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#### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	21 January 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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No. Cion doc.:	C(2021) 254 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 21.1.2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council by laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators

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Delegations will find attached document C(2021) 254 final.

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Encl.: C(2021) 254 final



Brussels, 21.1.2021  
C(2021) 254 final

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

**of 21.1.2021**

**supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council by laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

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

Following the adoption of the new organic regulation, which will enter into application on 1 January 2022, it is necessary to adopt a delegated regulation supplementing Regulation (EU) 2018/848 on the official controls by laying down further rules on traceability and mass balance checks as well as on specific controls on groups of operators. Organic sector needs to have legal certainty on the rules that will apply for these two issues and EU Member States need to have enough time to integrate these rules into their national legislation.

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

The 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, namely IFOAM, COPA-COGECA and EOCC. 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 specific rules for official controls to ensure the traceability at all stages of production, preparation and distribution and to ensure proper controls performed on groups of operators.

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

**of 21.1.2021**

**supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council by laying down specific criteria and conditions for the checks of documentary accounts in the framework of official controls in organic production and the official controls of groups of operators**

(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 Article 38(8)(a)(i) and (ii) thereof,

Whereas:

- (1) In order to ensure the integrity of organic production, it is necessary to lay down specific criteria and conditions for the performance of official controls conducted to ensure the traceability at all stages of production, preparation and distribution, and compliance with Regulation (EU) 2018/848, in particular with regard to the physical on-the-spot inspection of the organic operators or groups of operators as referred to in Article 38(3) of that Regulation. In order to be effective, that physical on-the-spot inspection should at least include a traceability check and a mass balance check by means of checks of documentary accounts. The traceability check is intended to confirm whether products received or sent by the operator or group of operators are organic or in-conversion. The purpose of the mass balance check is to determine the balance between the input and output of the operator or group of operators and, in particular, the plausibility of the volumes of organic or in-conversion products. The elements to be covered by the traceability check and the mass balance check should be laid down.
- (2) For the purpose of official controls, the concept of group of operators as laid down in Article 36(1) of Regulation (EU) 2018/848 consists of a specific category of operators who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed. Each group of operators has to establish a system for internal controls (ICS) comprising a documented set of control activities. The competent authority or, where appropriate, the control authority or control body, should be appropriately qualified to assess the ICS and carry out re-inspections on a risk based sample of the members of the group of operators in order to make a conclusion on the overall compliance of the group. Therefore, it is necessary to lay down requirements for the competence of the competent authority or, where appropriate, the control authority or control body, to assess that specific composition of operators within a group as well as the ICS, for a

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

harmonised framework for the assessment of the ICS and for the selection of the sample of the members for the re-inspections.

- (3) 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*

#### *Checks of documentary accounts*

1. The physical on-the-spot inspection pursuant to Article 38(3) of Regulation (EU) 2018/848 shall include a traceability check and a mass balance check of the operator or group of operators carried out by means of checks of documentary accounts.
2. The competent authority, or where appropriate, the control authority or control body shall perform the traceability and mass balance check according to the standard template documented in the written record referred to in Article 38 (6) of Regulation (EU) 2018/848.
3. For the purpose of the traceability check and mass balance check, the selection of products, groups of products and period under verification shall be made on a risk basis.
4. The traceability check shall cover at least the following elements justified by appropriate documents including stock and financial records:
  - (a) the name and address of the supplier and, where different, of the owner or the seller, or the exporter of the products;
  - (b) the name and address of the consignee and, where different, of the buyer or importer of the products;
  - (c) the certificate of the supplier in accordance with Article 35(6) of Regulation (EU) 2018/848;
  - (d) the information referred to in the first paragraph of point 2.1. of Annex III to Regulation (EU) 2018/848;
  - (e) the appropriate lot identification.
5. Where relevant, the mass balance check shall cover at least the following elements justified by appropriate documents including stock and financial records:
  - (a) the nature and the quantities of products delivered to the unit and, where relevant, of materials bought and the use of such materials, and, where relevant, the composition of products;
  - (b) the nature and the quantities of products held in storage at the premises;
  - (c) the nature and the quantities of the products that have left the unit of operator or group of operators to the consignee's premises or storage facilities;
  - (d) in case of operators who buy and sell the product(s) without physically handling the product(s), the nature and the quantities of products that have been bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees;

- (e) the yield of the products obtained, collected or harvested over the previous year;
- (f) the actual yield of the products obtained, collected or harvested over the current year;
- (g) the number and/or weight in case of livestock managed over the current and previous year;
- (h) any losses, increase or decrease in quantity of products at any stage of production, preparation and distribution;
- (i) organic or in-conversion products that are sold on the market as non-organic.

## *Article 2*

### *Official controls of groups of operators*

1. In order to certify and verify the compliance of a group of operators, the competent authority or, where appropriate, the control authority or control body, shall assign inspectors competent to assess systems for internal controls (ICS).
2. For the purpose of evaluating the set-up, functioning and maintaining of the ICS of a group of operators, the competent authority or, where appropriate, the control authority or control body, shall determine at least that:
  - (a) the documented procedures of the ICS that have been put in place comply with the requirements established in Regulation (EU) 2018/848;
  - (b) the list of members of the group of operators with the required information for each member is continuously updated and aligned with the scope of the certificate;
  - (c) all members of the group of operators comply with the criteria set out in Article 36(1)(a), (b) and (e) of Regulation (EU) 2018/848 throughout their participation in the group of operators;
  - (d) the number, training and competence of ICS inspectors are proportionate and adequate and ICS inspectors are without conflicts of interest;
  - (e) the internal inspections of all members of the group of operators and their activities and production units or premises including purchase and collection centres have been carried out at least annually and are documented;
  - (f) new members or new production units and new activities of existing members, including new purchase and collection centres, have been accepted only after they have been approved by the ICS manager on the basis of the internal inspection report according to the ICS documented procedures that have been put in place;
  - (g) the ICS manager takes appropriate measures in case of non-compliance, including their follow up, according to the ICS documented procedures that have been put in place;
  - (h) the ICS manager's notifications to the competent authority or, where appropriate, the control authority or control body, are appropriate and sufficient;

- (i) the internal traceability for all products and members of the group of operators is ensured by estimating quantities and by cross-checking the yields of each member of the group of operators;
  - (j) the members of the group of operators receive adequate training on the ICS procedures and the requirements of Regulation (EU) 2018/848.
3. The competent authority or, where appropriate, the control authority or control body, shall apply risk assessment to select the sample of the members of the group of operators for the re-inspections in accordance with Article 38(4) (d) of Regulation (EU) 2018/848. In doing so, it shall take into account at least the volume and the value of the production and the assessment of the likelihood of non-compliance with the provisions of Regulation (EU) 2018/848. Re-inspections shall be carried out physically on the spot with the presence of the members selected.
  4. The competent authority or, where appropriate, the control authority or control body, shall allocate reasonable time for the control of a group of operators, proportional to the type, structure, size, the products, the activities and output of organic production of the group of operators.
  5. The competent authority or, where appropriate, the control authority or control body, shall carry out witness audits in order to verify the competence and knowledge of ICS inspectors.
  6. The competent authority or, where appropriate, the control authority or control body, shall assess whether there is a failure of the ICS based on the number of non-compliances undetected by the ICS inspectors and the result of the investigation of the cause and the nature of the non-compliances.

### *Article 3*

#### *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.

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

Done at Brussels, 21.1.2021

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