) No 2092/91 should therefore be amended accordingly.

- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up in accordance with Article 14 of Regulation (EEC) No 2092/91,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EEC) No 2092/91 is amended in accordance with the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 August 2005.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 198, 22.7.1991, p. 1. Regulation as last amended by Commission Regulation (EC) No 2254/2004 (JO L 385, 29.12.2004, p. 20).

⁽²⁾ OJ L 65, 3.3.2004, p. 1.

ANNEX

Annex III to Regulation (EEC) No 2092/91 is amended as follows:

1. after the title, the following is inserted:

The General Provisions set out in this Annex shall apply to all operators referred to in Article 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.;

2. the General Provisions are amended as follows:

(a) points 3 to 6 are replaced by the following:

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.

4. Communications

The operator responsible must notify any change in the description or of the measures referred to in point 3 and in the initial inspection provisions foreseen in sections A, B, C, D and E of the Specific Provisions of this Annex to the inspection body or authority in due time.

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 223/2003, taking into account at least the results of previous inspections, the quantity of products concerned and the risk for exchange of products.

6. Documentary accounts

Stock and financial records must be kept in the unit or premises, to enable the operator to identify and the inspection body or authority to verify:

- the supplier and, where different, the seller, or the exporter of the products,
- the nature and the quantities of products as referred to in Article 1 delivered to the unit and, where relevant, of all materials bought and the use of such materials, and, where relevant, the composition of the compound feedingstuffs,
- the nature and the quantities of products as referred to in Article 1 held in storage at the premises,
- the nature, the quantities and the consignees and, where different, the buyers, other than the final consumers, of any products as referred to in Article 1, which have left the unit or the first consignee's premises or storage facilities,
- in case of operators who do not store or physically handle such products, the nature and the quantities of products as referred to in Article 1 bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees.

The documentary accounts must also comprise the results of the verification at reception of products and any other information required by the inspection body or authority for the purpose of proper inspection.

The data in the accounts must be documented with appropriate justification documents.

The accounts must demonstrate the balance between the input and the output.;

- (b) the title of point 7 is replaced by the following:

'7. Packaging and transport of products to other operators or units';

- (c) after point 7, the following point 7a is inserted:

'7a. Reception of products from other units and other operators

On receipt of a product as referred to in Article 1, the operator shall check the closing of the packaging or container where it is required and the presence of the indications referred to in point 7. The operator shall crosscheck the information on the label referred to in point 7 with the information on the accompanying documents. The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in point 6.;

(d) point 8 is replaced by the following

‘8. Storage of products

For the storage of products, areas must be managed in order to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with this Regulation. Products referred to in Article 1 must be clearly identifiable at all times.’;

3. the Specific Provisions are amended as follows:

(a) in section A, the sixth paragraph is deleted;

(b) Section B is replaced by the following:

‘B. Units for preparation of plant and livestock products and foodstuffs composed of plant and livestock products

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.

2. Preparation units handling also products not from organic production

Where products not referred to in Article 1 are also prepared, packaged or stored in the preparation unit concerned:

- the unit must have areas separated by place or time within the premises for the storage of products as referred to in Article 1, before and after the operations,
- operations must be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Article 1,
- if such operations are not carried out at regular times or on a fixed day, they must be announced in advance, with a deadline agreed on with the inspection body or authority,
- every measure must be taken to ensure identification of lots and to avoid mixtures or exchanges with products not obtained in accordance with the rules laid down in this Regulation,
- operations on products in accordance with the rules laid down in this Regulation must be carried out only after cleaning of the production equipment. The effectiveness of the cleaning measures must be checked and recorded.

3. Packaging and transport of products to preparation units

Milk, eggs and egg-products from organic farming shall be collected independently from products not produced in accordance with this Regulation. By derogation, and subject to prior approval by the inspection body or authority, simultaneous collection may occur, where appropriate measures are taken to prevent any possible mixture or exchange with products not produced in accordance with this Regulation and to ensure the identification of the products produced in accordance with the provisions of this Regulation. The operator keeps the information relating to collection days, hours, circuit and date and time of reception of the products available to the inspection body or authority.’;

(c) in section E, point 6 is deleted.
