

- (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).

#### Article 39

##### **Additional rules on actions to be taken by the operators and groups of operators**

1. In addition to the obligations laid down in Article 15 of Regulation (EU) 2017/625, operators and groups of operators shall:
- (a) keep records to demonstrate their compliance with this Regulation;
  - (b) make all declarations and other communications that are necessary for official controls;
  - (c) take relevant practical measures to ensure compliance with this Regulation;
  - (d) provide, in form of a declaration to be signed and updated as necessary:
    - (i) the full description of the organic or in-conversion production unit and of the activities to be performed in accordance with this Regulation;
    - (ii) the relevant practical measures to be taken to ensure compliance with this Regulation;

(iii) an undertaking:

- to inform in writing and without undue delay buyers of the products and to exchange relevant information with the competent authority, or, where appropriate, with the control authority or control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established,
- to accept the transfer of the control file in the case of change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for at least five years by the last control authority or control body,
- to immediately inform the competent authority or the authority or body designated in accordance with Article 34(4) in the event of withdrawal from organic production, and
- to accept the exchange of information among those authorities or bodies in the event that subcontractors are subject to controls by different control authorities or control bodies.

2. The Commission may adopt implementing acts to provide details and specifications regarding:

- (a) the records for demonstrating compliance with this Regulation;
- (b) the declarations and other communications that are necessary for official controls;
- (c) the relevant practical measures for ensuring compliance with this Regulation.

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

#### Article 40

##### **Additional rules on the delegation of official control tasks and tasks related to other official activities**

1. Competent authorities may delegate to control bodies certain official control tasks and certain tasks related to other official activities only if the following conditions, in addition to those set out in Chapter III of Regulation (EU) 2017/625, are satisfied:

- (a) the delegation contains a detailed description of the delegated official control tasks and tasks related to other official activities, including reporting obligations and other specific obligations, and of the conditions under which the control body may carry them out. In particular, the control body shall have submitted the following to the competent authorities for prior approval:
  - (i) its risk assessment procedure, which is to determine, in particular, the basis for the intensity and frequency of the verification of compliance of the operators and groups of operators, which is to be established on the basis of the elements referred to in Article 9 of Regulation (EU) 2017/625 and of Article 38 of this Regulation, and which is to be followed for official controls on operators and groups of operators;
  - (ii) the standard control procedure, which is to contain a detailed description of the control measures that the control body undertakes to apply to the operators and groups of operators that are subject to its controls;
  - (iii) a list of measures that are in conformity with the common catalogue referred to in Article 41(4), and that are to be applied to operators and groups of operators in cases of suspected or established non-compliance;
  - (iv) the arrangements for the effective monitoring of the official control tasks and tasks related to other official activities carried out in relation to operators and groups of operators and the arrangements for reporting on those tasks.

The control body shall notify subsequent amendment of the elements referred to in points (i) to (iv) to the competent authority;

- (b) those competent authorities have procedures and arrangements in place to ensure the supervision of control bodies, including to verify that the delegated tasks are carried out effectively, independently and objectively, in particular as regards the intensity and frequency of the verification of compliance.

At least once a year, competent authorities shall, pursuant to point (a) of Article 33 of Regulation (EU) 2017/625, organise audits of the control bodies to whom they have delegated official control tasks or tasks related to other official activities.

2. By way of derogation from Article 31(3) of Regulation (EU) 2017/625, competent authorities may delegate to a control body the decision concerning the tasks provided for in point (b) of Article 138(1) and in Article 138(2) and (3) of that Regulation.

3. For the purpose of point (b)(iv) of Article 29 of Regulation (EU) 2017/625, the standard for the delegation of certain official control tasks and certain tasks related to other official activities to verify compliance with this Regulation which is relevant in relation to the scope of this Regulation is the most recently notified version of the international 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*.

4. Competent authorities shall not delegate the following official control tasks and tasks related to other official activities to control bodies:

- (a) the supervision and audit of other control authorities or control bodies;
- (b) the power to grant derogations other than derogations for the use of plant reproductive material not obtained from organic production;
- (c) the authority to receive notifications of activities by operators or groups of operators under Article 34(1) of this Regulation;
- (d) the assessment of the likelihood of non-compliance with the provisions of this Regulation that determine the frequency with which physical checks are to be performed on organic consignments prior to their release for free circulation into the Union in accordance with Article 54 of Regulation (EU) 2017/625;
- (e) the establishment of the common catalogue of measures referred to in Article 41(4) of this Regulation.

5. Competent authorities shall not delegate official control tasks or tasks related to other official activities to natural persons.

6. Competent authorities shall ensure that information received from control bodies pursuant to Article 32 of Regulation (EU) 2017/625 and information on the measures applied by control bodies in the case of established or likely non-compliance is collected and used by the competent authorities in order to supervise the activities of those control bodies.

7. Where a competent authority has fully or partially withdrawn the delegation of certain official control tasks or certain tasks related to other official activities in accordance with point (b) of Article 33 of Regulation (EU) 2017/625, it shall decide whether any certificates issued by the control bodies concerned before the date of that partial or full withdrawal are to remain valid, and shall inform the operators concerned of that decision.

8. Without prejudice to point (b) of Article 33 of Regulation (EU) 2017/625, before fully or partly withdrawing the delegation of official control tasks or tasks related to other official activities in the cases referred to in that point, competent authorities may fully or partly suspend that delegation:

- (a) for a period that shall not exceed 12 months, during which the control body is to remedy the shortcomings identified during audits and inspections or to address the non-compliance about which information was shared with other control authorities and control bodies, with competent authorities as well as with the Commission in accordance with Article 43 of this Regulation; or
- (b) for the period during which the accreditation referred to in point (b)(iv) of Article 29 of Regulation (EU) 2017/625, in connection with Article 40(3) of this Regulation, is suspended.

Where the delegation of official control tasks or tasks related to other official activities has been suspended, the control bodies concerned shall not issue certificates referred to in Article 35 for those parts for which the delegation has been suspended. Competent authorities shall decide whether any certificates issued by the control bodies concerned before the date of that partial or full suspension are to remain valid, and shall inform the operators concerned of that decision.

Without prejudice to Article 33 of Regulation (EU) 2017/625, the competent authorities shall lift the suspension of the delegation of official control tasks or tasks related to other official activities as soon as possible once the control body has remedied the shortcomings or non-compliances referred to in point (a) of the first subparagraph or once the accreditation body has lifted the suspension of the accreditation referred to in point (b) of the first subparagraph.

9. Where a control body to whom competent authorities have delegated certain official control tasks or certain tasks related to other official activities has also been recognised by the Commission in accordance with Article 46(1) of this Regulation to carry out control activities in third countries, and the Commission intends to withdraw or has withdrawn the recognition of that control body, competent authorities shall organise audits or inspections on the control body as regards its activities in the Member State(s) concerned in accordance with point (a) of Article 33 of Regulation (EU) 2017/625.

10. The control bodies shall transmit to the competent authorities:

- (a) a list of the operators which were subject to their controls on 31 December of the previous year by 31 January of each year; and
- (b) information on the official controls and other official activities carried out in the previous year to support the preparation of the part on organic production and labelling of organic products of the annual report referred to in Article 113 of Regulation (EU) 2017/625 by 31 March of each year.

11. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards conditions for the delegation of official control tasks and tasks related to other official activities to control bodies additional to the conditions laid down in paragraph 1 of this Article.

#### Article 41

##### **Additional rules on actions in case of non-compliance**

1. Subject to Article 29, where a competent authority, or, where appropriate, a control authority or control body, suspects or receives substantiated information, including information from other competent authorities, or, where appropriate, from other control authorities or control bodies, that an operator intends to use or to place on the market a product which may not be in compliance with this Regulation but which bears terms referring to the organic production, or where such competent authority, control authority or control body has been informed by an operator of a suspicion of non-compliance in accordance with Article 27:

- (a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to verifying compliance with this Regulation; such investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;
- (b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a). Before taking such a decision, the competent authority, or, where appropriate, the control authority or control body, shall give the operator an opportunity to comment.

2. In the event that the results of the investigation referred to in point (a) of paragraph 1 do not show any non-compliance affecting the integrity of organic or in-conversion products, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products.

3. Member States shall take any measures, and provide for any necessary sanctions, to prevent fraudulent use of the indications referred to in Chapter IV of this Regulation.

4. Competent authorities shall provide a common catalogue of measures for cases of suspected non-compliance and established non-compliance to be applied in their territory, including by control authorities and control bodies.

5. The Commission may adopt implementing acts to specify uniform arrangements for the cases where competent authorities are to take measures in relation to suspected or established non-compliance.

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

#### Article 42

##### **Additional rules on measures in the event of non-compliance**

1. In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, for example as result of the use of non-authorised products, substances or techniques, or commingling with non-organic products, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure, in addition to the measures to be taken in accordance with Article 138 of Regulation (EU) 2017/625, that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned.

2. In the event of serious, or repetitive or continued non-compliance, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure that the operators or the groups of operators concerned, in addition to the measures laid down in paragraph 1 and any appropriate measures taken in particular in accordance with Article 138 of Regulation (EU) 2017/625, are prohibited from marketing products which refer to organic production for a given period, and that their certificate referred to in Article 35 be suspended or withdrawn, as appropriate.

*Article 43***Additional rules on the exchange of information**

1. In addition to the obligations laid down in Article 105(1) and Article 106(1) of Regulation (EU) 2017/625, competent authorities shall immediately share information with other competent authorities, as well as with the Commission, on any suspicion of non-compliance that affects the integrity of organic or in-conversion products.

Competent authorities shall share that information with other competent authorities and the Commission via a computer system that enables the electronic exchanges of documents and information made available by the Commission.

2. In cases where suspected or established non-compliance has been identified with regard to products under the control of other control authorities or control bodies, control authorities and control bodies shall immediately inform those other control authorities or control bodies.

3. Control authorities and control bodies shall exchange other relevant information with other control authorities and control bodies.

4. Upon receiving a request for information that is justified by the need to guarantee that a product has been produced in accordance with this Regulation, control authorities and control bodies shall exchange with other competent authorities, as well as with the Commission, information on the results of their controls.

5. Competent authorities shall exchange information on the supervision of the control bodies with national accreditation bodies as defined in point (11) of Article 2 of Regulation (EC) No 765/2008 of the European Parliament and of the Council <sup>(1)</sup>.

6. Competent authorities shall take appropriate measures and establish documented procedures in order to ensure that information about the results of controls is communicated to the paying agency in accordance with its needs for the purpose of Article 58 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council <sup>(2)</sup> and the acts adopted on the basis of that Article.

7. The Commission may adopt implementing acts to specify the information to be provided by the competent authorities, control authorities and control bodies in charge of the official controls and other official activities in accordance with this Article, the relevant recipients of that information and the procedures in accordance with which this information is to be provided, including the functionalities of the computer system referred to in paragraph 1.

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

## CHAPTER VII

**TRADE WITH THIRD COUNTRIES***Article 44***Export of organic products**

1. A product may be exported from the Union as an organic product and may bear the organic production logo of the European Union, provided that it complies with the rules for organic production under this Regulation.

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards documents intended for customs authorities in third countries, in particular as regards the issuing of organic export certificates in electronic form wherever possible and the provision of assurances that exported organic products comply with this Regulation.

<sup>(1)</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

<sup>(2)</sup> Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).