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### **Working document**

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Draft

### COMMISSION REGULATION (EC) No [..../2008]

of [date]

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

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#### COMMISSION REGULATION (EC) No [..../2008]

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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

#### THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91<sup>1</sup>, and in particular Article 32(2), Article 33(2), Article 38(d) and Article 40 thereof,

#### Whereas:

- (1) Articles 32 and 33 of Regulation (EC) No 834/2007 lay down general provisions for import of organic products. With a view to guarantee that these provisions will be applied in a correct and uniform way, detailed rules and procedures for the application of those provisions should be laid down.
- (2) As substantial experience has been built up since 1992 with the import of products providing equivalent guarantees, a relatively short period should be given to control bodies and control authorities to request their inclusion in the list for the purpose of equivalence in accordance with Article 33 of Regulation (EC) No 834/2007. However, as there is no experience with the direct application of Community rules on organic production and labelling of organic products outside the territory of the Community, more time should be given to control bodies and control authorities wishing to request their inclusion in the list for the purpose of compliance in accordance with Article 32 of Regulation (EC) No 834/2007. Therefore a longer period should be provided for sending in the requests and for examining them.
- (3) For products imported according to Article 32 of Regulation (EC) No 834/2007, the operators concerned should be able to provide documentary evidence. It is necessary to establish a model for this documentary evidence. Products imported according to Article 33 of Regulation (EC) No 834/2007 should be covered by a certificate of

OJ L 189, 20.7.2007, p. 1.

inspection. It is necessary to lay down detailed rules with regard to the issuing of this certificate. Moreover, a procedure in order to coordinate at Community level certain controls on products imported from third countries which are intended to be marketed in the Community as organic should be laid down.

- (4) Argentina, Australia, Costa Rica, India, Israel, New Zealand and Switzerland were previously listed as third countries from which imported products could be marketed in the Community as organic, under Commission Regulation (EC) No 345/2008 of 17 April 2008.2 The Commission has re-examined the situation of those countries according to the criteria set out in Regulation (EC) No 834/2007, taking into consideration the production rules applied and the experience gained with the import of organic products from these third countries as previously listed under to Article 11 (1) of Council Regulation (EEC) N° 2092/91. On this basis it is concluded that the conditions for inclusion of Argentina, Australia, Costa Rica, India, Israel, and New Zealand in the list of third countries for equivalency according to Article 33 (1) of Regulation (EC) No 834/2007 are fulfilled."
- (5) The European Community and the Swiss Confederation have concluded an Agreement on trade in agricultural products<sup>3</sup> approved by Decision 2002/309/EC of the Council and of the Commission<sup>4</sup>. Annex 9 to that Agreement covers organically produced agricultural products and foodstuffs and sets out that organic products complying with the regulation the Swiss Confederation on organic production can be imported and placed on the Community market as organic. For the sake of clarity, Switzerland should also be listed in the list of third countries for equivalency according to Article 33(1) of Regulation (EC) No 834/2007.
- (6) Member States' authorities have acquired substantial experience and expertise in the field of granting access for organic imported goods into the territory of the Community. To establish and maintain the lists of third countries and control bodies and control authorities, this experience should be used and the Commission should be able to take account of reports from Member States and other experts. The tasks involved should be divided in a just and proportionate way.
- (7) Provision should also be made for transitional measures applicable to third country applications received by the Commission before 1 January 2009, the date from which Regulation (EC) No 834/2007 applies.
- (8) In order not to disrupt international trade, and to facilitate the transition between the rules established by Regulation (EEC) N° 2092/91 and those established by Regulation (EC) No 834/2007, it is necessary to extend the possibility of Member States to continue to grant authorisations to importers on a case by case basis for placing on the Community market of products until the measures necessary for the functioning of the new import rules have been put in place, in particular as regards the recognition of control bodies and control authorities referred to in Article 33(3) of Regulation (EC) No 834/2007. This possibility should be gradually phased out as the list of control bodies referred to in that Article is being established.

OJ L 108, 18.4.2008, p. 8

<sup>&</sup>lt;sup>3</sup> OJ L 114, 30.4.2002, p. 132.

<sup>&</sup>lt;sup>4</sup> OJ L 114, 30.4.2002, p. 1.

- (9) In order to improve transparency and guarantee the application of this Regulation, an electronic system for exchange of information between the Commission, the Member States, the third countries, and the control bodies and control authorities should be foreseen.
- (10) The detailed rules laid down in this Regulation replace those laid down in Commission Regulation (EC) No 345/2008 of 17 April 2008 laying down detailed rules for implementing the arrangements for imports from third countries provided for in Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs<sup>5</sup> and in Commission Regulation (EC) No 605/2008 of 20 June 2008 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 foodstuffs<sup>6</sup>. Those Regulations should therefore be repealed.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the regulatory Committee on organic production,

HAS ADOPTED THIS REGULATION:

#### TITLE I

#### INTRODUCTORY PROVISIONS

#### Article 1

#### **Subject matter**

This Regulation lays down the detailed rules for the import of compliant products and the import of products providing equivalent guarantees as provided for in Articles 32 and 33 of Regulation (EC) No 834/2007.

#### Article 2

#### **Definitions**

For the purposes of this Regulation:

(1) 'certificate of inspection': means the certificate of inspection referred to in Article 33(1)(d) of Regulation (EC) No 834/2007 covering one consignment;

<sup>&</sup>lt;sup>5</sup> OJ L 108, 18.4.2008, p. 8.

<sup>&</sup>lt;sup>6</sup> OJ L 166, 27.6.2008, p. 3.

- (2) 'documentary evidence': means the document referred to in Article 68 of Regulation (EC) No ..../2008 [new implementing rules] and in Article 6 of this Regulation, for which the model is set out in Annex I to this Regulation;
- (3) 'consignment': means a quantity of products under one or more Combined Nomenclature Codes, covered by a single certificate of inspection, conveyed by the same means of transport and imported from the same third country;
- (4) 'first consignee': means the natural or legal person as defined in Article 2 (d) of Regulation (EC) No ..../2008[new implementing rules]
- 'verification of the consignment': means the verification by the relevant Member States' authorities of the certificate of inspection to satisfy Article 12(2) of this Regulation , and, where these authorities consider appropriate, of the products, in relation to the requirements of Regulation (EC) No 834/2007, of Regulation (EC) No ..../2008[new implementing rules] and of this Regulation;
- (6) 'relevant Member States authorities': mean the customs authorities or other authorities, designated by the Member States.

#### TITLE II

## **Import of compliant products**

## Chapter 1

# List of recognised control bodies and control authorities for the purpose of compliance

#### Article 3

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

- 1. The Commission shall draw up a list of control bodies and control authorities, recognised for the purpose of compliance in accordance with Article 32(2) of Regulation (EC) No 834/2007. The procedures for drawing up and amending the list are defined in Articles 4 and 16 of this regulation.
- 2. The list shall contain all the information necessary in respect of each control body or authority to permit the identification of products covered by Article 32(2) of Regulation (EC) No 834/2007 and in particular:
- (a) the name and address of the control body or authority, including e-mail and internet address;

- (b) the third countries concerned and in which the products have their origin;
- (c) the product categories concerned;
- (d) the duration of the inclusion in the list;
- (e) the internet or other address where the list of operators subject to the control system can be found, including their certification status and the product categories concerned, as well as suspended and decertified operators and products
- (f) an undertaking to comply with the provisions of Article 5
- (g) any other information deemed relevant by the control body or control authority.

#### Article 4

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

- 1. The Commission shall consider whether to recognise and include a control body or control authority in the list provided for in Article 3 upon receipt of a request for inclusion in this list from the representative of the control body or control authority concerned. Only complete requests that have been received before 31 October 2010 shall be considered, on the basis of the model of application made available by the Commission in accordance with Article 17(2), for the drawing up of the first list. For the following calendar years, only complete requests that have been received before 31 October of each year shall be considered.
- 2. The request can be introduced by control bodies and control authorities established in the Community or in a third country.
- 3. The request shall exist of a technical dossier, established in one of the official and working languages of the Commission within the meaning of Article 1 of Council Regulation No 1<sup>7</sup> and, if not established in German, English or French, of a translation in one of these three languages. It shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 32 (1) and (2) of Regulation (EC) No 834/2007 are met for all organic products intended for export to the Community information, namely:
  - (a) an overview of the activities of the control body or control authority in the third country concerned, including an indication of the number of operators involved and an indication of the expected nature and quantities of agricultural products and foodstuffs originated from the third country concerned and intended for export to the Community under the rules set out in Article 32 (1) and (2) of Regulation (EC) No 834/2007;

OJ 17, 6.10.1958, p. 385.

- (b) a detailed description of how Titles II, III and IV of Regulation (EC) No 834/2007 as well as the provisions of Regulation (EC) No ...../2008[new implementing rules] have been implemented in the third country.
- (c) a copy of the assessment report as set out in the fourth subparagraph of Article 32(2) 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 32(1) and (2) of Regulation (EC) No 834/2007;
  - (ii) giving guarantees on the elements referred to in Article 27(3), (5) and (6) of Regulation (EC) No 834/2007;
  - (iii) ensuring that the control body or control authority meets the control requirements and precautionary measures set out in Title IV of Regulation (EC) No ..../2008[new implementing rules]; and
  - (iv) confirming that it has effectively implemented its control activities according to these conditions and requirements;
- (d) proof that the control body or authority has notified its activities to the authorities of the third country concerned and its undertaking to respect the legal requirements imposed on it by the authorities of the third country concerned;
- (e) the internet or other address where the list of operators subject to the control system can be found, including their certification status and the product categories concerned, as well as suspended and decertified operators and products;
- (f) an undertaking to comply with the provisions of Article 5
- (g) any other information deemed relevant by the control body or control authority.
- 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 experts. Furthermore, the Commission may organize an on-the-spot examination by experts it designates.
- 5. The Commission shall assess whether the technical dossier referred to in paragraph 3 and the information referred to in paragraph 4 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.

# Management and review of the list of recognised control bodies and control authorities for the purpose of compliance

- 1. A control body or control authority may only be included in the list referred to in Article 3 when it fulfils the following obligations:
  - (a) if, after the 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;
  - (b) a control body or control authority included in the list shall keep available and communicate at first request all information related to its control activities in the third country. It shall give access to its offices and facilities to experts designated by the Commission:
  - (c) By 31 March every year, the control body or control authority shall send a summary report to the Commission regarding the control activities carried out during the previous year, as well as the most recent assessment report or update of such report. The Commission may request any other information deemed necessary.
  - (d) 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 in the list referred to in Article 3. A similar decision may also be made where a control body or authority has not supplied information required or where it has not agreed to an on-the-spot examination.
  - (e) The control body or control authority shall make available to interested parties, by electronic means, a continuously updated list of operators and products certified as organic.
- 2. If a control body or a control authority does not send the summary report, referred to in paragraph 1(c), does not keep available or 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.

### Chapter 2

### Documentary evidence required for import of compliant products

#### Article 6

#### **Documentary evidence**

- 1. The documentary evidence required for import of compliant products referred to in Article 32(1)(c) of Regulation (EC) No 834/2007, shall be established on the basis of the model set out in *Annex I* to this Regulation.
- 2. The original documentary evidence shall be established by a control authority or the control body which has been recognised for issuing that documentary by a decision as referred to in Article 4.
- 3. The authority or body issuing the documentary evidence shall be follow the rules established in accordance with Article 17(2) and in the model, notes and guidelines made available by the Commission via the computer system enabling electronic exchange of documents referred to in Article 17(1).

#### TITLE III

## Imports 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 is set out in Annex II. The procedures for drawing up and amending the list are defined in Articles 8 and 16 of this regulation.
- 2. The list shall contain all the information necessary in respect of each third country to permit the identification of products covered by 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 recognized 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 including, when appropriate, 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 6 upon receipt of a request for inclusion on the basis of the model of application made available by the Commission in accordance with Article 17(2), 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, established in one of the official and working languages of the Commission within the meaning of Article 1 of Regulation No 1 and, if not established in German, English or French, of a translation in one of these three languages. It 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, including 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;
- (h) an undertaking to comply with the provisions of Article 9;
- (i) any other information deemed relevant by the third country.
- 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 organize 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
  - 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 the 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 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 procedures for drawing up and amending the list are defined in Articles 11 and 16 of this regulation.
- 2. The list shall contain all the information necessary in respect of each control body or authority to permit the identification of products covered by Article 33(3) of Regulation (EC) No 834/2007 and in particular:
- (a) the name and address of the control body or authority, including, when appropriate, e-mail and internet address:
- (b) the product categories concerned, and the third countries not listed in the list provided for in Article 7 where the products have their origin;
- (d) the duration of the inclusion in the list;
- (e) the internet or other address where the list of operators subject to the control system can be found, including their certification status and the product categories concerned, as well as suspended and decertified operators and products,
- (f) an undertaking to comply with the provisions of Article 11
- (g) any other information deemed relevant by the control body or control authority.
- 3. By way of derogation from point (b) of the second paragraph, 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 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 exist of a technical dossier, established in one of the official and working languages of the Commission within the meaning of Article 1 of Regulation No 1 and, if not established in German, English or French, of a translation in one of these three languages. It 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 indication 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 ..../2008[new implementing rules];
  - (c) a copy of the assessment report as set out in the fourth subparagraph of Article 33(3) of Regulation (EC) No 834/2007 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 and confirming that it has effectively implemented its activities according to those conditions;
  - (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) an undertaking to comply with the provisions of article 12;
- (f) any other information deemed relevant by the control body or control authority.
- 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 organize an on-the-spot examination by experts it designates.
- 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 3 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.
  - b) By 31 March every year, the control body or control authority shall send a concise report to the Commission regarding the control activities carried out during the previous year as well as the most recent assessment report or update of such report. 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, the results obtained, the irregularities and infringements observed and the corrective measures taken. The Commission may request any other information deemed necessary.
  - c) In the light of the 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 summary report, referred to in paragraph 3, does not keep available or 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.

#### **CHAPTER 3**

# Release for free circulation of products imported in accordance with Article 33 of Regulation 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 III* 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 and 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 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 ..../2008[new implementing rules]. 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 for 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 ..../2008[new implementing rules].

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>8</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>9</sup>, and in its implementing rule<sup>10</sup>.

OJ L 13, 19.1.2000, p. 12.

<sup>&</sup>lt;sup>9</sup> OJ L 251, 27.7.2004, p. 9.

Document SEC(2005) 1578

#### **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>11</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 re-packaging; 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 IV*. 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.

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OJ L 302, 19.10.1992, p. 1.

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 ..../2008[new implementing rules].

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 ..../2008[new implementing rules].

#### Article 15

#### Non complying 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 ..../2008[new implementing rules], 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.

#### TITLE IV

#### **COMMON RULES**

#### Article 16

#### Assessment of the requests and publication of the lists

- 1. The Commission shall examine the requests received in accordance with Articles 4, 8 and 11 with the assistance of the Committee on organic production, referred to in Article 37(1) of Regulation (EC) No 834/2007 (hereafter called "the Committee"). For this purposes the Committee shall adopt specific internal rules of procedure.
  - In order to assist the Commission with the examination of the requests, the Commission shall set up an expert group consisting of governmental and private experts.
- 2. For each request received, the Committee shall nominate two Member States to act as co-reporters. The Commission shall divide the requests between the Member States proportionally with the number of votes of each Member State in the Committee on organic production. The co-reporting Member States shall examine the documentation and information as set out in Articles 4, 8 and 11 related to the request and shall draw up a report. They shall also examine the annual reports and

- any other information referred to in Articles 5, 9 and 12 related to the request under examination.
- 3. Taking into account the result of the examination by the co-reporting Member States, the Commission shall decide, in accordance with the procedure referred to in Article 37(2) of Regulation (EC) No 834/2007, on the recognition of third countries, control bodies or control authorities, their inclusion on the lists or any modification of the lists.
- 4. The Commission shall make the lists available to the public by any appropriate technical means, including publication on the Internet on its website <a href="http://ec.europa.eu">http://ec.europa.eu</a>.

#### Article 17

#### Communication

- 1. When transmitting documents or other information referred to in Articles 32 and 33 of Regulation (EC) No 834/2007 and in this Regulation to the Commission, the Member States, the competent authorities of third countries, the control authorities or the control bodies shall use the computer system enabling electronic exchanges of documents and information made available by the Commission. The Commission may also use this system to transmit documents and information to Member States.
- 2. For the form and content of documents and information referred to in Articles 32 and 33 of Regulation (EC) No 834/2007 and in this Regulation, the Commission shall set out guidelines, models and questionnaires where appropriate and make them available in the computer system referred to in paragraph 1 of this Article. These guidelines, models and questionnaires shall be adapted and updated by the Commission, after having informed the Member States and the competent authorities of third countries, as well as the control authorities and control bodies recognised in accordance with this Regulation.
- 3. The computer system provided for in paragraph 1 shall be able to process all the requests, documents and information referred to in this Regulation, including the authorisations granted pursuant to Article 19.
- 4. The supporting documents referred to in Regulation (EC) No 834/2007 and in this Regulation, in particular in Articles 4, 8 and 11 shall be kept by the competent authorities of third countries, the control authorities or the control bodies at the disposal of the Commission and the Member States for at least three years following the year in which the controls took place or the certificates of inspection and documentary evidence were delivered.
- 5. Where a document or procedure provided for in Regulation (EC) No 834/2007 or in the detailed rules for its application require the signature of an authorised person or the approval of a person at one or more of the stages of that procedure, the computer systems set up for the communication of those documents must make it possible to identify each person unambiguously and provide reasonable assurance that the contents of the documents, including as regards the stages of the procedure, cannot

be altered, in accordance with Community legislation, and in particular with Commission Decision 2004/563/EC, Euratom, and in its implementing rule.

#### TITLE V

#### FINAL AND TRANSITIONAL RULES

#### Article 18

#### Transitional rules on the list of third countries

Requests for inclusion from third countries submitted in accordance with Article 2 of Regulation (EC) No 345/2008 before the 1 January 2009 shall be treated as applications under Article 8 of this Regulation.

#### Article 19

# Transitional rules on equivalent import of products not originating in listed third countries

1. In accordance with Article 40 of Regulation (EC) No 834/2007 the competent authority of a Member State may authorise importers in that Member State, where the importer has notified his activity in accordance with Article 28 of that Regulation, to place on the market products imported from third countries which are not included in the list referred to in Article 33(2) of that Regulation, provided that the importer provides sufficient evidence showing that the conditions referred to in points (a) and (b) of Article 33(1) of that Regulation are satisfied.

Where, having first allowed the importer or any other person concerned to comment, the Member State considers that those conditions are no longer satisfied, it shall withdraw the authorisation.

Authorisations shall expire at the latest 24 months after the publication of the first list of control bodies and control authorities recognised pursuant to Article 10 of this Regulation.

The imported product shall be covered by a certificate of inspection as set out in Article 13, issued by the control authority or the control body which has been accepted for issuing the certificate of inspection by the competent authority of the authorising Member State. The original of the certificate must accompany the goods to the premises of the first consignee; thereafter the importer must keep the certificate at the disposal of the control body and, as appropriate the control authority, for not less than two years.

- 2. Each member State shall inform the other Member States and the Commission of each authorisation granted pursuant to this Article, including information on the production standards and control arrangements concerned.
- 3. At the request of a Member State or at the Commission's initiative, an authorisation granted pursuant to this Article shall be examined by the Committee on organic production. If this examination discloses that the conditions referred to in points (a) and (b) of Article 33(1) of Regulation (EC) No 834/2007 are not satisfied, the Commission shall require the Member State which granted the authorisation to withdraw it.
- 4. Member States may no longer grant the authorisations referred to in paragraph 1 of this Article from the date of 12 months after the publication of the first list of control bodies and control authorities referred to in Article 11(5) except if the imported products in question are goods whose production in the third country was controlled by a control body or control authority not on the list set up in accordance with Article 10).
- 5. Member States shall no longer grant any authorisation referred to in paragraph 1 from 1 January 2013.
- 6. Any authorisation to market products imported from a third country which had, prior to 31 December 2007 been granted to an importer by the Competent Authority of a Member State under Article 11(6) of Regulation (EEC) N° 2092/91 shall expire on 31 December 2009 at the latest.

#### Article 20

#### **Repeal**

Regulations (EC) No 345/2008 and (EC) No 605/2008 are repealed.

References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex V.

#### Article 21

#### **Entry into force**

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

It shall apply as from 1 January 2009.

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

Done at Brussels, [...]

For the Commission

Member of the Commission

### ANNEX I

#### MODEL OF THE DOCUMENTARY EVIDENCE

(referred to in Article 6(1))

Documentary evidence to the operator according to Articles 32(1)(c) and 29(1) of Regulation (EC) No 834/2007, required for import of compliant products in accordance with Article 6 of Regulation [this Regulation] **Document Number:** Name, address and code number of control Name and address of operator: body/authority: main activity (producer, processor, importer, etc): Product groups/Activity: defined as: - Plant and plant products: organic production, in-conversion products, and also non-organic production, where parallel production/processing pursuant to Article 11 of Regulation (EC) No 834/2007 occurs - Livestock and livestock products: - Processed products: Validity period: Date of control(s): Plant products from .....to...... Livestock products from .....to...... Processed products from.....to..... This document has been issued in accordance with Articles 32(1)(c) and 29(1) of Regulation (EC) No 834/2007 and Article 6 of Regulation (EC) No. [XXX/2008 = this Regulation]. The declared operator has submitted his activities under control, and meets the requirements laid down in the named Regulations.

Date, place:

Signature on behalf of the issuing control body/authority:

#### **ANNEX II**

#### LIST OF THIRD COUNTRIES AND RELEVANT SPECIFICATIONS

#### **ARGENTINA**

#### 1. **Product categories:**

- (a) live or unprocessed agricultural products and vegetative propagating material and seeds for cultivation with the exception of:
  - livestock and livestock products, bearing or intended to bear indications referring to conversion;
- (b) processed agricultural products for use as food with the exception of:
  - livestock products bearing or intended to bear indications referring to conversion.
- 2. **Origin:** Products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in Argentina.
- 3. **Production standards:** Ley 25.127 sobre "Producción ecológica, biológica y orgánica"
- 4. **Competent authority:** Servicio Nacional de Sanidad y Calidad Agroalimentaria SENASA, www.senasa.gov.ar

#### 5. Control bodies:

- Food Safety SA, www.foodsafety.com.ar
- Instituto Argentino para la Certificación y Promoción de Productos Agropecuarios Orgánicos SRL (Argencert), www.argencert.com
- Letis SA, www.letis.com.ar
- Organización Internacional Agropecuaria (OIA), www.oia.com.ar
- 6. **Certificate issuing bodies:** as at point 5.
- 7. **Duration of the inclusion:** 30 June 2013.

#### **AUSTRALIA**

#### 1. **Product categories:**

(a) unprocessed crop products and vegetative propagating material and seeds for cultivation.

- (b) processed agricultural products for use as food composed essentially of one or more ingredients of plant origin.
- 2. **Origin:** products of category 1 (a) and organically grown ingredients in products of category 1 (b) that have been grown in Australia.
- 3. **Production standards:** National standard for organic and bio-dynamic produce
- 4. **Competent authority:** Australian Quarantine and Inspection Service AQIS, www.aqis.gov.au

#### 5. Control bodies and authorities:

- Australian Certified Organic Pty. Ltd., www.australianorganic.com.au
- Australian Quarantine and Inspection Service (AQIS), www.aqis.gov.au
- Bio-dynamic Research Institute (BDRI), www.demeter.org.au
- National Association of Sustainable Agriculture, Australia (NASAA), www.nasaa.com.au
- Organic Food Chain Pty Ltd (OFC), www.organicfoodchain.com.au
- 6. **Certificate issuing bodies and authorities:** as at point 5.
- 7. **Duration of the inclusion:** 30 June 2013.

#### **COSTA RICA**

#### 1. **Product categories:**

- (a) unprocessed crop products and vegetative propagating material and seeds for cultivation;
- (b) processed crop products for use as food.

#### 2. **Origin:**

Products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in Costa Rica.

- 3. **Production standards:** Reglamento sobre la agricultura orgánica
- 4. **Competent authority:** Servicio Fitosanitario del Estado, Ministerio de Agricultura y Ganadería, www.protecnet.go.cr/SFE/Organica.htm

#### 5. Control bodies:

- BCS Oko-Garantie, www.bcs-oeko.com
- Eco-LOGICA, www.eco-logica.com

- 6. **Certificate issuing authority:** Ministerio de Agricultura y Ganadería.
- 7. **Duration of the inclusion:** 30 June 2011.

#### **INDIA**

#### 1. **Product categories**:

- (a) unprocessed crop and vegetative propagating material and seeds for cultivation;
- (b) processed agricultural products for use as food composed essentially of one or more ingredients of plant origin.
- 2. **Origin**: products of category 1(a) and organically grown ingredients in products of category 1(b) that have been grown in India.
- 3. **Production standards:** National Programme for Organic Production
- 4. **Competent authority:** Agricultural and Processed Food Export Development Authority APEDA, www.apeda.com/organic

#### 5. Control bodies and authorities:

- APOF Organic Certification Agency (AOCA), www.aoca.in
- Bureau Veritas Certification India Pvt. Ltd, www.bureauveritas.co.in
- Control Union Certifications, www.controlunion.com
- Ecocert SA (India Branch Office), www.ecocert.in
- IMO Control Private Limited, www.imo.ch
- Indian Organic Certification Agency (Indocert), www.indocert.org
- Lacon Quality Certification Pvt. Ltd, www.laconindia.com
- Natural Organic Certification Association, www.nocaindia.com
- OneCert Asia Agri Certification private Limited, www.onecertasia.in
- SGS India Pvt. Ltd, www.in.sgs.com
- Uttaranchal State Organic Certification Agency (USOCA),
   www.organicuttarakhand.org/products certification.htm
- Rajasthan Organic Certification Agency (ROCA),
   http://www.rajasthankrishi.gov.in/Departments/SeedCert/index\_eng.asp
- 6. **Certificate issuing bodies and authorities**: as at point 5.

7. **Duration of the inclusion**: 30 June 2009.

#### **ISRAEL**

#### 1. **Product categories:**

- (a) unprocessed crop products and vegetative propagating material and seeds for cultivation,
- (b) processed agricultural products for use as food composed essentially of one or more ingredients of plant origin.
- 2. **Origin:** Products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in Israel or that have been imported into Israel:
  - either from the Community,
  - or from a third country in the framework of a regime which is recognised as equivalent in accordance with the provisions of Article 33(2) of Regulation (EC) No 834/2007.
- 3. **Production standards:** National Standard for organically grown plants and their products
- 4. **Competent authority:** Plant Protection and Inspection Services (PPIS), www.ppis.moag.gov.il
- 5. Control **bodies and authorities:** 
  - AGRIOR Ltd.-Organic Inspection & Certification, www.agrior.co.il
  - IQC Institute of Quality & Control, www.iqc.co.il
  - Plant Protection and Inspection Services (PPIS), www.ppis.moag.gov.il
  - Skal Israel Inspection & Certification, www.skal.co.il
- 6. **Certificate issuing bodies and authorities:** as at point 5.
- 7. **Duration of the inclusion:** 30 June 2013.

#### **SWITZERLAND**

- 1. **Product categories:** live or unprocessed agricultural products and vegetative propagating material, processed agricultural products for use as food, feed and seeds for cultivation with the exception of
  - products produced during the conversion period and products containing an ingredient of agricultural origin produced during the conversion period

- 2. **Origin:** Products and organically produced ingredients in products that have been produced in Switzerland or that have been imported into Switzerland:
  - either from the Community,
  - or from a third country for which Switzerland has recognised that the products have been produced and controlled in that third country to rules equivalent to those laid down in the Swiss legislation
- 3. **Production standards:** Ordinance on organic farming and the labelling of organically produced plant products and foodstuffs
- 4. **Competent authority:** Federal Office for Agriculture FOAG, http://www.blw.admin.ch/themen/00013/00085/00092/index.html?lang=en

#### 5. **Control bodies:**

- Bio Test Agro (BTA), www.bio-test-agro.ch
- bio.inspecta AG, www.bio-inspecta.ch
- Institut für Marktökologie (IMO); www.imo.ch
- ProCert Safety AG, www.procert.ch
- Schweizerische Vereinigung für Qualitäts- und Management-Systeme (SQS)
- 6. **Certificate issuing bodies:** as at point 5.
- 7. **Duration of the inclusion:** 30 June 2013.

#### **NEW ZEALAND**

#### 1. **Product categories:**

- (a) live or unprocessed agricultural products and vegetative propagating material and seeds for cultivation, with the exception of:
  - livestock and livestock products bearing or intended to bear indications referring to conversion,
  - products from aquaculture;
- (b) processed agricultural products for use as food with the exception of:
  - livestock products bearing or intended to bear indications referring to conversion,
  - products containing products from aquaculture.

#### 2. **Origin:**

Products of category 1(a) and organically produced ingredients in products of category 1(b) that have been produced in New Zealand or that have been imported into New Zealand:

- either from the Community,
- or from a third country within the framework of a regime which is recognised as equivalent in accordance with the provisions of Article 33(2) of Regulation (EEC) No 2092/91,
- or from a third country whose rules of production and inspection system have been recognised as equivalent to the MAF Food Official Organic Assurance Programme on the basis of assurances and information provided by this country's competent authority in accordance with the provisions established by MAF and provided that only organically produced ingredients intended to be incorporated, up to a maximum of 5 % of products of agricultural origin, in products of category 1(b) prepared in New Zealand are imported.
- 3. **Production standards:** NZFSA Technical Rules for Organic Production
- 4. **Competent authority:** New Zealand Food Safety Authority NZFSA, http://www.nzfsa.govt.nz/organics/
- 5. **Control bodies:** 
  - AsureQuality, www.organiccertification.co.nz
  - BIO-GRO New Zealand, www.bio-gro.co.nz
- 6. **Certificate issuing authority:** Ministry of Agriculture and Forestry (MAF) New Zealand Food Safety Authority (NZFSA).
- 7. **Duration of the inclusion**: 30 June 2011.

### **ANNEX III**

#### MODEL OF THE CERTIFICATE OF INSPECTION

for import of products from organic production into the European Community referred to in Article 13

Existing model: Annex I to Regulation (EC) No 605/2008.

### **ANNEX IV**

# MODEL OF THE EXTRACT OF THE CERTIFCATE OF INSPECTION referred to in Article 14

Existing model: Annex II to Regulation (EC) No 605/2008.

Annex V

Correlation Table referred to in Article 20

Regulation (EC) No 345/2008	Regulation (EC) No 605/2008	This Regulation
_	Article 1(1)	Article 1
_	Article 1(2)	_
_	Article 2, introductory words and point (1)	Article 2, introductory words and point (1)
	_	Article 2, point (2)
	Article 2, point (2)	Article 2, point (3)
	Article 2, point (3)	Article 2, point (4)
	Article 2, point (4)	
	Article 2, point (5)	Article 2, point (5)
_	_	Article 3
_	-	Article 4
-	-	Article 5
_	-	Article 6
Article 1	_	Article 7
Article 2(1)	-	Article 8(1)
Article 2(2)	-	Article 8(2)
Article 2(3)	-	Article 8(3)
Article 2(4)	_	Article 8(3) and 9(2)
_	_	Article 8(4)
Article 2(5)		Article 9(1)
Article 2(6)		Article 9(3) and 9(4)
_	_	Article 10

Regulation (EC) No 345/2008	Regulation (EC) No 605/2008	This Regulation
_	_	Article 11
_	_	Article 12
_	Articles 3 and 4	Article 13
_	Article 5	Article 14
_	Article 6	Article 15
_	_	Article 16
_	_	Article 17
_	Article 7(1)	Article 1
_	Article 7(2)	Article 17
-	-	Article 18
_	_	Article 19
Article 3	Article 8	Article 20
Article 4	Article 9	Article 21
Annex I	_	Article 16(6)
Annex II	_	-
-	-	Annex I
_	Annex I	Annex II
_	Annex II	Annex III
Annex III	Annex IV	Annex IV