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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 27.5.2021 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

Delegations will find attached document C(2021) 3572 final.

Encl.: C(2021) 3572 final



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

of 27.5.2021

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Following the entry into force of Regulation (EU) 2018/848 of the European Parliament and of the Council¹, it is necessary to adopt this Delegated Regulation supplementing that Regulation as regards the 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 imports of organic products into the Union and the measures to be taken in the exercise of that supervision.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The act was thoroughly discussed with Member States at the Group of Experts on Organic Production as well as with the main organisations representing the organic sector.

WTO partners were notified and general public consultations were carried out. Following the general public consultation, all comments received via the feedback mechanism have been considered and the act has not been amended.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Regulation (EU) 2018/848 underlines in its recital 96 that third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 should continue to be recognised as such under Regulation (EU) 2018/848, for a limited period necessary to ensure a smooth transition to the scheme of recognition through an international agreement, provided that they continue to ensure their organic production and control rules are equivalent to the relevant Union rules and they fulfil all the requirements related to the supervision of their recognition by the Commission. In order to ensure that supervision supplementing rules are necessary.

Moreover, recital 97 of Regulation (EU) 2018/848 states that sufficient time should be given to control authorities and control bodies recognised by the Commission under the equivalence scheme to issue certificates in third countries for the purpose of importing products in order to allow those control authorities and control bodies to prepare themselves to obtain recognition for the purposes of import of products that comply with Union rules.

As provided for in Article 48(4) and 57(3) of Regulation (EU) 2018/848, this delegated act supplements that Regulation with provisions concerning the appropriate supervision of such third countries or the control authorities and control bodies concerned. In particular, it provides for rules on the procedures for the regular review of their recognition during the transitional periods. In addition, this Regulation set out the measures to be taken by the Commission in the exercise of that supervision, including suspension or withdrawal of

¹ 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 834/2007 (OJ L 150, 14.6.2018, p. 1).

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).

recognised third countries or control authorities and control bodies from the lists established pursuant to Articles 48(3) and 57(2) of Regulation (EU) 2018/848.

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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)

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) Pursuant to Article 48(1) of Regulation (EU) 2018/848, the recognition of third countries for the purposes of equivalence under Article 33(2) of Council Regulation (EC) No 834/2007² for imports of organic products into the Union will expire on 31 December 2026.
- (2) Pursuant to Article 57(1) of Regulation (EU) 2018/848, the recognition of control authorities and control bodies for the purposes of equivalence under Article 33(3) of Regulation (EC) No 834/2007 for imports of organic products into the Union will expire on 31 December 2024.
- (3) When placed on the Union market until the end of those transitional periods, organic products imported into the Union under those import schemes have to be produced in accordance with the production rules and subject to control arrangements equivalent to those laid down in Regulation (EC) No 834/2007 as well as with the associated

¹ OJ L 150, 14.6.2018, p. 1.

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 L189, 20.7.2007, p. 1).

implementing rules laid down in Commission Regulations (EC) No 889/2008³ and (EC) No 1235/2008⁴.

- (4) Therefore, at all stages of production, preparation and distribution in third countries, operators should continue to submit their activities either to a control system of a third country recognised for the purposes of equivalence as referred to in Article 48(1) of Regulation (EU) 2018/848, or to a control authority or control body as referred to in Article 57(1) of that Regulation.
- (5) In order to ensure the appropriate supervision of such third countries or the control authorities and control bodies concerned, it is necessary to lay down rules on the procedures for the regular review of their recognition during the transitional periods. For that purpose, this Regulation should specify, in particular, the information to be provided by the third countries or the control authorities and control bodies to the Commission for the exercise of that supervision, including through on-the-spot examination. In addition, this Regulation should set out the measures to be taken by the Commission in the exercise of that supervision, including suspension or withdrawal of recognised third countries or control authorities and control bodies from the lists established pursuant to Articles 48(3) and 57(2) of Regulation (EU) 2018/848.
- (6) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848 until the expiry of the recognition of the third countries or control authorities and control bodies,

HAS ADOPTED THIS REGULATION:

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;

³ 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).

⁴ 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).

- (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.
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.
 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 action taken.

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 multiannual re-assessment of their activities by an accreditation body or, as appropriate, by a competent authority.
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);

- (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.

3. The Commission may request any additional information concerning the annual report. That additional information shall be provided in electronic form.

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:

- (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) the Commission shall 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; or

- (iv) after a request from the Commission, the third country does not agree to an on-the-spot examination.

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;
 - (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 or where it has not agreed to an on-the-spot examination;
 - (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;
 - (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;
 - (iv) the control authority or control body does not keep available information on the investigations of a non-compliance;
 - (v) the control authority or control body fails to take adequate corrective measures in response to the non-compliance and infringements observed;
 - (vi) the control authority or control body does not agree to an on-the-spot examination required by the Commission, or if an on-the-spot

examination comes up with a negative result due to a systematic malfunctioning of the control measures; or

(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.

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.

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.

Articles 1 and 3 shall apply until 31 December 2026.

Articles 2 and 4 shall apply until 31 December 2024.

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

Done at Brussels, 27.5.2021

For the Commission
The President
Ursula VON DER LEYEN