



Brussels, **XXX**  
[...](2021) **XXX** draft

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

**of **XXX****

**amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the criteria for the recognition of control authorities and control bodies that are competent to carry out controls on organic products in third countries, and for the withdrawal of their recognition**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Following the adoption of the Regulation (EU) 2018/848, which will enter into application on 1 January 2022, the Commission may recognise control authorities and control bodies that are competent to carry out controls of imported organic products and to issue organic certificates in third countries.

Building on the Commission's experience with the supervision of control authorities and control bodies operating in third countries, and with a view to ensuring the robustness of controls performed by control authorities and control bodies and to guaranteeing the integrity of organic products imported from third countries, it is necessary to reinforce the capacity of control authorities and control bodies to carry out effective controls on operators producing organic products in third countries.

In order to achieve these objectives, and in the interest of transparency, additional criteria for the recognition or the withdrawal of control authorities and control bodies should be laid down.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

The draft delegated act was discussed thoroughly with Member States at the Group of Experts on Organic Production as well as with the main organisations representing the organic sector. DG AGRI cooperated closely with other DGs in the field of their specific expertise when drafting these rules. WTO partners were notified and general public consultations were carried out.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

This delegated act lays down further criteria to those laid down in Article 46(2) of Regulation (EU) 2018/848 for the recognition of the control authorities and control bodies and criteria for the withdrawal of such recognition.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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<sup>1</sup>, and in particular point (a) of Article 46(7) thereof,

Whereas:

- (1) Pursuant to Article 46 of Regulation (EU) 2018/848, the Commission may recognise control authorities and control bodies that are competent to carry out controls of imported organic products and to issue organic certificates in third countries.
- (2) Building on the Commission's experience with the supervision of control authorities and control bodies operating in third countries, and with a view to ensuring the robustness of controls performed by control authorities and control bodies and to guaranteeing the integrity of organic products imported from third countries, it is necessary to reinforce the capacity of control authorities and control bodies to carry out effective controls on operators producing organic products in third countries. In order to achieve this objective, additional criteria for the recognition of control authorities and control bodies should be introduced.
- (3) In particular, point (b) of Article 46(2) of Regulation (EU) 2018/848 requires control authorities and control bodies to have the capacity to carry out controls to ensure that the conditions set out in points (a), (b)(i) and (c) of Article 45(1) of that Regulation are met in relation to organic products and in-conversion products. As those controls are essential to ensure compliance with Regulation (EU) 2018/848, a control authority or control body should not be allowed to delegate control tasks. However, in order to give the necessary flexibility to control authorities or control bodies, sampling should not be included in the prohibition to delegate control tasks.
- (4) In case of serious or repetitive infringements as regards the certification of operators or the controls and actions performed by the control authority or control body, or when the control authority or control body has failed to take appropriate and timely remedial action, the Commission should be able to withdraw the recognition of the control authority or control body. Therefore, in the interest of transparency, criteria for the withdrawal of the recognition of control authorities and control bodies should be laid down.

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<sup>1</sup> OJ L 150, 14.6.2018, p. 1.

- (5) Regulation (EU) 2018/848 should therefore be amended accordingly.
- (6) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

In Article 46 of Regulation (EU) 2018/848, paragraph 2 is replaced by the following:

‘2. Control authorities and control bodies shall be recognised in accordance with paragraph 1 for the control of the import of the categories of products listed in Article 35(7) if they fulfil the following criteria:

- (a) they are legally established in one Member State or third country;
- (b) they have the capacity to carry out controls to ensure that the conditions set out in points (a), (b)(i) and (c) of Article 45(1) and in this Article are met in relation to organic products and in-conversion products intended for import into the Union, without delegating control tasks; for the purposes of this point, control tasks carried out by persons working under an individual contract or a formal agreement that place them under the management control and the procedures of the contracted control authorities or control bodies shall not be considered as delegation, and the prohibition to delegate control tasks shall not apply to sampling;
- (c) they offer adequate guarantees of objectivity and impartiality and are free from any conflict of interest as regards the exercise of their control tasks; in particular, they have procedures in place ensuring that the staff performing controls and other actions is free from any conflict of interest, and that the operators are not inspected by the same inspectors for more than 3 years consecutively;
- (d) in the case of control bodies, they are accredited for the purpose of their recognition in accordance with this Regulation by only one accreditation body under the relevant harmonised standard for ‘Conformity assessment – Requirements for bodies certifying products, processes and services’, the reference of which has been published in the *Official Journal of the European Union*;
- (e) they have the expertise, equipment and infrastructure required to carry out control tasks, and have a sufficient number of suitable qualified and experienced staff;
- (f) they have the capacity and the competency to carry out their certification and control activities in accordance with the requirements of this Regulation and in particular Commission Delegated Regulation (EU) 2021/XXX\* for each type of operator (single operator or group of operators) in each third country and for each category of products they want to be recognised for;
- (g) they have procedures and arrangements in place to ensure the impartiality, the quality, the consistency, the effectiveness and the appropriateness of controls and other actions performed by them;
- (h) they have sufficient qualified and experienced staff so that controls and other actions can be performed effectively and in due time;
- (i) they have appropriate and properly maintained facilities and equipment to ensure that staff can perform controls and other actions effectively and in due time;

- (j) they have procedures in place in order to ensure that their staff have access to the premises of, and documents kept by operators so as to be able to accomplish their tasks;
- (k) they have internal skills, training and procedures suitable to supervise and inspect operators as well as the internal control system of a group of operators, if any;
- (l) their previous recognition for a specific third country and/or for a category of products has not been withdrawn in accordance with paragraph 2a or their accreditation has not been withdrawn or suspended by any accreditation body in accordance with its procedures for the suspension or withdrawal established in accordance with the relevant international standard, in particular the International Organisation for Standardisation (ISO) standard 17011 – Conformity assessment – general requirements for accreditation bodies accrediting conformity assessment bodies, during the 24 months preceding:
  - (i) their request for recognition for the same third country and/or for the same category of products, except where the previous recognition was withdrawn in accordance with point (k) of paragraph 2a;
  - (ii) their request for an extension of the scope of recognition to an additional third country in accordance with Article 2 of Delegated Regulation (EU) 2021/XXX, except where the previous recognition was withdrawn in accordance with point (k) of paragraph 2a of this Article;
  - (iii) their request for an extension of the scope of recognition to an additional category of products in accordance with Article 2 of Delegated Regulation (EU) 2021/XXX;
- (m) in the case of control authorities, they are public administrative organisations in the third country for which they request recognition;
- (n) they meet the procedural requirements laid down in Chapter I of Delegated Regulation (EU) 2021/XXX; and
- (o) they meet any additional criteria that may be laid down in a delegated act adopted pursuant to paragraph 7.

2a. The Commission may withdraw the recognition of a control authority or control body for a specific third country and/or a category of products if:

- (a) one of the recognition criteria set out in paragraph 2 is no longer met;
- (b) the Commission has not received the annual report referred to in Article 4 of Delegated Regulation (EU) 2021/XXX by the deadline specified in that Article or the information included in the annual report is incomplete, inaccurate or does not comply with the requirements set out in that Regulation;
- (c) the control authority or control body does not make available or does not communicate all the information related to the technical dossier referred to in paragraph 4, to the control system applied by it, or to the up-to-date list of operators or groups of operators or to the organic products covered by the scope of its recognition;
- (d) the control authority or control body does not notify the Commission within 30 calendar days of changes to its technical dossier referred to in paragraph 4;

- (e) the control authority or control body does not provide information requested by the Commission or by a Member State within the deadlines set, or the information is incomplete, inaccurate or does not comply with the requirements set out in this Regulation, in Delegated Regulation (EU 2021/XXX and in an implementing act to be adopted pursuant to paragraph 8, or does not cooperate with the Commission, in particular during the investigations of a non-compliance;
- (f) the control authority or control body does not agree to an on-the-spot examination or audit initiated by the Commission;
- (g) the result of the on-the-spot examination or audit indicates a systematic malfunctioning of control measures or the control authority or control body is unable to implement all the recommendations made by the Commission after the on-the-spot examination or audit, in their proposed action plan submitted to the Commission;
- (h) the control authority or control body fails to take adequate corrective measures in response to the non-compliances and infringements observed within a deadline set by the Commission according to the severity of the situation, which shall not be shorter than 30 calendar days;
- (i) in case an operator changes its control authority or control body, the control authority or control body does not communicate to the new control authority or control body the relevant elements of the control file, including written records, of the operator within a maximum of 30 calendar days after having received the request for transfer from the operator or the new control authority or control body;
- (j) there is a risk for the consumer to be misled about the true nature of the products covered by the scope of the recognition; or
- (k) the control authority or control body has not certified any operator for 48 consecutive months in the third country for which it is recognised.

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\* Commission Delegated Regulation (EU) 2021/... of [date] 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 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 xxx, xxx, p. x).’

## *Article 2*

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.

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

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*