

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

CHAPTER VI

OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES

Article 38

Additional rules on official controls and on action to be taken by the competent authorities

1 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall include, in particular:

- a the verification of the application by operators of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of this Regulation, at every stage of production, preparation and distribution;
- b where the holding includes non-organic or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units as well as between the respective products produced by those units, and of the substances and products used for organic, in-conversion and non-organic production units; such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period, and checks on the non-organic production units;
- c where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and, where appropriate, measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times and that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other;
- d the verification of the set-up and functioning of the internal control system of groups of operators;
- e where operators are exempted from the notification obligation in accordance with Article 34(2) of this Regulation or from the obligation to be in the possession of a certificate in accordance with Article 35(8) of this Regulation, the verification that the requirements for that exemption have been fulfilled and the verification of the products sold by those operators.

2 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall be performed throughout the entire process at all stages of production, preparation and distribution on the basis of the likelihood of non-compliance as defined in point (57) of Article 3 of this Regulation, which shall be determined taking into account, in addition to the elements referred to in Article 9 of Regulation (EU) 2017/625, in particular the following elements:

- a the type, size and structure of the operators and groups of operators;
- b the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution;
- c the results of the controls performed in accordance with this Article;
- d the point in time relevant for the activities carried out;
- e the product categories;
- f the type, quantity and value of products and their development over time;
- g the possibility of commingling of products or contamination with non-authorised products or substances;
- h the application of derogations or exceptions to the rules by operators and groups of operators;
- i the critical points for non-compliance and the likelihood of non-compliance at every stage of production, preparation and distribution;
- j subcontracting activities.

3 In any case, all operators and groups of operators, with the exception of those referred to in Articles 34(2) and 35(8), shall be subject to a verification of compliance at least once a year.

The verification of compliance shall include a physical on-the-spot inspection, except where the following conditions have been satisfied:

- a the previous controls of the operator or group of operators concerned have not revealed any non-compliance affecting the integrity of organic or in-conversion products during at least three consecutive years; and
- b the operator or group of operators concerned has been assessed on the basis of the elements referred to in paragraph 2 of this Article and in Article 9 of Regulation (EU) 2017/625 as presenting a low likelihood of non-compliance.

In this case, the period between two physical on-the-spot inspections shall not exceed 24 months.

4 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall:

- a be performed in accordance with Article 9(4) of Regulation (EU) 2017/625 while ensuring that a minimum percentage of all official controls of operators or groups of operators are carried out without prior notice;
- b ensure that a minimum percentage of additional controls to those referred in paragraph 3 of this Article are carried out;
- c be carried out by taking a minimum number of the samples that have been taken in accordance with point (h) of Article 14 of Regulation (EU) 2017/625;
- d ensure that a minimum number of operators that are members of a group of operators are controlled in connection with the verification of compliance referred to in paragraph 3 of this Article.

5 The delivery or renewal of the certificate referred to in Article 35(1) shall be based on the results of the verification of compliance referred to in paragraphs 1 to 4 of this Article.

6 The written record to be drawn up regarding each official control that has been performed to verify compliance with this Regulation in accordance with Article 13(1) of Regulation (EU) 2017/625 shall be countersigned by the operator or groups of operators as confirmation of their receipt of that written record.

7 Article 13(1) of Regulation (EU) 2017/625 shall not apply to audits and inspections carried out by competent authorities in the context of their supervisory activities over control

bodies to which certain official control tasks or certain tasks related to other official activities have been delegated.

- 8 The Commission is empowered to adopt delegated acts in accordance with Article 54:
- a supplementing this Regulation by laying 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 this Regulation, concerning:
 - (i) checks of documentary accounts;
 - (ii) controls performed on specific categories of operators;
 - (iii) where appropriate, the period within which the controls provided for in this Regulation, including the physical on-the-spot inspections referred to in paragraph 3 of this Article, are to be performed and the particular premises in or area on which they are to be performed;
 - b amending paragraph 2 of this Article by adding further elements based on practical experience, or by amending those added elements.
- 9 The Commission may adopt implementing acts to specify:
- a the minimum percentage of all official controls of operators or groups of operators that are to be carried out without prior notice as referred to in point (a) of paragraph 4;
 - b the minimum percentage of additional controls referred to in point (b) of paragraph 4;
 - c the minimum number of samples referred to in point (c) of paragraph 4;
 - d the minimum number of operators that are members of a group of operators referred to in point (d) of paragraph 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).