

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)

*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>(1)</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>(2)</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>(3)</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:

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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>(4)</sup>.

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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>(5)</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>(6)</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>(7)</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.

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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:

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### *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

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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)

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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

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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>(8)</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:



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- (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>(9)</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;

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- 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>(10)</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

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- (1) 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).’;
- (2) 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).
- (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) 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).
- (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) 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).
- (7) Commission Decision 2004/563/EC, Euratom of 7 July 2004 amending its Rules of Procedure (OJ L 251, 27.7.2004, p. 9).’;
- (8) 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.’;
- (9) 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).’;
- (10) 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).’;

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