

## II

*(Non-legislative acts)*

## REGULATIONS

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/2119  
of 1 December 2021****laying down detailed rules on certain records and declarations required from operators and groups of operators and on the technical means for the issuance of certificates in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2021/1378 as regards the issuance of the certificate for operators, groups of operators and exporters in third countries**

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 35(10), Article 39(2), points (a) and (b) and Article 45(4), thereof,

Whereas:

- (1) In accordance with Article 35(1), point (a), of Regulation (EU) 2018/848, the certificate provided by the competent authorities or, where appropriate, control authorities or control bodies to operators or groups of operators is to be issued in electronic form wherever possible. With the development and full deployment of the electronic Trade Control and Expert System (TRACES) referred to in Article 2, point (36), of Commission Implementing Regulation (EU) 2019/1715 <sup>(2)</sup>, the issuance of certificates in electronic form will become possible from 1 January 2023 for all competent authorities, control authorities and control bodies in the Union. For this reason, it is necessary to provide that the certificate referred to in Article 35 of Regulation (EU) 2018/848 has to be issued in electronic form, using TRACES from 1 January 2023.
- (2) Regulation (EU) 2018/848 requires operators and groups of operators to keep records to demonstrate their compliance with that Regulation. Certain minimum record-keeping requirements and details are laid down in Article 9(10), point (c), and Article 34(5) of Regulation (EU) 2018/848 and in Annexes II and III to that Regulation.
- (3) In accordance with the general production rules of Regulation (EU) 2018/848, preventive and precautionary measures must be put in place, where appropriate, at every stage of production, preparation and distribution. For that reason, the relevant official controls include, in particular, the verification of the application of such measures by operators and groups of operators. Although the application of some of those measures can be verified by physical on-the-spot inspections, for other measures records are necessary to demonstrate their application. Therefore, operators and groups of operators should keep those records to allow them to provide evidence when needed. For example, evidence of measures taken to avoid contamination with non-authorised products and substances and the commingling with non-organic products can be provided by keeping proof of cleaning of facilities, equipment and transport vehicles, and proof of training.

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

<sup>(2)</sup> Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation') (OJ L 261 14.10.2019, p. 37).

- (4) Documentary accounts are also relevant for traceability purposes and mass balance, and consequently for the assessment of compliance with Regulation (EU) 2018/848. The traceability and mass balance checks under Commission Delegated Regulation (EU) 2021/771 <sup>(3)</sup> cover specific information that is to be justified by appropriate documents. Operators and groups of operators should keep those documents in order to provide evidence of compliance of their activities.
- (5) In accordance with Article 38(2) of Regulation (EU) 2018/848, official controls are to be performed in particular based on the likelihood of non-compliance. For that purpose, competent authorities or, where appropriate, control authorities or control bodies need relevant information. Therefore, Article 39(1), point (b), of Regulation (EU) 2018/848 requires operators and groups of operators to make all declarations and other communications that are necessary for official controls. In addition, Article 39(1), point (d)(i), of that Regulation requires, inter alia, a full description of their organic or in-conversion production units and of their activities.
- (6) In order to ensure that official controls can be appropriately planned, it is necessary to specify the information that is to be included in those declarations and other communications, in particular, information relating to the activities that are subcontracted and certain details of the production units and other premises, facilities and units used for the activities of the operators and groups of operators, and the planned forecast of production.
- (7) In accordance with Article 1, first paragraph and second paragraph, point (a), of Commission Implementing Regulation (EU) 2021/1378 <sup>(4)</sup>, which applies from 1 January 2022, control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 are to provide operators, groups of operators and exporters in third countries that have been subject to the controls referred to in Article 45(1), point (b)(i), of that Regulation with a certificate, to be issued in electronic form and by using TRACES. As the use of TRACES will not be possible before 1 January 2023, it is necessary to defer the obligation to use TRACES also in Implementing Regulation (EU) 2021/1378.
- (8) Implementing Regulation (EU) 2021/1378 should therefore be amended accordingly.
- (9) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848. However, the provision on the use of TRACES should apply from 1 January 2023.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Organic Production Committee,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### **Issuance of the certificate referred to in Article 35(1) of Regulation (EU) 2018/848 in electronic form**

The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 shall be issued as follows:

- (a) in accordance with the model set out in Annex VI to Regulation (EU) 2018/848;
- (b) in electronic form, using the electronic Trade Control and Expert System (TRACES) referred to in Article 2, point (36), of Implementing Regulation (EU) 2019/1715.

<sup>(3)</sup> Commission Delegated Regulation (EU) 2021/771 of 21 January 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 (OJ L 165, 11.5.2021, p. 25).

<sup>(4)</sup> Commission Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council (OJ L 297, 20.8.2021, p. 24).

*Article 2***Records to be kept by operators and groups of operators**

1. Operators and groups of operators shall keep all the necessary documents, including stock and financial records, that will enable competent authorities or, where appropriate, control authorities or control bodies to carry out, in particular, the following checks:

- (a) checks on the preventive and precautionary measures taken in accordance with Article 9(6) and Article 28 of Regulation (EU) 2018/848;
- (b) the traceability check in accordance with Article 1(4) of Delegated Regulation (EU) 2021/771;
- (c) the mass balance check in accordance with Article 1(5) of Delegated Regulation (EU) 2021/771.

2. The documents to be kept for the purposes of the checks referred to in paragraph 1, point (a), shall include, in particular, documents confirming that the operator or group of operators has taken the proportionate and appropriate measures in order to:

- (a) prevent pests and diseases;
- (b) avoid contamination with products and substances that are not authorised for use in organic production in accordance with Regulation (EU) 2018/848 and the commingling with non-organic products.

*Article 3***Declarations and other communications necessary for official controls**

Operators and groups of operators shall include the following information in their declarations or communications pursuant to Article 39(1), point (b), of Regulation (EU) 2018/848 to the competent authority, control authority or control body that performs official controls:

- (a) which activities covered by the certificate referred to in Article 35(1) of Regulation (EU) 2018/848 are subcontracted;
- (b) the address or the geolocation of the organic, in-conversion and non-organic production units, the area of collection of wild plants or algae and of other premises and units used for their activities;
- (c) in case of holdings split into different production units in accordance with Article 9(7) of Regulation (EU) 2018/848, the description and the address or geolocation of the non-organic production units;
- (d) their planned forecast of production.

Those declarations and communications shall be updated where appropriate.

*Article 4***Amendment to Implementing Regulation (EU) 2021/1378**

Implementing Regulation (EU) 2021/1378 is amended as follows:

(1) in Article 1, second paragraph, point (a) is replaced by the following:

‘(a) be issued as follows:

- (i) in accordance with the model set out in Annex I to this Regulation;

(ii) in electronic form by using the electronic Trade Control and Expert System (TRACES) referred to in Article 2, point (36), of Commission Implementing Regulation (EU) 2019/1715 (\*);

(\*) Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) (OJ L 261, 14.10.2019, p. 37).;

(2) in Article 3, the following third paragraph is added:

‘Article 1, second paragraph, point (a)(ii), shall apply from 1 January 2023.’.

#### *Article 5*

#### **Entry into force and application**

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

It shall apply from 1 January 2022.

Article 1, point (b), shall apply from 1 January 2023.

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

Done at Brussels, 1 December 2021.

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

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