

Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

### TITLE III

## IMPORT OF PRODUCTS PROVIDING EQUIVALENT GUARANTEES

### CHAPTER 1

#### List of recognised third countries

##### *Article 7*

#### Compilation and content of the list of third countries

1 The Commission shall establish a list of recognised third countries in accordance with Article 33(2) of Regulation (EC) No 834/2007. The list of recognised countries is set out in Annex III to this Regulation. The procedures for drawing up and amending the list are defined in Articles 8 and 16 of this Regulation. Amendments to the list shall be made available to the public on the Internet in accordance with Articles 16(4) and 17 of this Regulation.

2 The list shall contain all the information necessary in respect of each third country to allow verifying whether products placed on the Community market have been subject to the control system of the third country recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007 and in particular:

- a the product categories concerned;
- b the origin of the products;
- c a reference to the production standards applied in the third country;
- d the competent authority in the third country responsible for the control system, its address, including e-mail and Internet addresses;
- e the control authority or authorities in the third country and/or the control body or bodies recognised by the said competent authority to carry out controls, their addresses, including, when appropriate, e-mail and Internet addresses;
- f the authority or authorities or the control body or bodies responsible in the third country for issuing certificates with a view to importing into the Community, their addresses and their code numbers and, when appropriate, their e-mail and Internet addresses;
- g the duration of the inclusion in the list.

##### *Article 8*

#### Procedure for requesting inclusion in the list of third countries

1 The Commission shall consider whether to include a third country in the list provided for in Article 7 upon receipt of a request for inclusion, from the representative of the third country concerned.

2 The Commission shall only be required to consider a request for inclusion which meets the following preconditions.

The request for inclusion shall be completed by a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(1) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely:

- a general information on the development of organic production in the third country, the products produced, the area in cultivation, the production regions, the number of producers, the food processing taking place;
- b an indication of the expected nature and quantities of organic agricultural products and foodstuffs intended for export to the Community;
- c the production standards applied in the third country as well as an assessment of their equivalence to the standards applied in the Community;
- d the control system applied in the third country, including the monitoring and supervisory activities carried out by the competent authorities in the third country, as well as an assessment of its equivalent effectiveness when compared to the control system applied in the Community;
- e the Internet or other address where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status and the product categories concerned;
- f the information the third country proposes to include in the list as referred to in Article 7;
- g an undertaking to comply with the provisions of Article 9;
- h any other information deemed relevant by the third country or by the Commission.

3 When examining a request for inclusion in the list of recognised third countries, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent experts. Furthermore, the Commission may, based on risk-assessment and in case of suspected irregularities organise an on-the-spot examination by experts it designates.

4 The Commission shall assess whether the technical dossier referred to in paragraph 2 and the information referred to in paragraph 3 are satisfactory and may subsequently decide to recognise and include a third country in the list. The decision shall be taken in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

#### *Article 9*

### **Management and review of the list of third countries**

1 The Commission shall only be required to consider a request for inclusion when the third country undertakes to accept the following conditions:

- a if, after a third country has been included in the list, any changes are made to the measures in force in the third country or their implementation and in particular to its control system, that third country shall notify the Commission thereof; requests to amend the information in respect of a third country referred to in Article 7(2) shall also be notified to the Commission;
- b the annual report referred to in Article 33(2) of Regulation (EC) No 834/2007 shall update the information of the technical dossier referred to in Article 8(2) of this Regulation; it shall describe in particular the monitoring and supervisory activities carried out by the competent authority of the third country, the results obtained and the corrective measures taken;

- c in the light of any information received, the Commission may at any time amend the specifications relating to the third country and may suspend the entry of that country from the list referred to in Article 7; a similar decision may also be made where a third country has not supplied information required or where it has not agreed to an on-the-spot examination.

2 If a third country does not send the annual report, referred to Article 33(2) of Regulation (EC) No 834/2007, does not keep available or does not communicate all information related to its technical dossier or control system or does not agree to an on-the-spot examination, after request by the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days, that third country may be withdrawn from the list, in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

## CHAPTER 2

### **List of recognised control bodies and control authorities for the purpose of equivalence**

#### *Article 10*

#### **Compilation and content of the list of recognised control bodies and control authorities for the purpose of equivalence**

1 The Commission shall draw up a list of control bodies and control authorities, recognised for the purpose of equivalence in accordance with Article 33(3) of Regulation (EC) No 834/2007. The list shall be published in Annex IV to this Regulation. The procedures for drawing up and amending the list are defined in Articles 11, 16 and 17 of this Regulation. The list shall be made available to the public on the Internet in accordance with Articles 16(4) and 17 of this Regulation.

2 The list shall contain all the information necessary in respect of each control body or authority to allow verifying whether products placed on the Community market have been controlled by a control body or authority recognised in accordance with Article 33(3) of Regulation (EC) No 834/2007 and in particular:

- a the name, address and code number of the control body or authority, and, when appropriate, its e-mail and Internet address;
- b the third countries not listed in the list provided for in Article 7 where the products have their origin;
- c the product categories concerned for each third country;
- d the duration of the inclusion in the list; and
- e the Internet website where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products.

3 By way of derogation from paragraph 2(b), those products originating from third countries listed in the list of recognised third countries as referred to in Article 7 which belong to a category which is not referred to in that list may be listed in the list provided for in this Article.

## Article 11

### **Procedure for requesting inclusion in the list of recognised control bodies and control authorities for the purpose of equivalence**

1 The Commission shall consider whether to include a control body or control authority in the list provided for in Article 10 upon receipt of a request for inclusion from the representative of the control body or control authority concerned on the basis of the model of application made available by the Commission in accordance with Article 17(2). Only complete requests that have been received by 31 October 2009 shall be considered for the drawing up of the first list. For the following calendar years, the Commission shall undertake regular updates of the list as appropriate on the basis of complete requests that have been received before 31 October of each year.

2 The request can be introduced by control bodies and control authorities established in the Community or in a third country.

3 The request for inclusion shall consist of a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(3) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely:

- a an overview of the activities of the control body or control authority in the third country or third countries, including an estimate of the number of operators involved and the expected nature and quantities of agricultural products and foodstuffs intended for export to the Community under the rules set out in Article 33(1) and (3) of Regulation (EC) No 834/2007;
- b a description of the production standards and control measures applied in the third countries, including an assessment of the equivalence of these standards and measures with Titles III, IV and V of Regulation (EC) No 834/2007 as well as with the associated implementing rules laid down in Regulation (EC) No 889/2008;
- c a copy of the assessment report as set out in the fourth subparagraph of Article 33(3) of Regulation (EC) No 834/2007:
  - (i) proving that the control body or control authority has been satisfactorily assessed on its ability to meet the conditions set out in Article 33(1) and (3) of Regulation (EC) No 834/2007;
  - (ii) confirming that it has effectively implemented its activities according to those conditions; and
  - (iii) demonstrating and confirming the equivalence of the production standards and control measures referred to in subparagraph (b) of this paragraph;
- d proof that the control body or control authority has notified its activities to the authorities of each of the third countries concerned and its undertaking to respect the legal requirements imposed on it by the authorities of each of the third countries concerned;
- e the Internet website where the list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products;
- f an undertaking to comply with the provisions of Article 12;

- g any other information deemed relevant by the control body or control authority or by the Commission.

4 When examining a request for inclusion in the list of control body or control authority, and also any time after its inclusion, the Commission may request any further information, including the presentation of one or more on-the-spot examination reports established by independent expert. Furthermore, the Commission may organise an on-the-spot examination by experts it designates on a risk-based approach and in case of suspected irregularities.

5 The Commission shall assess whether the technical dossier referred to in paragraph 2 and the information referred to in paragraph 3 are satisfactory and may subsequently decide to recognise and include a control body or control authority in the list. The decision shall be taken in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

#### *Article 12*

### **Management and review of the list of control bodies and control authorities for the purpose of equivalence**

1 A control body or control authority may only be included in the list referred to in Article 10 when it fulfils the following obligations:

- a if, after a control body or control authority has been included in the list, any changes are made to the measures applied by the control body or control authority, that control body or control authority shall notify the Commission thereof; requests to amend the information in respect of a control body or authority referred to in Article 10(2), shall also be notified to the Commission;
- b by 31 March every year, the control body or control authority shall send a concise annual report to the Commission. The annual report shall update the information of the technical dossier referred to in Article 11(3); it shall describe in particular the control activities carried out by the control body or control authority in the third countries in the previous year, the results obtained, the irregularities and infringements observed and the corrective measures taken; It shall furthermore contain the most recent assessment report or update of such report, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual reassessment as referred to in Article 33(3) of Regulation (EC) No 834/2007; the Commission may request any other information deemed necessary;
- c in the light of any information received, the Commission may at any time amend the specifications relating to the control body or control authority and may suspend the entry of that body or authority from the list referred to in Article 10; a similar decision may also be made where a control body or control authority has not supplied information required or where it has not agreed to an on-the-spot examination;
- d the control body or control authority shall make available to interested parties, by electronic means, a continuously updated list of operators, and of products certified as organic.

2 If a control body or a control authority does not send the annual report, referred to in paragraph 1(b), does not keep available or does not communicate all information related to its technical dossier, control system or updated list of operators and products certified as organic, or does not agree to an on-the-spot examination, after request by the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days, that control body or control authority may be withdrawn from the list of control bodies and control authorities, in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007.

If a control body or a control authority fails to take appropriate and timely remedial action, the Commission shall withdraw it from the list without delay.

## CHAPTER 3

### **Release for free circulation of products imported in accordance with Article 33 of Regulation (EC) No 834/2007**

#### *Article 13*

#### **Certificate of inspection**

1 The release for free circulation in the Community of a consignment of products referred to in Article 1(2) of Regulation (EC) No 834/2007 and imported in accordance with Article 33 of that Regulation shall be conditional on:

- a the submission of an original certificate of inspection to the relevant Member State's authority; and
- b on the verification of the consignment by the relevant Member State's authority and the endorsement of the certificate of inspection in accordance with paragraph 8 of this Article.

2 The original certificate of inspection shall be established in accordance with Article 17(2) and paragraphs 3 to 7 of this Article, on the basis of the model and the notes set out in Annex V. The model notes, together with guidelines referred to in Article 17(2), shall be made available by the Commission via the computer system enabling electronic exchange of documents referred to in Article 17.

3 To be accepted, the certificate of inspection must have been issued by:

- a the control authority or control body which has been accepted for issuing the certificate of inspection, as referred to in Article 7(2), from a third country recognised under Article 8(4); or
- b the control authority or control body in the third country listed for the third country concerned recognised under Article 11(5).

4 The authority or body issuing the certificate of inspection shall only issue the certificate of inspection and endorse the declaration in box 15 of the certificate, after:

- a it has carried out a documentary check on the basis of all relevant inspection documents, including in particular the production plan for the products concerned, transport documents and commercial documents; and
- b it has either made a physical check of the consignment, or it has received an explicit declaration of the exporter declaring that the consignment concerned has been produced and/or prepared in accordance with Article 33 of Regulation (EC) No 834/2007; it shall carry out a risk-oriented verification of the credibility of this declaration.

It shall furthermore give a serial number to each issued certificate and keep a register of the delivered certificates in chronological order.

5 The certificate of inspection shall be drawn up in one of the official languages of the Community and filled in, except for the stamps and signatures, either entirely in capital letters or entirely in typescript.

The certificate of inspection shall be in one of the official languages of the Member State of destination. Where necessary, the relevant Member State's authorities may request a translation of the certificate of inspection in one of its official languages.

Uncertified alterations or erasures shall invalidate the certificate.

6 The certificate of inspection shall be made in one single original.

The first consignee or, where relevant, the importer may make a copy for the purpose of informing the control authorities and control bodies in accordance with Article 83 of Regulation (EC) No 889/2008. Any such copy shall carry the indication 'COPY' or 'DUPLICATE' printed or stamped thereon.

7 For products imported under the transitional rules stipulated in Article 19 of this Regulation, the following shall apply:

- a the certificate of inspection referred to in paragraph 3(b) shall, at the time it is submitted in accordance with paragraph 1, include in box 16 the declaration of the competent authority in the Member State which granted the authorisation according to the procedure provided for in Article 19;
- b the competent authority in the Member State which granted the authorisation may delegate the competence for the declaration in box 16 to the control authority or control body inspecting the importer in accordance with the control measures set out in Title V of Regulation (EC) No 834/2007, or to the authorities defined as the Member State's relevant authorities;
- c the declaration in box 16 is not required:
  - (i) when the importer presents an original document, issued by the competent authority of the Member State which granted the authorisation in accordance with Article 19 of this Regulation, demonstrating that the consignment is covered by that authorisation; or
  - (ii) when the Member State's authority, which granted the authorisation referred to in Article 19, has given satisfactory evidence that the consignment is covered by that authorisation, directly to the authority in charge of the verification of the consignment; this procedure of direct information is optional for the Member State which granted the authorisation;
- d the document giving the evidence required in points c(i) and (ii), shall include:
  - (i) the reference number of the import authorisation and the date of expiration of the authorisation;
  - (ii) the name and address of the importer;
  - (iii) the third country of origin;
  - (iv) the details of the issuing body or authority, and, where different, the details of the inspection body or authority in the third country;
  - (v) the names of the products concerned.

8 At the verification of a consignment, the original certificate of inspection shall be endorsed by the relevant Member State's authorities in box 17 and returned to the person who submitted the certificate.

9 The first consignee shall, at the reception of the consignment, complete box 18 of the original of the certificate of inspection, to certify that the reception of the consignment has been carried out in accordance with Article 34 of Regulation (EC) No 889/2008.

The first consignee shall then send the original of the certificate to the importer mentioned in box 11 of the certificate, for the purpose of the requirement laid down in the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007, unless the certificate has to further accompany the consignment referred to in paragraph 1 of this Article.

10 The certificate of inspection may be established by electronic means, using the method made available to the control authorities or control bodies by the Member State concerned. The competent authorities of the Member States may require that the electronic certificate of inspection be accompanied by an advance electronic signature within the meaning of Article 2(2) of Directive 1999/93/EC of the European Parliament and of the Council<sup>(1)</sup>. In all other cases, the competent authorities shall require an electronic signature offering equivalent assurances with regard to the functionalities attributed to a signature by applying the same rules and conditions as these defined in the Commission's provisions on electronic and digitised documents, set out by Commission Decision 2004/563/EC, Euratom<sup>(2)</sup>.

#### *Article 14*

### **Special customs procedures**

1 Where a consignment coming from a third country is assigned to customs warehousing or inward processing in the form of a system of suspension as provided for in Council Regulation (EEC) No 2913/92<sup>(3)</sup>, and subject to one or more preparations as defined in Article 2(i) of Regulation (EC) No 834/2007, the consignment shall be subject, before the first preparation is carried out, to the measures referred to in Article 13(1) of this Regulation.

The preparation may include operations such as:

- a packaging or repackaging; or
- b labelling concerning the presentation of the organic production method.

After this preparation, the endorsed original of the certificate of inspection shall accompany the consignment, and shall be presented to the relevant Member State's authority, which shall verify the consignment for the purpose of its release for free circulation.

After this procedure, the original of the certificate of inspection shall, where relevant, be returned to the importer of the consignment, referred to in box 11 of the certificate to fulfil the requirement laid down in the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007.

2 Where, under a suspensive customs procedure pursuant to Regulation (EEC) No 2913/92, a consignment coming from a third country is intended to be submitted in a Member State, before its release for free circulation in the Community, to a splitting into different batches, the consignment shall be subject, before this splitting is carried out, to the measures referred to in Article 13(1) of this Regulation.

For each of the batches which results from the splitting, an extract of the certificate of inspection shall be submitted to the relevant Member State's authority, in accordance with the model and the notes set out in Annex VI. The extract from the certificate of inspection shall be endorsed by the relevant Member State's authorities in box 14.



A copy of each endorsed extract from the certificate of inspection shall be kept together with the original certificate of inspection by the person identified as the original importer of the consignment and mentioned in box 11 of the certificate of inspection. This copy shall carry the indication 'COPY' or 'DUPLICATE' printed or stamped thereon.

After the splitting, the endorsed original of each extract of the certificate of inspection shall accompany the batch concerned, and shall be presented to the relevant Member State's authority, which shall verify the batch concerned for the purpose of its release for free circulation.

The consignee of a batch shall, at the reception thereof complete the original of the extract of the certificate of inspection in box 15, in order to certify that the reception of the batch has been carried out in accordance with Article 34 of Regulation (EC) No 889/2008.

The consignee of a batch shall keep the extract of the certificate of inspection at the disposal of the control authorities and/or control bodies for not less than two years.

3 The preparation and splitting operations referred to in paragraphs 1 and 2 shall be carried out in accordance with the relevant provisions set out in Title V of Regulation (EC) No 834/2007 and in Title IV of Regulation (EC) No 889/2008.

#### *Article 15*

#### **Non-compliant products**

Without prejudice to any measures or actions taken in accordance with Article 30 of Regulation (EC) No 834/2007 and/or Article 85 of Regulation (EC) No 889/2008, the release for free circulation in the Community of products not in conformity with the requirements of that Regulation shall be conditional on the removal of references to organic production from the labelling, advertising and accompanying documents.

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**Status:** This is the original version (as it was originally adopted).

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- (1) OJ L 13, 19.1.2000, p. 12.
- (2) OJ L 251, 27.7.2004, p. 9.
- (3) OJ L 302, 19.10.1992, p. 1.