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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	25 October 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2023) 7080 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 25.10.2023 amending Commission Delegated Regulation (EU) 2021/1342 as regards 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 and the measures to be taken in the exercise of that supervision

Delegations will find attached document C(2023) 7080 final.

Encl.: C(2023) 7080 final



EUROPEAN
COMMISSION

Brussels, 25.10.2023
C(2023) 7080 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 25.10.2023

amending Commission Delegated Regulation (EU) 2021/1342 as regards 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 and the measures to be taken in the exercise of that supervision

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2021/1342¹ supplements Regulation (EU) 2018/848 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 834/2007² for imported organic products and the measures to be taken in the exercise of that supervision.

In order to ensure the appropriate supervision of the third countries recognised under Article 33(2) of Regulation (EC) No 834/2007, it is necessary to clarify and further specify provisions concerning actions taken by the competent authorities following a notification by the Commission of a substantiated suspicion of an irregularity or infringement.

In addition, it is necessary to elaborate further the grounds for measures to be taken by the Commission in the exercise of its supervision of recognised third countries.

In order to ensure the appropriate supervision of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007, it is necessary to lay down additional rules on the procedures for the regular review of their recognition.

Furthermore, it is necessary to elaborate further the grounds for measures to be taken by the Commission in the exercise of its supervision of recognised control authorities and control bodies.

Finally, considering that Member State authorities have acquired substantial experience and expertise in the field of granting access to imported organic goods into the Union, this act provides specific provisions for the roles of Member State authorities in assisting the Commission with the review of the recognitions of third Countries and control authorities and control bodies.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The act was discussed thoroughly with the Group of Experts on Organic Production as well as with the main organisations representing accreditation and control bodies active in the import of organic products from third countries. DG AGRI cooperated closely with other DGs in the field of their specific expertise when drafting these rules. The draft delegated regulation was published for feedback on the European Commission portal “Have your say” from 11 July 2023 until 8 August 2023. Five comments were received, and they were closely analysed. The act was not revised following the feedback received.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This delegated act modifies the provisions laid out in Article 1(6) and in point (d) of Article 3 of Delegated Regulation (EU) 2021/1342 as regards the actions taken by the competent authorities of third countries following a notification by the Commission of a substantiated

¹ 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 ([OJ L 292, 16.8.2021, p. 20](#)).

² 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 ([OJ L 189, 20.7.2007, p. 1](#));

suspicion of an irregularity or infringement and the way that those competent authorities should inform the Commission and the Member State concerned of the result of the investigation. Furthermore, it elaborates further the grounds for measures to be taken by the Commission in the exercise of its supervision of recognised third countries.

The act amends provisions in Article 2 and in Article 4(1) of the Delegated Regulation (EU) 2021/1342 to specify additional information to be provided by control authorities and control bodies to the Commission and to elaborate further the grounds for measures to be taken by the Commission in the exercise of its supervision of the control authorities and control bodies.

The act lays down an additional provision in Article 4a of the Regulation concerning the role of Member State authorities in assisting the Commission with the review of the recognitions of third countries and control authorities and control bodies. This Articles regulates the way the tasks of assisting the Commission with the review of the recognitions should be divided between the Member States.

COMMISSION DELEGATED REGULATION (EU) .../...

of 25.10.2023

amending Commission Delegated Regulation (EU) 2021/1342 as regards 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 and the measures to be taken in the exercise of that supervision

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007¹, and in particular Articles 48(4) and 57(3) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2021/1342² supplements Regulation (EU) 2018/848 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.
- (2) In order to ensure the appropriate supervision of the third countries recognised under Article 33(2) of Regulation (EC) No 834/2007, it is necessary to clarify that the actions taken by the competent authorities in third countries following a notification by the Commission 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, production standards and control measures accepted as equivalent may include on-the-spot examinations of operators. It is also necessary to specify that the competent authorities should inform the Commission and the Member State concerned of the result of the investigation and the action taken using the template in Annex III to Commission Delegated Regulation (EU) 2021/1698³.

¹ 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 (OJ L 189, 20.7.2007, p. 1).

² 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 ([OJ L 292, 16.8.2021, p. 20](#)).

³ 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](#)).

- (3) Furthermore, it is necessary to elaborate further the grounds for measures to be taken by the Commission in the exercise of its supervision of recognised third countries.
- (4) In order to ensure the appropriate supervision of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007, it is necessary to lay down additional rules on the procedures for the regular review of their recognition.
- (5) For that purpose, this Regulation should specify additional information to be provided by those control authorities and control bodies to the Commission for the exercise of that supervision. This Regulation should also provide for the possibility for the Commission to organise risk-based on-the-spot examinations of the control authorities and control bodies as well as for the modalities of carrying out those examinations. For the exercise of the supervision of the control authorities and control bodies by the Commission, it is also necessary to provide for the checks to be carried out for certifications of new operators or groups of operators.
- (6) Furthermore, it is necessary to elaborate further the grounds for measures to be taken by the Commission in the exercise of its supervision of recognised control authorities and control bodies.
- (7) Member State authorities have acquired substantial experience and expertise in the field of granting access to imported organic goods into the Union. The Commission should be able to draw on the experience of Member States in checks performed during import controls for the purpose of supervision of recognised third countries and control authorities and control bodies, including the evaluation of their operational performance. The tasks of assisting the Commission with the review of the recognitions should be divided in a just and proportionate way between the Member States taking into account the number of votes of each Member State in the Committee of Organic Production.
- (8) Delegated Regulation (EU) 2021/1342 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2021/1342 is amended as follows:

- (1) in Article 1, paragraph 6 is replaced by the following:

‘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.’;
- (2) Article 2 is amended as follows:

(a) the following paragraph 1a is inserted:

‘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.’;

(b) paragraph 3 is replaced by the following:

‘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.’;

(c) the following paragraphs 4 to 7 are added:

‘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;
- (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 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.';

(3) in Article 3, point (d) is amended as follows:

(a) the introductory wording is replaced by the following:

‘the Commission may withdraw the entry of a third country from the list where:’;

(b) point (iv) is replaced with the following:

‘(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;’;

(c) the following point (v) is added:

‘(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.’;

(4) in Article 4, paragraph (1) is amended as follows:

(a) point (b) is replaced with the following:

‘(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;’

(b) point (d) is amended as follows:

(i) point (iii) is replaced by the following:

‘(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);’

(ii) point (iv) is replaced by the following:

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

(iii) point (vi) is replaced by the following:

‘(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’

(5) the following Article 4a is inserted:

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.’;
- (6) in Article 5, the third and fourth paragraph are replaced by the following:
- ‘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.’

Article 2

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

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

Done at Brussels, 25.10.2023

For the Commission
The President
Ursula VON DER LEYEN