

Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

TITLE IV

CONTROLS

CHAPTER 1

Minimum control requirements

Article 63

Control arrangements and undertaking by the operator

1 When the control arrangements are first implemented, the operator shall draw up and subsequently maintain:

- a a full description of the unit and/or premises and/or activity;
- b 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;
- c 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.

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:

- a to perform the operations in accordance with the organic production rules;
- b to accept, in the event of infringement or irregularities, the enforcement of the measures of the organic production rules;
- c 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.

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.

3 For the application of Article 28(1) of Regulation (EC) No 834/2007 the operator shall notify the following information to the competent authority:

- a Name and address of operator;
- b Location of premises and, where appropriate, parcels (land register data) where operations are carried out;

- c Nature of operations and products;
- d 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;
- e 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;
- f The name of the approved body to which the operator entrusted control of his undertaking, where the Member State has implemented the control system by approving such bodies.

Article 64

Modification of control arrangements

The operator responsible shall notify any change in the description or of the measures referred to in Article 63 and in the initial control arrangements set out in Articles 70, 74, 80, 82, 86 and 88 to the control authority or control body in due time.

Article 65

Control visits

- 1 The control authority or control body shall carry out at least once a year a physical inspection of all operators.
- 2 The control authority or control body 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.
- 3 A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.
- 4 Moreover, the control authority or control body 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.

Article 66

Documentary accounts

- 1 Stock and financial records shall be kept in the unit or premises and shall enable the operator to identify and the control authority or control body to verify:
 - a the supplier and, where different, the seller, or the exporter of the products;
 - b the nature and the quantities of organic products 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;
 - c the nature and the quantities of organic products held in storage at the premises;

- d the nature, the quantities and the consignees and, where different, the buyers, other than the final consumers, of any products which have left the unit or the first consignee's premises or storage facilities;
- e in case of operators who do not store or physically handle such organic products, the nature and the quantities of organic products bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees.

2 The documentary accounts shall also comprise the results of the verification at reception of organic products and any other information required by the control authority or control body for the purpose of proper control. The data in the accounts shall be documented with appropriate justification documents. The accounts shall demonstrate the balance between the input and the output.

3 Where an operator runs several production units in the same area, the units for non organic products, together with storage premises for input products must also be subject to the minimum control requirements.

Article 67

Access to facilities

- 1 The operator shall:
 - a 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;
 - b provide the control authority or control body with any information reasonably necessary for the purposes of the control;
 - c submit, when requested by the control authority or control body, the results of its own quality assurance programmes.
- 2 In addition to the requirements set out in paragraph 1, importers and first consignees shall submit the information on imported consignments referred to in Article 84.

Article 68

Documentary evidence

For the purpose of the application of Article 29(1) of Regulation (EC) No 834/2007 the control authorities and the control bodies shall use the model of the documentary evidence set out in Annex XII to this Regulation.

Article 69

Vendor declaration

For the purpose of the application of Article 9(3) of Regulation (EC) No 834/2007 the vendor declaration that products supplied have not been produced from or by GMOs may follow the model set out in Annex XIII to this Regulation.

CHAPTER 2

Specific control requirements for plants and plant products from farm production or collection

Article 70

Control arrangements

- 1 The full description of the unit referred to in Article 63(1)(a) shall:
 - a be drawn up even where the operator limits his activity to the collection of wild plants;
 - b indicate the storage and production premises and land parcels and/or collection areas and, where applicable, premises where certain processing and/or packaging operations take place; and
 - c specify the date of the last application on the parcels and/or collection areas concerned of products, the use of which is not compatible with the organic production rules.
- 2 In case of collection of wild plants, the practical measures referred to in Article 63(1)(b) shall include any guarantees given by third parties which the operator can provide to ensure that the provisions of Article 12(2) of Regulation (EC) No 834/2007 are complied with.

Article 71

Communications

Each year, before the date indicated by the control authority or control body, the operator shall notify the control authority or control body of its schedule of production of crop products, giving a breakdown by parcel.

Article 72

Plant production records

Plant production records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. In addition to Article 71 such records shall provide at least the following information:

- (a) as regards the use of fertiliser: date of application, type and amount of fertiliser, parcels concerned;
- (b) as regards the use of plant protection products: reason and date of treatment, type of product, method of treatment;
- (c) as regards purchase of farm inputs: date, type and amount of purchased product;
- (d) as regards harvest: date, type and amount of organic or in conversion crop production.

Article 73

Several production units run by the same operator

Where an operator runs several production units in the same area, the units producing non-organic crops, together with storage premises for farm input products shall also be subject to the general and the specific control requirements laid down in Chapter 1 and this Chapter of this Title.

CHAPTER 3

Control requirements for livestock and livestock products produced by animal husbandry

Article 74

Control arrangements

1 When the control system applying specifically to livestock production is first implemented, the full description of the unit referred to in Article 63(1)(a) shall include:

- a a full description of the livestock buildings, pasturage, open air areas, etc., and, where applicable, the premises for the storage, packaging and processing of livestock, livestock products, raw materials and inputs;
- b a full description of the installations for the storage of livestock manure.

2 The practical measures referred to in Article 63(1)(b) shall include:

- a a plan for spreading manure agreed with the control body or authority, together with a full description of the areas given over to crop production;
- b where appropriate, as regards the spreading of manure, the written arrangements with other holdings as referred to in Article 3(3) complying with the provisions of the organic production rules;
- c a management plan for the organic-production livestock unit.

Article 75

Identification of livestock

The livestock shall be identified permanently using techniques adapted to each species, individually in the case of large mammals and individually or by batch in the case of poultry and small mammals.

Article 76

Livestock records

Livestock records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. Such records

shall provide a full description of the herd or flock management system comprising at least the following information:

- (a) as regards animals arriving at the holding: origin and date of arrival, conversion period, identification mark and veterinary record;
- (b) as regards livestock leaving the holding: age, number of heads, weight in case of slaughter, identification mark and destination;
- (c) details of any animals lost and reasons thereof;
- (d) as regards feed: type, including feed supplements, proportions of various ingredients of rations and periods of access to free-range areas, periods of transhumance where restrictions apply;
- (e) as regards disease prevention and treatment and veterinary care: date of treatment, details of the diagnosis, the posology; type of treatment product, the indication of the active pharmacological substances involved method of treatment and veterinary prescription for veterinary care with reasons and withdrawal periods applying before livestock products can be marketed labelled as organic.

Article 77

Control measures on veterinary medicinal products for livestock

Whenever veterinary medicinal products are used the information according to Article 76(e) is to be declared to the control authority or body before the livestock or livestock products are marketed as organically produced. Livestock treated shall be clearly identified, individually in the case of large animals; individually, or by batch, or by hive, in the case of poultry, small animals and bees.

Article 78

Specific control measures on beekeeping

1 A map on an appropriate scale listing the location of hives shall be provided to the control authority or control body by the beekeeper. Where no areas are identified in accordance with Article 13(2), the beekeeper shall provide the control authority or control body with appropriate documentation and evidence, including suitable analyses if necessary, that the areas accessible to his colonies meet the conditions required in this Regulation.

2 The following information shall be entered in the register of the apiary with regard to the use of feeding: type of product, dates, quantities and hives where it is used.

3 Whenever veterinary medicinal products are to be used, the type of product, including the indication of the active pharmacological substance, together with details of the diagnosis, the posology, the method of administration, the duration of the treatment and the legal withdrawal period shall be recorded clearly and declared to the control body or authority before the products are marketed as organically produced.

4 The zone where the apiary is situated shall be registered together with the identification of the hives. The control body or authority shall be informed of the moving of apiaries by a deadline agreed on with the control authority or body.

5 Particular care shall be taken to ensure adequate extraction, processing and storage of beekeeping products. All the measures to comply with this requirement shall be recorded.

6 The removals of the supers and the honey extraction operations shall be entered in the register of the apiary.

Article 79

Several production units run by the same operator

Where an operator manages several production units, as provided for in Articles 17(1), 40 and 41, the units which produce non-organic livestock or non-organic livestock products shall also be subject to the control system as laid down in Chapter 1 and this Chapter of this Title.

CHAPTER 4

Control requirements for units for preparation of plant and livestock products and foodstuffs composed of plant and livestock products

Article 80

Control arrangements

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 Article 63(1)(a) 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.

CHAPTER 5

Control requirements for 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

Article 81

Scope

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.

Article 82

Control arrangements

1 In the case of the importer, the full description of the unit referred to in Article 63(1) (a) 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.

In addition, the declaration referred to in Article 63(2) 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.

2 In the case of the first consignee, the full description of the unit referred to in Article 63(1)(a) shall show the facilities used for the reception and storage.

3 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 Article 63(2) may be formalised within one single report.

Article 83

Documentary accounts

The importer and the first consignee shall keep separate stock and financial records, unless where they are operating in one single unit.

On request of the control authority or control 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 Community shall be provided.

Article 84

Information on imported consignments

The importer shall, in due time, inform the control body or control authority of each consignment to be imported into the Community, providing:

- (a) the name and address of the first consignee;
- (b) any details the control body or authority may reasonably require,
 - (i) in case of products imported in accordance with Article 32 of Regulation (EC) No 834/2007, the documentary evidence referred to in that Article;
 - (ii) in case of products imported in accordance with Article 33 of Regulation (EC) No 834/2007, a copy of the certificate of inspection referred to in that Article.

On the request of the control body or control authority of the importer, the latter shall forward the information referred to in the first paragraph to the control body or control authority of the first consignee.

Article 85

Control visits

The control authority or control body shall check the documentary accounts referred to in Article 83 of this Regulation and the certificate referred to in Article 33(1)(d) of Regulation (EC) No 834/2007 or the documentary evidence referred to in Article 32(1)(c) of the latter Regulation.

Where the importer performs the import operations by different units or premises, he shall make available on request the reports referred to in the second subparagraph of Article 63(2) of this Regulation for each of these facilities.

CHAPTER 6

Control requirements for units involved in the production, preparation or import of organic products and which have contracted out to third parties in part or in total the actual operations concerned

Article 86

Control arrangements

With regard to the operations, which are contracted out to third parties, the full description of the unit referred to in Article 63(1)(a) shall include:

- (a) 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;
- (b) written agreement by the subcontractors that their holding will be subject to the control regime of Title V of Regulation (EC) No 834/2007;
- (c) 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.

CHAPTER 7

Control requirements for units preparing feed

Article 87

Scope

This Chapter applies to any unit involved in the preparation of products referred to in Article 1(2)(c) of Regulation (EC) No 834/2007 on its own account or on behalf of a third party.

Article 88

Control arrangements

- 1 The full description of the unit referred to in Article 63(1)(a) shall indicate:
 - a the facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them;
 - b the facilities used for the storage of other products used to prepare feedingstuffs;
 - c the facilities used to store products for cleaning and disinfection;
 - d 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;
 - e where necessary, the name of the feed materials that the operator intends to prepare.
- 2 The measures to be taken by operators, as referred to in Article 63(1)(b), to guarantee compliance with the organic production rules shall include the indications of measures referred to in Article 26.
- 3 The control authority or control body 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.

Article 89

Documentary accounts

For the purposes of proper control of the operations, the documentary accounts referred to in Article 66 shall include information on the origin, nature and quantities of feed materials, additives, sales and finished products.

Article 90

Control visits

The control visit referred to in Article 65 shall comprise a full physical inspection of all premises. Moreover, the control authority or control body shall make targeted visits based on a general evaluation of the potential risks of non-compliance with the organic production rules.

The control body or authority 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.

CHAPTER 8

Infringements and exchange of information

Article 91

Measures in case of suspicion of infringements and irregularities

1 Where an operator considers or suspects that a product which he has produced, prepared, imported or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the control body or authority. The control authority or control body may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

2 Where a control authority or control body has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, this control authority or control body can require that the operator may provisionally not market the product with this reference for a time period to be set by that control authority or control body. Before taking such a decision, the control authority or control body shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the control authority or control body is sure that the product does not fulfil the requirements of organic production.

However, if the suspicion is not confirmed within the said time period, the decision referred to in the first subparagraph shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with the control body or authority in resolving the suspicion.

3 Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Title IV of Regulation (EC) No 834/2007 and Title III and/or Annex XI of this Regulation.

Article 92

Exchange of information

1 Where the operator and his subcontractors are checked by different control authorities or control bodies, the declaration referred to in Article 63(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.

2 Where a Member State finds irregularities or infringements relating to the application of this Regulation in a product coming from another Member State and bearing indications as referred to in Title IV of Regulation (EC) No 834/2007 and Title III and/or Annex XI of this Regulation, it shall inform the Member State which designated the control body or control authority and the Commission thereby.