

Commission Implementing Regulation (EU) 2016/1842 of 14 October 2016 amending Regulation (EC) No 1235/2008 as regards the electronic certificate of inspection for imported organic products and certain other elements, and Regulation (EC) No 889/2008 as regards the requirements for preserved or processed organic products and the transmission of information (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1842

of 14 October 2016

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 38 (a), (d) and (e) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1235/2008<sup>(2)</sup> lays down detailed rules for imports of organic products from third countries.
- (2) A period for the control bodies and control authorities to submit their request for recognition for the purpose of compliance in accordance with Article 32 of Regulation (EC) No 834/2007 is provided for in Regulation (EC) No 1235/2008. As the implementation of the provisions regarding the import of compliant products is still under assessment and the related guidelines, models, questionnaires and the necessary electronic transmission system are still under development, the deadline for the submission of requests by control bodies and control authorities should be extended.
- (3) Experience has shown diverging practices in Member States as regards the verification of the consignments of organic products prior to their release for free circulation into the Union. For the sake of consistent and effective controls, the types of checks necessary for the verification of the consignments should be clarified, in the light of the risk assessment to be carried out in accordance with Article 27(3) of Regulation (EC) No 834/2007. It is also appropriate to reword the definition of the authorities responsible for the verification of the consignments and the endorsement of the certificates of inspection in order to clarify that those authorities are a competent authority responsible for the organisation of official controls in the field of organic production and designated pursuant to Article 27(1) of Regulation (EC) No 834/2007.

- (4) Diverging practices by control bodies and control authorities have also been observed as regards the classification of products to be imported under the product categories referred to in Annexes III and IV to Regulation (EC) No 1235/2008. For a more uniform classification under those product categories certain definitions should therefore be laid down in the interest of clarity and legal certainty for operators, to ensure uniform implementation of the rules by the control bodies and control authorities, and to facilitate supervision by the competent authorities.
- (5) For product categories referring to unprocessed or processed, those terms should have the same meaning as in the definitions of processed and unprocessed products in Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>(3)</sup> with a view to simplification and consistency with the hygiene rules. However, it should be clarified that labelling and packaging operations are irrelevant for the qualification of the product as unprocessed or processed.
- (6) The two import schemes provided for in Article 33(2) and (3) of Regulation (EC) No 834/2007 are, in principle, mutually exclusive. If a third country is recognised as equivalent in accordance with Article 33(2) of Regulation (EC) No 834/2007, there is no need to recognise a control authority or control body for that country in accordance with Article 33(3). As a consequence, Article 10(2)(b) of Regulation (EC) No 1235/2008 provides that a control authority or control body can only be recognised in accordance with Article 33(3) of Regulation (EC) No 834/2007 for a country that is not recognised in accordance with Article 33(2) of Regulation (EC) No 834/2007. However, in order to avoid any barrier to imports for organic products, it should be possible for control bodies or control authorities to be recognised for a recognised third country where the recognition of that third country does not cover the product to be imported. The existing derogation in Article 10(3) of Regulation (EC) No 1235/2008 should therefore be reworded to take into account the practice in place by referring to products rather than to the category of products.
- (7) On the basis of Regulation (EC) No 834/2007 products imported from a third country may be placed on the Union market as organic if they, in particular, are covered by a certificate of inspection issued by the competent authorities, control authorities or control bodies of a recognised third country or by a recognised control authority or control body.
- (8) In accordance with Action 12 of the Action Plan for the Future of Organic Production in the European Union<sup>(4)</sup> the Commission has developed a system of electronic certification for imports of organic products, as a module integrated into the electronic Trade Control and Expert System (TRACES) provided for in Commission Decision 2003/24/EC<sup>(5)</sup>.
- (9) Certain provisions of Regulation (EC) No 1235/2008 need to be amended in order to introduce the electronic certification system and to ensure the proper functioning of that system. Therefore, the rules for the release for free circulation by the relevant Member State's customs authority and the workflow for the issuing and endorsing of the certificate of inspection, including the verification of the link between the certificate of inspection and the customs declaration, should be clarified. In this context, the

workflow for the issue and endorsement of the certificate of inspection under special customs procedures should also be clarified. For the proper functioning of the electronic system, it is appropriate to refer to email addresses of recognised control bodies and control authorities.

- (10) In order to ensure the integrity of the organic products imported into the Union, it is necessary to clarify that, as a general rule, the control body or control authority issuing the certificate of inspection is the control body or authority certifying the producer or the processor of the product. In case the operator carrying out the last operation for the purposes of preparation as defined in Article 2(i) of Regulation (EC) No 834/2007 is different from the original producer or processor of the product, the certificate of inspection should be issued by the control body or control authority having checked the last operation. Furthermore, it is necessary to clarify that control bodies or control authorities listed in Annex III to Regulation (EC) No 1235/2008 may only issue certificates of inspection according to the terms of their recognition, while those listed in Annex IV to that Regulation may only issue certificates of inspections for the products and origins for which they are listed for.
- (11) Experience has shown diverging practices as regards checks to be carried out by the control body or control authority issuing the certificate of inspection. Therefore, it is necessary to specify the checks to be carried out prior to issuing the certificate. Control bodies or control authorities should only issue the certificate of inspection after full documentary checks and, as appropriate according to their risk assessment, physical checks of the products concerned. For processed agricultural products, control bodies and control authorities listed in Annex III to Regulation (EC) No 1235/2008 should check that all their ingredients have been submitted to a control system in accordance with the terms of recognition of the relevant third country, while control bodies and control authorities listed in Annex IV to that Regulation should check that ingredients have been controlled and certified by control bodies or control authorities recognised in accordance with Union legislation or produced in the Union. Similarly it is necessary to specify the checks to be carried out by control bodies or control authorities listed in Annex IV to Regulation (EC) No 1235/2008 that certify operators in the final stages of the production chain, such as those only carrying out labelling or packaging operations. In such cases, it should be verified that the products concerned have been controlled and certified by control bodies or control authorities listed in that Annex and recognised for the relevant country and product category.
- (12) The authorities responsible for granting and updating the rights to access TRACES for the purpose of electronic certification of inspection should be identified. In addition, rules should be laid down to ensure that TRACES guarantees the authenticity, integrity and legibility over time of the information and the associated metadata throughout the period for which they are required to be kept.
- (13) Provision should also be made for an effective and efficient exchange of information between Member States' authorities in cases of irregularities detected, in particular where products are labelled as organic, but are not accompanied by a certificate of inspection.

- (14) As the last import authorisations issued by Member States expired on 30 June 2015, any reference to import authorisations should be deleted from Regulation (EC) No 1235/2008.
- (15) Operators and Member States should have time to adapt their procedures to the electronic certificate of inspection provided by TRACES. Therefore it is necessary to provide for a transitional period in which the issue and endorsement of the certificate of inspection in paper form is still possible.
- (16) For the sake of ensuring the proper functioning of the electronic certificate of inspection, and in particular to clarify that in-conversion products are excluded from the recognitions granted to third countries, to harmonise the wording regarding the origin of products coming from recognised third countries and to change product category C to cover algae, including micro-algae, it is appropriate to amend certain elements of Annexes III and IV to Regulation (EC) No 1235/2008 without changing the scope of the recognitions previously granted to third countries or to control bodies and control authorities.
- (17) According to the information provided by the United States, the treatment with antibiotics of apples and pears to control fire blight is not allowed in that third country since October 2014. Therefore, it is justified to remove the relevant limitation for product categories A and D from Annex III to Regulation (EC) No 1235/2008.
- (18) In the light of the experience gained with the implementation of the equivalence system, it is necessary to adapt the model of the certificate of inspection and extracts thereof as set out in Annexes V and VI to Regulation (EC) No 1235/2008, in order to provide information on the producer or processor of the product, as well as on the relevant country of origin, when different from the country of export of the product.
- (19) Commission Regulation (EC) No 889/2008<sup>(6)</sup> lays down detailed rules relating to organic production, labelling and control.
- (20) As the new definitions of ‘processed’ and ‘unprocessed’ inserted in Regulation (EC) No 1235/2008 would imply that some of the operations included in the definition of preparation in Article 2(i) of Regulation (EC) No 834/2007 are not to be considered as entailing processing, the rules set out in Article 26 of Regulation (EC) No 889/2008 for the production of processed food and feed would become unclear. Therefore, the rules on the precautionary measures to be taken to avoid the risk of contamination by unauthorised substances or products or mixtures or exchanges with non-organic products should be reworded to make clear that they apply, as appropriate, to operators carrying out preserving activities. For that purpose, it is also appropriate to include definitions of the terms ‘preserving’ and ‘processing’.
- (21) The transmission of information on imported consignments in accordance with Regulation (EC) No 889/2008 should also be done through TRACES.
- (22) A proper functioning of the electronic certification system requires that the information to be notified by the Member States to the Commission on the competent authorities and

control bodies or control authorities includes e-mails addresses and internet websites. It is appropriate to set a new ultimate date for the notification of that information.

- (23) Regulations (EC) No 1235/2008 and (EC) No 889/2008 should therefore be amended accordingly.
- (24) In order to ensure a smooth transition to the new electronic certification system, this Regulation should apply from a date which is six months after its publication. However, the amendment of product category C to cover algae, including micro-algae, should apply from the date of application of the relevant provision of Commission Implementing Regulation (EU) 2016/673<sup>(7)</sup> amending Regulation (EC) No 889/2008 to allow the use of micro-algae for food.
- (25) The measures provided for in this Regulation are in accordance with the opinion of the Committee on organic production,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendment of Regulation (EC) No 1235/2008**

Regulation (EC) No 1235/2008 is amended as follows:

- (1) Article 2 is amended as follows:
- (a) points 5 and 6 are replaced by the following:
5. “verification of the consignment” means the verification carried out by the relevant Member State's competent authority, in the framework of the official controls provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>(8)</sup>, of the fulfilment of the requirements of Regulation (EC) No 834/2007, of Regulation (EC) No 889/2008 and of this Regulation through systematic documentary checks, random identity checks and, as appropriate according to its risk assessment, physical checks, prior to the release of the consignment for free circulation into the Union in accordance with Article 13 of this Regulation;
6. “relevant Member State's competent authority”: means the customs authority, food safety authority or other authorities designated by the Member States pursuant to Article 27(1) of Regulation (EC) No 834/2007 responsible for the verification of the consignments and the endorsement of the certificates of inspection;
- (b) the following points 8 to 11 are added:
8. “aquaculture products”: means aquaculture products as defined in point 34 of Article 4(1) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council<sup>(9)</sup>;
9. “unprocessed”: means unprocessed as used in the definition of unprocessed products in point (n) of Article 2(1) of Regulation

(EC) No 852/2004 of the European Parliament and of the Council<sup>(10)</sup>, irrespective of packaging or labelling operations;

10. “processed”: means processed as used in the definition of processed products in point (o) of Article 2(1) of Regulation (EC) No 852/2004, irrespective of packaging or labelling operations;
  11. “point of entry”: means the point of release for free circulation.;
- (2) in Article 4, paragraph 1 is replaced by the following:
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 thereto 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 before 31 October 2017 shall be taken into account for the drawing up of the first list.;
- (3) in Article 7(2), points (e) and (f) are replaced by the following:
- (e) the name, address, email address, internet address and code number of the control authority or authorities and the control body or bodies recognised by the competent authority referred to in point (d) to carry out controls;
  - (f) the name, address, email address, internet address and code number of the authority or authorities and the control body or bodies responsible in the third country for issuing certificates with a view to importing into the Union.;
- (4) in Article 9(1), point (a) is replaced by the following:
- (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 without delay; any changes made to the information referred to in points (d), (e) and (f) of Article 7(2) shall be notified to the Commission without delay via the computer system referred to in Article 94(1) of Regulation (EC) No 889/2008.;
- (5) in Article 10, paragraph 3 is replaced by the following:
3. By way of derogation from paragraph 2(b), those products originating from a recognised third country listed in accordance with Article 7, but not covered by the recognition granted to that third country, may be included in the list provided for in this Article.;
- (6) Article 13 is replaced by the following:

### *Article 13*

#### **Certificate of inspection**

1. The release for free circulation in the Union 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 competent authority;

- b the verification of the consignment and the endorsement of the certificate of inspection by the relevant Member State's competent authority; and
- c the indication of the number of the certificate of inspection in the customs declaration for release for free circulation as referred to in Article 158(1) of Regulation (EU) No 952/2013 of the European Parliament and of the Council<sup>(11)</sup>.

The verification of the consignment and the endorsement of the certificate of inspection shall be carried out by the relevant Member State's competent authority in that Member State where the consignment is released for free circulation in the Union.

Member States shall designate the points of entry in their territory and inform the Commission of the designated points of entry.

- 2 The certificate of inspection shall be issued by the relevant control authority or control body, endorsed by the relevant Member State's competent authority and completed by the first consignee on the basis of the model and the notes set out in Annex V and using the electronic Trade Control and Expert System (TRACES) established by Commission Decision 2003/24/EC<sup>(12)</sup>.

The original certificate of inspection shall be a printed and hand-signed copy of the completed electronic certificate in TRACES or, alternatively, a certificate of inspection signed in TRACES with an advanced electronic signature within the meaning of Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council<sup>(13)</sup> or with an electronic signature offering equivalent assurances with regard to the functionalities attributed to a signature by applying the same rules and conditions as those laid down in the Commission's provisions on electronic and digitised documents, set out in the Annex to Commission Decision 2004/563/EC, Euratom<sup>(14)</sup>.

When the original certificate of inspection is a printed and hand-signed copy of the completed electronic certificate in TRACES, control authorities, control bodies, relevant Member State's competent authorities and the first consignee shall verify at each stage of issuing, endorsement and reception of the certificate of inspection that this copy corresponds to the information indicated in TRACES.

- 3 To be accepted for endorsement, the certificate of inspection shall have been issued by the control authority or control body of the producer or the processor of the product concerned or, where the operator carrying out the last operation for the purposes of preparation is different from the producer or processor of the product, by the control authority or control body of the operator carrying out the last operation for the purposes of preparation as defined in Article 2(i) of Regulation (EC) No 834/2007.

That control authority or control body shall be:

- a a control authority or control body listed in Annex III to this Regulation for the products concerned and for the third country in which the products have their origin, or, where applicable, in which the last operation for the purposes of preparation has been carried out; or
- b a control authority or control body listed in Annex IV to this Regulation for the products concerned and for the third country in which the products have their origin or in which the last operation for the purposes of preparation has been carried out.

- 4 The control authority or control body issuing the certificate of inspection shall only issue the certificate of inspection and sign the declaration in box 18 of the

certificate after it has carried out a documentary check on the basis of all relevant inspection documents, including in particular the production plan for the product concerned, transport documents and commercial documents and, as appropriate according to its risk assessment, it has carried out a physical check of the consignment.

However, for processed products, if the control authority or control body issuing the certificate of inspection is a control authority or control body listed in Annex III, it shall only issue the certificate of inspection and sign the declaration in box 18 of the certificate after it has verified that all organic ingredients of the product have been controlled and certified by a control authority or control body recognised by the third country concerned listed in that Annex, or if the issuing control authority or control body is a control authority or control body listed in Annex IV, it shall only issue the certificate of inspection and sign the declaration in box 18 of the certificate after it has verified that all organic ingredients of such products have been controlled and certified by a control authority or control body listed in Annex III or IV or have been produced and certified in the Union in accordance with Regulation (EC) No 834/2007.

Where the operator carrying out the last operation for the purposes of preparation is different from the producer or processor of the product, the control authority or control body issuing the certificate of inspection and listed in Annex IV shall only issue the certificate of inspection and sign the declaration in box 18 of the certificate after it has carried out a documentary check on the basis of all relevant inspection documents, including transport documents and commercial documents, it has verified that the production or the processing of the product concerned has been controlled and certified by a control body or control authority recognised for the products concerned and the country concerned in accordance with Article 33(3) of Regulation (EC) No 834/2007 and it has carried out, as appropriate according to its risk assessment, a physical check of the consignment.

At the request of the Commission or of the competent authority of a Member State, the control authority or control body issuing the certificate of inspection in accordance with the second and third subparagraphs shall make available without delay the list of all operators in the organic production chain and the control authorities or control bodies under whose control those operators have placed their operations.

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

The first consignee or, where relevant, the importer may make a copy of the certificate of inspection 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" printed or stamped thereon.

6 At the verification of a consignment, the relevant Member State's competent authority shall endorse the original certificate of inspection in box 20 and shall return it to the person who submitted the certificate.

7 The first consignee shall, at the reception of the consignment, complete box 21 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 purposes of the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007.;

(7) the following Articles 13a to 13d are inserted:



### *Article 13a*

#### **Force majeure or exceptional circumstances**

1 In cases of *force majeure* or exceptional circumstances preventing the electronic system from working, and in particular of malfunctioning of the system or a lack of a lasting connection, certificates of inspection and their extracts may be issued and endorsed pursuant to Article 13(3) to (7) without using TRACES in accordance with paragraphs 2, 3 and 4 of this Article, and on the basis of the models and the notes set out in Annex V or VI. The competent authorities, control authorities, control bodies and operators shall inform the Commission without delay and shall insert in TRACES all the necessary details within ten calendar days following the re-establishment of the system.

2 When the certificate of inspection is issued without using TRACES, it shall be drawn up in one of the official languages of the Union 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 the official language or one of the official languages of the Member State of clearance. Where necessary, the relevant Member State's competent authorities may request a translation of the certificate of inspection into its official language or one of its official languages.

Uncertified alterations or erasures shall invalidate the certificate.

3 The control authority or control body issuing the certificate of inspection shall give a serial number to each issued certificate and keep a register of the issued certificates in chronological order and make the correspondence afterward with the serial number given by TRACES.

4 Where the certificate of inspection is issued and endorsed without using TRACES, the second and third subparagraphs of Article 15(1) and Article 15(5) shall not apply.

### *Article 13b*

#### **Importer**

The importer shall indicate the number of the certificate of inspection in the customs declaration for release for free circulation as referred to in Article 158(1) of Regulation (EU) No 952/2013.

### *Article 13c*

#### **Access rights**

The Commission shall be in charge of granting and updating access rights to TRACES of the competent authorities as defined in Article 2(n) of Regulation (EC) No 834/2007, of competent authorities of third countries recognised in accordance with Article 33(2) of that Regulation and of control authorities and control bodies listed in Annex III or IV to this Regulation. Before granting access rights to TRACES, the

Commission shall verify the identity of the competent authorities, control authorities and control bodies concerned.

The competent authorities as defined in Article 2(n) of Regulation (EC) No 834/2007 shall be in charge of granting and updating access rights to TRACES of operators, control authorities and control bodies in the Union. Before granting access rights to TRACES, the competent authorities shall verify the identity of the operators, control authorities and control bodies concerned. Member States shall designate a single authority responsible to coordinate the cooperation and the contacts with the Commission in this area.

The competent authorities shall communicate the granted access rights to the Commission. The Commission shall activate those access rights in TRACES.

#### *Article 13d*

### **Integrity and legibility of information**

TRACES shall protect the integrity of the information encoded in accordance with this Regulation.

In particular, it shall offer the following guarantees:

- (a) it shall allow each user to be unequivocally identified and shall incorporate effective control measures of access rights in order to protect against illegal, malicious or unauthorised access, deletion, alteration or movement of the information, files and metadata;
- (b) it shall be equipped with physical protection systems against intrusions and environmental incidents and software protection against cyber-attacks;
- (c) it shall safeguard stored data in an environment which is secure in both physical and software terms;
- (d) it shall prevent, by various means, any unauthorised changes and incorporate integrity mechanisms to check if the information has been altered over time;
- (e) it shall keep an audit trail for each essential stage of the procedure;
- (f) it shall provide reliable format conversion and migration procedures in order to guarantee that the information is legible and accessible throughout the entire storage period required;
- (g) it shall have sufficiently detailed and up-to-date functional and technical documentation on the operation and characteristics of the system, that documentation being accessible at all times to the organisational entities responsible for the functional and/or technical specifications.;

(8) Article 14 is amended as follows:

(a) Paragraph 1 is replaced by the following:

1. Where a consignment coming from a third country is placed under customs warehousing or inward processing as provided for in Regulation (EU) No 952/2013, and subject to one or more preparations as referred to in the second subparagraph, the relevant Member State's competent authority shall carry out the verification of the consignment as referred to in point (b)

of the first subparagraph of Article 13(1) of this Regulation before the first preparation is carried out. The reference number of the customs declaration by which the goods have been declared for customs warehousing or for inward processing procedure shall be indicated in box 19 of the certificate of inspection.

The preparation shall be limited to the following types of operations:

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

After this preparation, the consignment shall be subject, before the release for free circulation, to the measures referred to in Article 13(1) of this Regulation.

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 for the purposes of the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007.

(b) Paragraph 2 is amended as follows:

(i) the second subparagraph is replaced by the following:

For each of the batches which results from the splitting, the importer mentioned in box 11 of the certificate of inspection shall submit an extract of the certificate of inspection through TRACES to the relevant Member State's competent authority, in accordance with the model and the notes set out in Annex VI. After verification of the batch, the relevant Member State's competent authority shall endorse the extract of the certificate of inspection in box 13 for the purpose of the release for free circulation. The verification of the batch and the endorsement of the extract of the certificate of inspection shall be carried out by the relevant Member State's competent authority in that Member State where the batch is released for free circulation in the Union.;

(ii) the fourth subparagraph is deleted;

(9) Article 15 is amended as follows:

(a) in paragraph 1, the following second and third subparagraphs are added:

When the verification of a consignment by a relevant Member State's competent authority leads to the detection of an infringement or an irregularity that leads to the refusal of the endorsement of the certificate and of the release for free circulation of products, that authority shall without delay notify that infringement or irregularity to the Commission and to the other Member States through TRACES.

Member States shall ensure effective and efficient coordination amongst competent authorities performing official controls with a view to exchanging without delay information on the detection of consignments of products referred to in Article 1(2) of Regulation (EC) No 834/2007 bearing terms referring to the organic production method, but not declared

as intended to be imported in accordance with Regulation (EC) No 834/2007. The relevant Member State's competent authority shall without delay notify the Commission and the other Member States of those findings through TRACES.

(b) the following paragraph 5 is added:

5. The importer, the first consignee or their control authority or control body shall send the information on infringements or irregularities as regards imported products to the competent authorities of the Member States concerned via the computer system referred to in Article 94(1) of Regulation (EC) No 889/2008 through TRACES.;

(10) in Article 17, paragraph 3 is replaced by the following:

3. The computer system provided for in paragraph 1 shall be able to collect the requests, documents and information referred to in this Regulation where appropriate.;

(11) in Article 18, the second paragraph is replaced by the following:

The first list of recognised countries shall include Argentina, Australia, Costa Rica, India, Israel<sup>(15)</sup>, New Zealand and Switzerland. It shall not contain the code numbers referred to in Article 7(2)(f) of this Regulation. These code numbers shall be added before 1 July 2010 by updating the list in accordance with Article 17(2).;

(12) Article 19 is deleted;

(13) the following Article 19a is inserted:

*Article 19a*

**Transitional rules on the use of certificates  
of inspection not issued in TRACES**

Until 19 October 2017 certificates of inspection as referred to in Article 13(1)(a) and their extracts as referred to in Article 14(2) may be issued and endorsed pursuant to Article 13(3) to (7) without using TRACES in accordance with Article 13a(1), (2) and (3) and on the basis of the models and the notes set out in Annex V or VI.;

(14) Annex III is amended in accordance with Annex I to this Regulation;

(15) in Annex IV, in the list of product categories, 'C: Aquaculture products and seaweeds' is replaced by 'C: Unprocessed aquaculture products and algae';

(16) Annex V is replaced by the text set out in Annex II to this Regulation;

(17) Annex VI is replaced by the text set out in Annex III to this Regulation.

*Article 2*

**Amendment of Regulation (EC) No 889/2008**

Regulation (EC) No 889/2008 is amended as follows:

(1) in Article 2, the following points (t) and (u) are added:

- (t) “preserving” means any action, different from farming and harvesting, that is carried out on products, but which does not qualify as processing as defined in point (u), including all actions referred to in point (n) of Article 2(1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>(16)</sup> and excluding packaging or labelling of the product;
- (u) “processing” means any action referred to in point (m) of Article 2(1) of Regulation (EC) No 852/2004, including the use of substances referred to in Article 19(2)(b) of Regulation (EC) No 834/2007. Packaging or labelling operations shall not be considered as processing.;
- (2) the title of Title II is replaced by the following:  
**TITLE II RULES ON PRODUCTION, PRESERVATION, PROCESSING, PACKAGING, TRANSPORT AND STORAGE OF ORGANIC PRODUCTS;**
- (3) the title of Chapter 3 of Title II is replaced by the following:  
**CHAPTER 3 Preserved and processed products;**
- (4) Article 26 is replaced by the following:

*Article 26*

**Rules for preserving products and for the production of processed feed and food**

- 1 Operators preserving products or producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
- The application of those procedures shall guarantee at all times that preserved or processed products comply with the organic production rules.
- 2 Operators shall comply with and implement the procedures referred to in paragraph 1. In particular, operators shall:
- a take precautionary measures to avoid the risk of contamination by unauthorised substances or products;
  - b implement suitable cleaning measures, monitor their effectiveness and record those measures;
  - c guarantee that non-organic products are not placed on the market with an indication referring to the organic production method.
- 3 Where non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:
- a carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations carried out on non-organic products;
  - b store organic products, before and after the operations, separate by place or time from non-organic products;
  - c inform the control authority or control body of the operations referred to in points (a) and (b) and keep available an updated register of all operations and quantities processed;
  - d take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;

- e carry out operations on organic products only after suitable cleaning of the production equipment.
- 4 Additives, processing aids and other substances and ingredients used for processing feed or food and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.;
- (5) in Article 84, the following third paragraph is added:
- The importer shall transmit the information referred to in the first and second paragraphs by using the electronic Trade Control and Expert System (TRACES) established by Commission Decision 2003/24/EC<sup>(17)</sup>.;
- (6) Article 94(1) is amended as follows:
- (a) points (a) and (b) are replaced by the following:
    - (a) by 30 June 2017, the information referred to in Article 35(a) of Regulation (EC) No 834/2007, including email address and internet address, and afterwards any changes thereto;
    - (b) by 30 June 2017, the information referred to in Article 35(b) of Regulation (EC) No 834/2007, including address, email address and internet address, and afterwards any changes thereto;;
  - (b) the following point (e) is added:
    - (e) by 30 June 2017, the name, address, email address and internet address of the relevant Member State's competent authorities as defined in point (6) of Article 2 of Regulation (EC) No 1235/2008, and afterwards any changes thereto..

### *Article 3*

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

It shall apply from 19 April 2017. However, point (2) of Article 1 shall apply from the date of entry into force of this Regulation and point (15) of Article 1 shall apply from 7 May 2017.

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

Done at Brussels, 14 October 2016.

*For the Commission*

*The President*

Jean-Claude JUNCKER

## ANNEX I

Annex III to Regulation (EC) No 1235/2008 is amended as follows:

- (1) after the heading ‘**LIST OF THIRD COUNTRIES AND RELEVANT SPECIFICATIONS REFERRED TO IN ARTICLE 7**’ the following Note is inserted:

*Note:* According to Article 17(1)(f) of Regulation (EC) No 834/2007 animals and animal products produced during the conversion period shall not be marketed in the Union with the indications referred to in Articles 23 and 24 of that Regulation used in the labelling and advertising of products. Such products are therefore also excluded from the recognitions as regards product categories B and D for all third countries listed in this Annex.;

- (2) in the entries relating to Argentina, Australia, Costa-Rica, India, Israel, Japan, Switzerland, Tunisia and New Zealand, the footnote ‘<sup>(1)</sup> Seaweed not included’ is deleted;

- (3) the entry relating to Argentina is amended as follows:

- (a) in point 1, the limitations on product categories B and D are deleted;
- (b) point 2 is replaced by the following:
2. **Origin:** products of categories A, B and F that have been grown in Argentina and products of category D processed in Argentina with organically grown ingredients that have been grown in Argentina.;

- (4) in the entry relating to Australia, point 2 is replaced by the following:

2. **Origin:** products of categories A and F that have been grown in Australia and products of category D processed in Australia with organically grown ingredients that have been grown in Australia.;

- (5) the entry relating to Costa-Rica is amended as follows:

- (a) the limitation ‘Processed crop products only’ is replaced by ‘Processed plant products only’;
- (b) point 2 is replaced by the following:
2. **Origin:** products of categories A and F that have been grown in Costa-Rica and products of category D processed in Costa-Rica with organically grown ingredients that have been grown in Costa-Rica.;

- (6) in the entry relating to Israel, point 2 is replaced by the following:

2. **Origin:** products of category A and F that have been grown in Israel and products of category D processed in Israel with organically grown ingredients that have been grown in Israel or that have been imported into Israel:
- either from the Union,
- or from a third country in the framework of a regime which is recognised as equivalent in accordance with Article 33(2) of Regulation (EC) No 834/2007.;

- (7) in the entry relating to Japan, point 2 is replaced by the following:
2. **Origin:** products of categories A and F that have been grown in Japan and products of category D processed in Japan with organically grown ingredients that have been grown in Japan or that have been imported into Japan:
- either from the Union,
  - or from a third country for which Japan has recognised that the products have been produced and controlled in that third country in accordance with rules equivalent to those laid down in the Japanese legislation.;
- (8) the entry relating to Switzerland is amended as follows:
- (a) in point 1, the limitation on product category B is deleted;
- (b) point 2 is replaced by the following:
2. **Origin:** products of categories A and F that have been grown in Switzerland and products of category D and E processed in Switzerland with organically grown ingredients that have been grown in Switzerland or that have been imported into Switzerland:
- either from the Union,
  - or from a third country for which Switzerland has recognised that the products have been produced and controlled in that third country in accordance with rules equivalent to those laid down in the Swiss legislation.;
- (9) in the entry relating to Tunisia, point 2 is replaced by the following:
2. **Origin:** products of categories A and F that have been grown in Tunisia and products of category D processed in Tunisia with organically grown ingredients that have been grown in Tunisia.;
- (10) in the entry relating to the United States, in point 1, the limitations on product categories A and D are deleted;
- (11) the entry relating to New Zealand is amended as follows:
- (a) in point 1, the limitations on product categories B and D are deleted;
- (b) point 2 is replaced by the following:
2. **Origin:** products of category A, B and F that have been grown in New Zealand and products of category D processed in New Zealand with organically grown ingredients that have been grown in New Zealand or that have been imported into New Zealand:
- either from the Union,
  - or from a third country in the framework of a regime which is recognised as equivalent in accordance with Article 33(2) of Regulation (EC) No 834/2007,
  - or from a third country whose rules of production and inspection have been recognised as equivalent to the MAF 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 D prepared in New Zealand are imported.;

- (12) in the entry relating to the Republic of Korea, point 2 is replaced by the following:
2. **Origin:** products of category D processed in the Republic of Korea with organically grown ingredients that have been grown in the Republic of Korea or that have been imported into the Republic of Korea:
    - either from the Union,
    - or from a third country for which the Republic of Korea has recognised that the products have been produced and controlled in that third country in accordance with the rules equivalent to those laid down in the legislation of the Republic of Korea..

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

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## ANNEX II

ANNEX  
V

**CERTIFICATE OF INSPECTION  
FOR IMPORT OF PRODUCTS FROM ORGANIC PRODUCTION INTO THE EUROPEAN UNION**

1. Issuing control body or authority (name, address and code)		2. Council Regulation (EC) No 834/2007: — Article 33(2) <input type="checkbox"/> or — Article 33(3) <input type="checkbox"/>		18. Declarati  This is to Regulatio rules of p with Regu  Date  Name an										
3. Serial number of the certificate of inspection		4. Exporter (name and address)		19. Customs  Name an  Control b  Customs										
5. Producer or processor of the product (name and address)		6. Control body or control authority (name, address and code)												
7. Country of origin		8. Country of export		20. Verificati  Authority  Date:  Name an										
9. Country of clearance/Point of entry		10. Country of destination												
11. Importer (name, address and EORI number)		12. First consignee in the Union (name and address)		21. Declarati  This is to (EC) No 8  Name of  Name an										
13. Description of products														
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">CN code</th> <th style="text-align: left;">Trade name</th> <th style="text-align: left;">Number of packages</th> <th style="text-align: left;">Lot number</th> <th style="text-align: left;">Net weight</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>					CN code	Trade name	Number of packages	Lot number	Net weight					
CN code	Trade name	Number of packages	Lot number	Net weight										
14. Container number	15. Seal number		16. Total gross weight											
17. Means of transport before point of entry into the Union														
Mode														
Identification														
International transport document														



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

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- (1) [OJ L 189, 20.7.2007, p. 1.](#)
- (2) 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 ([OJ L 334, 12.12.2008, p. 25.](#))
- (3) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([OJ L 139, 30.4.2004, p. 1.](#))
- (4) COM(2014) 179 final.
- (5) Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system ([OJ L 8, 14.1.2003, p. 44.](#))
- (6) 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 ([OJ L 250, 18.9.2008, p. 1.](#))
- (7) Commission Implementing Regulation (EU) 2016/673 of 29 April 2016 amending Regulation (EC) No 889/2008 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 ([OJ L 116, 30.4.2016, p. 8.](#))
- (8) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([OJ L 165, 30.4.2004, p. 1.](#));
- (9) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC ([OJ L 354, 28.12.2013, p. 22.](#))
- (10) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([OJ L 139, 30.4.2004, p. 1.](#));
- (11) Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([OJ L 269, 10.10.2013, p. 1.](#))
- (12) Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system ([OJ L 8, 14.1.2003, p. 44.](#))
- (13) Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC ([OJ L 257, 28.8.2014, p. 73.](#))
- (14) Commission Decision 2004/563/EC, Euratom of 7 July 2004 amending its Rules of Procedure ([OJ L 251, 27.7.2004, p. 9.](#));
- (15) Hereafter understood as the State of Israel, excluding the territories under Israeli administration since June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.;
- (16) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([OJ L 139, 30.4.2004, p. 1.](#));
- (17) Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system ([OJ L 8, 14.1.2003, p. 44.](#));