



**COMMISSION DELEGATED REGULATION (EU) 2021/1342****of 27 May 2021**

**supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the information to be sent by third countries and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for imported organic products and the measures to be taken in the exercise of that supervision**

**(Text with EEA relevance)**

*Article 1***Supervision of third countries**

1. The annual report to be sent to the Commission in accordance with Article 48(2) of Regulation (EU) 2018/848, by 31 March of each year, by a third country referred to in Article 48(1) of that Regulation and included in the list established by an Implementing Regulation to be adopted pursuant to Article 48(3) of Regulation (EU) 2018/848 ('third country') shall include:

- (a) information on the development of organic production in the third country, including the products produced, the area in cultivation, the production regions, the number of producers, and the food processing activities;
- (b) information on the nature of organic agricultural products and foodstuffs exported to the Union;
- (c) a description of the monitoring and supervisory activities carried out by the competent authority of the third country in the previous year, the results obtained and the corrective measures taken;
- (d) any updates on the production standards applied in the third country assessed as equivalent to the production rules referred to in Titles III and IV of Regulation (EC) No 834/2007;
- (e) any updates on the control measures applied in the third country, assessed as having equivalent effectiveness to those referred to in Title V of Regulation (EC) No 834/2007, and confirmation that such control measures have been permanently and effectively applied;
- (f) any other updates on the third country's technical dossier;
- (g) the internet website or other address where the up-to-date list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status and the product categories concerned;
- (h) any other information deemed relevant by the third country.

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2. The third country shall notify the Commission without delay, via the electronic platform Organic Farming Information System (OFIS), of any changes made to the measures in force in that third country or to their implementation, and in particular to its control system.

3. The third country shall notify the Commission without delay, via OFIS, of any changes made to the administrative data included in the list established by an Implementing Regulation to be adopted pursuant to Article 48(3) of Regulation (EU) 2018/848.

4. The Commission may at any time request any further information from the third country, including the submission of one or more on-the-spot examination reports established by independent experts.

5. The Commission may, based on a risk-assessment or in case of suspected non-compliances, organise an on-the-spot examination in the third country by experts it designates.

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6. Where the Commission has received a notification from a Member State informing it of a substantiated suspicion of an irregularity or infringement as regards compliance of imported organic products with the requirements laid down in Regulation (EC) No 834/2007 and production standards and control measures accepted as equivalent on the basis of the assessment made, it shall notify the competent authority of the third country thereof. That competent authority shall investigate the origin of the suspected irregularity or infringement and shall, within 30 calendar days from the Commission's notification, inform the Commission and the Member State concerned of the result of the investigation and of the actions taken, including, as appropriate, on the spot examinations of operators, using the template set out in Annex III to Commission Delegated Regulation (EU) 2021/1698 <sup>(1)</sup>.

**▼B***Article 2***Supervision of control authorities and control bodies**

1. On the basis of annual reports and in the light of any other information received, the Commission shall ensure appropriate supervision of the control authorities and control bodies referred to in Article 57(1) of Regulation (EU) 2018/848 and included in the list established by an Implementing Regulation to be adopted pursuant to Article 57(2) of Regulation (EU) 2018/848 ('control authorities and control bodies') by regularly reviewing their recognition. For this purpose, the Commission may request the assistance of Member States. The nature of the supervision of the control authorities and control bodies shall be determined on the basis of a risk based approach of non-compliance, taking into account in particular the volume of certified products and their exports to the Union and the results of the regular on-the-spot evaluation, surveillance and multi-annual re-assessment of their activities by an accreditation body or, as appropriate, by a competent authority.

<sup>(1)</sup> Commission Delegated Regulation (EU) 2021/1698 of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies (OJ L 336, 23.9.2021, p. 7).

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1a. The control authority or control body shall notify to the Commission in due time, and no later than within 30 calendar days, of the occurrence of changes to the content of its technical dossier.

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2. By 28 February of each year, the control authorities and control bodies shall send the Commission an annual report. The annual report shall update the information of the technical dossier included in the initial application for the recognition, as last modified. It shall at least include:

- (a) an overview of the activities of the control authority or control body in the third country or third countries for which it has been recognised, including the number of operators and groups of operators involved and the nature of agricultural products and foodstuffs, sorted by categories and grouped by tariff codes;
- (b) any updates on the production standards applied in the third country or third countries for which the control authority or control body has been recognised, including an assessment of the equivalence of those standards to the production rules referred to in Titles III and IV of Regulation (EC) No 834/2007;
- (c) any updates on the control measures applied in the third country or third countries for which the control authority or control body has been recognised, including an assessment of the equivalence to those referred to in Title V of Regulation (EC) No 834/2007, and confirmation that such control measures have been permanently and effectively applied;
- (d) a description of the control activities carried out by the control authority or control body in the previous year in the third country or third countries for which it has been recognised, the results obtained, the irregularities and infringements observed and the corrective measures taken;
- (e) any other updates on the information of the technical dossier that was sent with the initial application for the recognition and its further updates;
- (f) a copy of the latest assessment report issued by the accreditation body or, where appropriate, by a competent authority, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual re-assessment of the activities of the control authority or control body in the third country or third countries for which it has been recognised. That assessment report shall confirm that the control authority or control body has been satisfactorily assessed on its ability to meet the conditions applicable to its recognition by the Commission and that it has effectively implemented its activities according to those conditions. Furthermore, the assessment report shall demonstrate and confirm the equivalence of the production standards and control measures referred to in points (b) and (c);

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- (g) the internet website where the list of operators subject to the control system can be found in an official language of the Union, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products;
- (h) any other information deemed relevant by the control authority or control body.

The annual report and any additional information requested by the Commission concerning the annual report shall be provided via OFIS.

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3. The Commission may at any time request any further information from the control authorities and control bodies, including concerning the annual report. That additional information shall be provided in electronic form.

4. The Commission may organise risk-based on-the-spot examinations of the control authorities and control bodies to evaluate the quality and effectiveness of the controls carried out by each control authority or control body. Those examinations may be coordinated with the relevant accreditation body. The Commission may be accompanied by independent experts during those on-the-spot examinations.

The Commission may request any further information, including the presentation of one or more ad hoc on-the-spot examination reports established by independent experts that it designates.

On-the-spot examinations may include:

- (a) a visit to the offices or premises of the control authorities and control bodies, their outsourced services and operators or groups of operators under their control, in the Union and in third countries;
- (b) a document review of the relevant documents describing the structure, functioning and quality management of the control authorities or control bodies;
- (c) a document review of staff files, including evidence of their competencies, training records, conflict of interest statements and records of evaluation and supervision of staff;
- (d) a check of operators' or groups of operators' files in order to verify the treatment of non-compliances and complaints, the minimum control frequency, the use of a risk-based approach in the conduct of inspections, the implementation of follow-up visits and visits without prior notice, the sampling policy and the exchange of information with other control bodies and control authorities;

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- (e) a review audit, which is the inspection of operators or groups of operators to verify compliance with the standard control and risk assessment procedures of the control authority or control body and to verify its effectiveness, taking into account the evolution of the operators' situation from the last inspection of the control authority or control body;
  
- (f) a witness audit, which is the evaluation of the performance of the physical on-the-spot inspection carried out by an inspector of the control authority or control body.

5. For the purpose of preparing on-the-spot examinations of the control authorities and control bodies, the Commission may request information from the control bodies and control authorities. That information must be provided within a period to be determined by the Commission.

6. Where the Commission has received a notification from a Member State informing it of a substantiated suspicion of an irregularity or infringement as regards compliance of imported organic products with the requirements laid down in Regulation (EC) No 834/2007 and production standards and control measures accepted as equivalent on the basis of the assessment made, it shall notify the control authority and control body thereof. The control authority or the control body shall investigate the origin of the suspected irregularity or infringement and shall, within 30 calendar days from the Commission's notification, inform the Commission and the Member State concerned of the result of the investigation and of the actions taken by the control authority or the control body, including, as appropriate, on the spot examinations of operators, using the template set out in Annex III to Delegated Regulation (EU) 2021/1698.

7. Before certifying a new operator or group of operators, the control authority or control body shall ensure that, if the operator or group of operators have been suspended or withdrawn within the last 2 years by their previous control authority or control body, the non-conformities identified by those control authorities or control bodies have been or are being addressed by the operator or group of operators. If the control authority or control body cannot ensure that the non-conformities have been or are being addressed, the control authority or control body shall not certify the operator or group of operators.

**▼ B***Article 3***Review of the recognition of third countries**

In the framework of its regular review of the recognition of third countries pursuant to Article 48(2) of Regulation (EU) 2018/848, the Commission shall apply the following rules and amend the list of third countries accordingly pursuant to Article 48(3) of that Regulation:

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- (a) the Commission may at any time amend the specifications in the list on the basis of the information received;
- (b) the Commission may suspend the entry of a third country from the list either on the basis of the information received, or where a third country has not supplied sufficient information as required or where it has not agreed to an on-the-spot examination;
- (c) the Commission shall suspend the entry of a third country from the list where, after a request from the Commission, the third country fails to take appropriate and timely remedial action within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days;
- (d) ► **M1** the Commission may withdraw the entry of a third country from the list where: ◀
  - (i) the third country does not send on time the annual report referred to Article 1(1) of this Regulation;
  - (ii) the information included in that annual report is incomplete;
  - (iii) after a request from the Commission within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days, the third country does not keep available the information or does not communicate all information related to its technical dossier or control system;

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- (iv) after a request from the Commission, the third country does not agree to an on-the-spot examination, or if an on-the-spot examination comes up with a negative result due to a systematic malfunctioning of the control measures; or
- (v) in any other situation where there is a risk for the consumer to be misled about the true nature of the products certified by the third country.

**▼ B***Article 4***Review of the recognition of control authorities and control bodies**

1. In the framework of its regular review of the recognition of control authorities and control bodies pursuant to Article 2(1) of this Regulation, the Commission shall apply the following rules and amend the list of control authorities and control bodies accordingly pursuant to Article 57(2) of Regulation (EU) 2018/848:

- (a) the Commission may at any time amend the specifications relating to a control authority or control body in the list on the basis of the information received;

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- (b) the Commission may suspend the entry of a control authority or control body from the list either on the basis of the information received, or where the control authority or control body has not supplied sufficient information as required within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days, or where it has not agreed to an on-the-spot examination;

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- (c) the Commission shall suspend the entry of a control authority or control body from the list where, after a request from the Commission, the control authority or control body fails to take appropriate and timely remedial action within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days;

- (d) the Commission shall withdraw the entry of a control authority or control body from the list where:

- (i) the control authority or control body does not send on time the annual report referred to in Article 2(2) of this Regulation;

- (ii) the information included in the annual report is incomplete;

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- (iii) the control authority or control body does not keep available or does not communicate all information related to its technical dossier or control system after a request from the Commission within a period to be determined by the Commission, according to the severity of the problem and which shall not be less than 30 days or in accordance with Article 2(1a);

- (iv) the control authority or control body does not keep available or does not communicate information on the investigations of a non-compliance;

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- (v) the control authority or control body fails to take adequate corrective measures in response to the non-compliance and infringements observed;

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- (vi) the control authority or control body does not agree to an on-the-spot examination required by the Commission, or does not send all the information requested under Article 2(5), or if an on-the-spot examination comes up with a negative result due to a systematic malfunctioning of the control measures; or

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- (vii) in any other situation, there is a risk for the consumer to be misled about the true nature of the products certified by the control authority or control body.

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2. Prior to a withdrawal in accordance with point (d) of paragraph 1, the Commission shall request the control authority or control body to remedy the situations referred to in that point within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days.

**▼ M1***Article 4a***Assistance to supervision by Member States**

1. For the purpose of the review of the recognition of third countries in accordance with Article 3, the Commission, when requesting the assistance of Member States, shall be assisted by two Member States to act as co-rapporteurs for the examination of the annual report and any other information received, and for the evaluation of the operational performance of the third countries.

2. For the purpose of the review of the recognition of control authorities and control bodies in accordance with Article 2, the Commission, when requesting the assistance of Member States, shall be assisted by two Member States to act as co-rapporteurs for the examination of the annual report and any other information received, and for the evaluation of the operational performance of the control authorities and control bodies.

3. The Commission may divide the requests for assistance in accordance with paragraphs 1 and 2 between the Member States proportionally with the number of votes of each Member State in the Committee on organic production.

**▼ B***Article 5***Entry into force and application**

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

It shall apply from 1 January 2022.

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Articles 1, 3 and Article 4a(1) shall apply until 31 December 2026.

Articles 2, 4 and Article 4a(2) shall apply until 31 December 2024.

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