



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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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 834/2007¹, and in particular Articles 28(3)(a), 29(8)(a), 30(8), 32(5), 36(4), 38(9), 41(5) and 43(7) thereof,

Whereas:

- (1) Chapter III of Regulation (EU) 2018/848 lays down general production rules for operators, including necessary measures to avoid the presence of non-authorized products and substances and measures to be taken in the event of the presence of non-authorized products or substances. In order to ensure harmonised conditions for the implementation of that Regulation, some additional rules should be laid down.
- (2) Considering the importance of the precautionary measures that operators have to take to avoid the presence of non-authorized products and substances referred to in Article 28 of Regulation (EU) 2018/848, it is appropriate to establish procedural steps to be followed and the relevant documents to be provided in case operators suspect, due to presence of non-authorized products or substances, that the product that is intended to be used or marketed as organic or in-conversion product does not comply with Regulation (EU) 2018/848.
- (3) In order to ensure a harmonised approach across the Union as regards the official investigation referred to in Article 29(1)(a) of Regulation (EU) 2018/848 in the event of suspected non-compliance due to the presence of non-authorized products or substances in organic or in-conversion products, further rules covering the elements to be determined when carrying out the investigation, the expected results of the investigation as well as minimum reporting obligations should be established.
- (4) Chapter IV of Regulation (EU) 2018/848 lays down labelling rules for organic products. In order to ensure uniform conditions for the implementation of that Regulation, some additional rules should be laid down as regards the place and the appearance of certain indications on the label.
- (5) Chapter V of Regulation (EU) 2018/848 lays down rules for certification of operators and groups of operators. In order to ensure harmonised conditions for the

¹ OJ L 150, 14.6.2018, p. 1.

implementation of that Regulation, some additional rules for the certification of a group of operators should be laid down.

- (6) In the interest of the efficiency and affordable operational cost of the system for internal controls (ICS), it is appropriate to provide for a maximum size of a group of operators. By setting this limit, it is expected that the ICS can ensure the compliance of all members of the group with Regulation (EU) 2018/848 by means of internal controls, necessary training and support. Furthermore, the competent authority or, where appropriate, the control authority or control body that certifies the group can re-inspect a reasonable number of members. The limitation of the size will provide additional guarantees for an updated list of members, rapid and regular exchange of information with control authorities or control bodies, and ensure the implementation of adequate measures. However, the maximum size should take into consideration that a group of operators should be able to generate sufficient resources to establish an efficient ICS relying on qualified staff.
- (7) In order to provide evidence of compliance and to allow the exchange of information and sharing of knowledge, the list of documents and records that a group of operators has to keep for the purposes of the ICS should be laid down.
- (8) The ICS should constitute the basis for the certification of a group of operators. Therefore, ICS managers should be required to inform the competent authority or, where appropriate, the control authority or control body that provides the certificate of the most important issues, such as suspicions of non-compliances, suspensions or withdrawals of members and any prohibition of the placing on the market of products as organic or in-conversion products.
- (9) Chapter VI of Regulation (EU) 2018/848 lays down rules for official controls and other official activities. In order to ensure harmonised conditions for the implementation of that Regulation, some additional rules should be laid down.
- (10) In order to ensure the continuity of the current national control systems in the Member States, rules on minimum percentages for official controls and sampling should be established.
- (11) With a view to eliminating the substantial divergence in the current application of national catalogues of measures in the Member States, a common template for a catalogue of measures should be established and further guidelines on the classification of non-compliances and the appropriate measures should be provided for.
- (12) Information on suspicion of non-compliance should be shared between the Member States and the Commission directly and as effectively as possible, primarily in order to allow all competent authorities concerned to carry out investigations and apply necessary measures as required in Article 29(1) and (2), Article 41(1), (2) and (3) and Article 42 of Regulation (EU) 2018/848. Furthermore, it is appropriate to specify the details and procedures for sharing that information, including functionalities of the Organic Farming Information System. In that context, this Regulation should also clarify that in case of any suspicion or established non-compliance that affects the integrity of organic or in-conversion products discovered by the control authority or control body, such information should be transferred without delay to their competent authorities. Finally, this Regulation should specify which information should at least be shared by control authorities and control bodies with other control authorities and control bodies and their competent authorities and set an obligation for the competent

authorities to take the appropriate measures and establish documented procedures to enable such exchange of information on their territory.

- (13) Groups of operators in third countries operating in compliance with Council Regulation (EC) No 834/2007² and Commission Regulations (EC) No 889/2008³ and (EC) No 1235/2008⁴ may have a number of members significantly higher than the maximum size set by this Regulation. Establishing new groups of operators complying with this new requirement may imply tangible adaptations for establishing the corresponding legal entity, an efficient ICS and the necessary elements for the certification by a control authority or control body. Hence, a transitional period of maximum 3 years from 1 January 2021 should be provided for in respect of those groups of operators to permit them to carry out the necessary adaptations to comply with the new maximum size.
- (14) The requirement related to the national catalogue of measures may imply the changing of already existing national catalogues of measures that have been developed in Member States until now in compliance with Regulations (EC) No 834/2007 and (EC) No 889/2008. Hence, a transitional period of maximum 1 year from 1 January 2021 should be provided for all Member States in respect of those existing national catalogues of measures in order to permit them to carry out the necessary improvements or the replacement of their national catalogues of measures to comply with the new requirements.
- (15) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Organic Production,

HAS ADOPTED THIS REGULATION:

Article 1

Procedural steps in case of a suspicion of non-compliance due to the presence of non- authorised products or substances

1. In order to check whether the suspicion of non-compliance can be eliminated or to establish that the suspicion is substantiated in accordance with Article 28(2)(b) of Regulation (EU) 2018/848, the operator shall take into account the following elements:
 - (a) where the suspicion of non-compliance concerns an incoming organic or in-conversion product, the operator shall check whether:
 - (i) the information on the label of the organic or in-conversion organic or in-conversion product and the information on the accompanying documents match;

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).

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).

- (ii) the certificate provided by the supplier refers to the product actually purchased;
 - (b) where there is a suspicion that the cause of the presence of the non-authorised products or substances lies under the control of the operator, the operator shall examine any possible cause for the presence of non-authorised products or substances.
2. When the operator informs the competent authority or, where appropriate, the control authority or control body in accordance with Article 28(2)(d) of Regulation (EU) 2018/848 about a substantiated suspicion or when the suspicion cannot be immediately eliminated, the operator shall provide at least the following elements:
- (a) information and documents about the supplier (delivery note, invoice, certificate of the supplier, Certificate of Inspection for organic products (COI) where relevant);
 - (b) the internal traceability of the product with the batch number, stock quantity, quantity of product sold;
 - (c) accredited laboratory results;
 - (d) the sampling sheet detailing the time, place and method used to submit the sample;
 - (e) any information about any previous suspicion with regard to the specific product or substance;
 - (f) every other relevant document to clarify the case.

Article 2

Methodology of an official investigation

1. Without prejudice to Article 38(2) of Regulation (EU) 2018/848, when carrying out an official investigation referred to in Article 29(1)(a) of that Regulation, the competent authorities or, where appropriate, control bodies or control authorities shall determine at least the following:
- (a) the name, batch number, ownership and physical location of the organic or in-conversion products concerned;
 - (b) whether the products concerned are still placed on the market as organic or in-conversion products or used in organic production;
 - (c) the type, name, quantity and other relevant information of the present non-authorised products or substances;
 - (d) at which stage of production, preparation or distribution and where exactly the presence of non-authorised products or substances has been detected, in particular for plant production, whether the sample was taken pre-harvest or post-harvest;
 - (e) whether other operators in the supply chain are affected;
 - (f) the results of previous official investigations on the products and operators concerned.

2. The official investigation shall be pursued by using appropriate methods and techniques, including those referred to in Article 14 and Article 137(3) of Regulation (EU) 2017/625 of the European Parliament and of the Council⁵.
3. The official investigation shall at least conclude on:
 - (a) the integrity of organic and in-conversion products;
 - (b) the source and the cause of the presence of non-authorised products or substances;
 - (c) the elements provided in Article 29(2)(a), (b) and (c) of Regulation (EU) 2018/848.
4. The competent authorities or, where appropriate, control bodies or control authorities shall draw up a final report for each official investigation. That final report shall contain:
 - (a) the records of the specific elements required pursuant to this Article;
 - (b) the records of the information exchanged with the competent authority, other control authorities and control bodies and the Commission related to this investigation.

Article 3

Conditions for the uses of certain indications

1. The indication provided for the in-conversion products of plant origin as referred to in Article 30(3) of Regulation (EU) 2018/848 shall appear in:
 - (a) a colour, size and style of lettering that is not more prominent than the sales description of the product, while the entire indication shall have the same size of letters;
 - (b) the same visual field as the code number of the control authority or control body as referred to in Article 32(1)(a) of Regulation (EU) 2018/848.
2. The indication of the code number of the control authority or control body referred to in Article 32(1)(a) of Regulation (EU) 2018/848 shall appear in the same visual field as the organic production logo of the European Union, where it is used in the labelling.
3. The indication of the place where the agricultural raw materials of which the products are composed have been farmed, as referred to in Article 32(2) of Regulation (EU) 2018/848, shall be placed immediately below the code number referred to in paragraph 2 of this Article.

⁵ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

Article 4

Composition and maximum size of a group of operators

A member of a group of operators shall register to only one group of operators for the same activity for a given product.

The maximum size of a group of operators shall be 2000 members.

Article 5

Documents and records of a group of operators

The group of operators shall keep the following documents and records for the purposes of the system for internal controls (ICS):

- (a) the list of members of the group of operators based on their registration of each member and consisting of the following elements for each member of the group of operators:
 - (i) name and identification (code number);
 - (ii) contact details;
 - (iii) date of registration;
 - (iv) total land surface under the management of the member and whether organic, in-conversion or non-organic;
 - (v) a map with each production unit and/or activity: size, location, product, date of the beginning of the conversion period and yield estimates;
 - (vi) date of the last internal inspection with the name of the ICS inspector;
 - (vii) date of the last official control performed by the competent authority or, where appropriate, control authority or control body with the name of the inspector;
- (b) the signed membership agreements between the member and the group as legal person, which shall include the rights and responsibilities of the member;
- (c) the internal inspection reports signed by the ICS inspector and the inspected member of the group and including at least the following elements:
 - (i) the name of the member and the location of the production unit or premises where the activity subject to the inspection takes place;
 - (ii) the date and duration of the internal inspection;
- (d) the training records of the ICS inspectors consisting of:
 - (i) the dates of the training;
 - (ii) the subject matter of the training;
 - (iii) the name of the trainer;
 - (iv) the signature of the trainee;
 - (v) where appropriate, an assessment of the knowledge acquired;
- (e) the records of the measures taken in case of non-compliance by the ICS manager, which shall include:

- (i) the list of members subject to measures in case of non-compliance, including those suspended, withdrawn or required to comply with a new conversion period;
- (ii) documentation of identified non-compliance;
- (f) traceability records, including information on the quantities, on the following activities, where relevant:
 - (i) purchase and distribution of farm inputs including seeds by the group;
 - (ii) production including harvest;
 - (iii) storing;
 - (iv) preparation;
 - (v) delivery of products from each member to the joint marketing system;
 - (vi) placing on the market of products by the group;
- (g) the written agreements and contracts between the group of operators and subcontractors including information on the nature of the subcontracted activities.

The list of members referred to in point (a) of the first paragraph shall be updated by the ICS manager after any modification of the elements listed in point (a)(i) to (vii) and of the status of a member due to measures in case of non-compliance resulting from internal inspections or official controls.

Article 6

Notifications from the ICS manager

The ICS manager shall immediately notify the competent authority or, where appropriate, the control authority or control body of the following information:

- (a) any suspicion of major and critical non-compliance;
- (b) any suspension or withdrawal of a member or a production unit or premises from the group;
- (c) any prohibition of the placing on the market of a product as organic or in-conversion product, including the name of the operator or operators concerned, the relevant quantities and lot/batch information.

Article 7

Minimum percentages of controls and sampling

The following rules on minimum percentages shall apply to the official controls referred to in Article 38(4) of Regulation (EU) 2018/848 to be carried out by each competent authority or, where appropriate, control authority or control body according to the risk of non-compliance:

- (a) minimum 10% of all official controls of operators or groups of operators shall be carried out without prior notice every year;
- (b) minimum 10% of additional controls to those referred to in Article 38(3) of Regulation (EU) 2018/848 shall be carried out every year;

- (c) minimum 5% of the number of operators shall be subject to sampling in accordance with Article 14(h) of Regulation (EU) 2017/625 every year;
- (d) minimum 2% of the members of each group of operators shall be subject to sampling in accordance with Article 14(h) of Regulation (EU) 2017/625 every year;
- (e) minimum 5% of the operators that are members of a group of operators, but not less than 10 members, shall be controlled in connection with the verification of compliance referred to in Article 38(3) of Regulation (EU) 2018/848 every year. Where the group has 10 members or less, all members shall be controlled in connection with the verification of compliance referred to in Article 38(3) of that Regulation.

Article 8

Measures in case of established non-compliance

The competent authorities may use the uniform arrangements set out in the Annex I to this Regulation to develop a national catalogue of measures as referred to in Article 41(4) of Regulation (EU) 2018/848.

That national catalogue of measures shall cover at least:

- (a) a list of non-compliances with a reference to the specific rules of Regulation (EU) 2018/848 or of the delegated or implementing act adopted in accordance with that Regulation;
- (b) the classification of the non-compliances into three categories: minor, major and critical, taking into account at least the following criteria:
 - (i) the precautionary measures referred to in Article 28(1) of Regulation (EU) 2018/848 and the own controls referred to in Article 9(1)(d) of Regulation (EU) 2017/625;
 - (ii) the integrity of the organic or in-conversion status of products;
 - (iii) the ability of the traceability system to locate the affected product(s) in the supply chain and prohibition of placing products on the market with reference to organic production;
 - (iv) the response to previous requests by the competent authority or, where appropriate, the control authority or control body;
- (c) the measures corresponding to different categories of non-compliances.

Article 9

Exchange of information

1. For the purposes of Article 43(1) of Regulation (EU) 2018/848, the competent authorities shall use the Organic Farming Information System (OFIS) and the templates set out in Annex II to this Regulation to exchange information with other Member States and the Commission in accordance with the following rules:
 - (a) a Member State (notifying Member State) shall notify the relevant Member State or Member States (notified Member State or Member States) at least in the following situations:

- (i) when the suspected or established non-compliance affects the integrity of organic or in-conversion products coming from another Member State;
 - (ii) when the suspected or established non-compliance affects the integrity of organic or in-conversion products imported from a third country pursuant to Article 45(1) or Article 57 of Regulation (EU) 2018/848;
 - (iii) when the suspected or established non-compliance affects the integrity of organic or in-conversion products coming from the notifying Member State, since it could have implications for one or more notified Member States (alert notification);
- (b) in the situations referred to in point (a)(i) and (ii) the notified Member State or Member States shall reply within 30 calendar days from the date of receipt of the notification and shall inform about the actions and measures taken, including the results of the investigation and provide any other information available and/or required by the notifying Member State;
- (c) the notifying Member State may ask the notified Member State or Member States for any necessary additional information;
- (d) the notifying Member State shall, as soon as possible, make the necessary entries and updates in OFIS, including the updates relating to the results of its own investigations.
2. In addition to information obligation referred to in Article 32(b) of Regulation (EU) 2017/625, the control authority or control body shall, without delay, inform the competent authority that has conferred to it or has delegated to it certain official control tasks or certain tasks related to other official activities in accordance with Article 4(3) and Article 28(1) or Article 31 of that Regulation, about any suspicion or established non-compliance that affects the integrity of organic or in-conversion products. It shall also provide any other information required by that competent authority.
3. For the purposes of Article 43(3) of Regulation (EU) 2018/848, where operators or groups of operators and/or their subcontractors are checked by different control authorities or control bodies, those control authorities and control bodies shall exchange the relevant information on the operations under their control.
4. For the purposes of Article 43(3) of Regulation (EU) 2018/848, where operators or groups of operators and/or their subcontractors change their control authority or control body, the control authority or control body concerned shall notify the competent authority without delay of that change.
- The previous control authority or control body shall hand over to the new control authority or control body the control file of the operator or group of operators concerned, including the written records referred to in Article 38(6) of Regulation (EU) 2018/848, the status of the certification, the list of non-compliances and the corresponding measures taken by the previous control authority or control body.
- The new control authority or control body shall ensure that non-compliances noted in the records of the previous control authority or control body have been or will be addressed by the operator.
5. For the purposes of Article 43(3) of Regulation (EU) 2018/848, where operators or groups of operators are subject to a traceability check and a mass balance check,

control authorities and control bodies shall exchange the relevant information allowing finalisation of these checks.

6. The competent authorities shall take the appropriate measures and establish documented procedures to enable the exchange of information between them and the control authorities and/or control bodies to which they have conferred or delegated certain official control tasks or certain tasks related to other official activities as well as between those control authorities and/or control bodies.

Article 10

Transitional provisions

1. Groups of operators in third countries complying with Regulations (EC) No 834/2007, (EC) No 889/2008 and (EC) No 1235/2008 before the date of entry into application of this Regulation and for which important administrative, legal and structural changes are necessary with regard to the maximum size of the group of operators laid down in the second paragraph of Article 4 of this Regulation, shall comply with that provision from 1 January 2024 at the latest.
2. The national catalogue of measures developed in accordance with Article 8 shall apply from 1 January 2022 at the latest.

Article 11

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 2021.

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