

3. The certificate referred to in this Article shall be an official certificate within the meaning of point (a) of Article 86(1) of Regulation (EU) 2017/625.

4. An operator or a group of operators shall not be entitled to obtain a certificate from more than one control body in relation to activities carried out in the same Member State regarding the same category of products, including cases in which that operator or group of operators operates at different stages of production, preparation and distribution.

5. Members of a group of operators shall not be entitled to obtain an individual certificate for any of the activities covered by the certification of the group of operators to which they belong.

6. Operators shall verify the certificates of those operators that are their suppliers.

7. For the purposes of paragraphs 1 and 4 of this Article, products shall be classified in accordance with the following categories:

- (a) unprocessed plants and plant products, including seeds and other plant reproductive material;
- (b) livestock and unprocessed livestock products;
- (c) algae and unprocessed aquaculture products;
- (d) processed agricultural products, including aquaculture products, for use as food;
- (e) feed;
- (f) wine;
- (g) other products listed in Annex I to this Regulation or not covered by the previous categories.

8. Member States may exempt from the obligation to be in the possession of a certificate, provided for in paragraph 2, operators that sell unpacked organic products other than feed directly to the final consumer, provided that those operators do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to a third party, and provided that:

- (a) such sales do not exceed 5 000 kg per year;
- (b) such sales do not represent an annual turnover in relation to unpacked organic products exceeding EUR 20 000; or
- (c) the potential certification cost of the operator exceeds 2 % of the total turnover on unpacked organic products sold by that operator.

If a Member State decides to exempt the operators referred to in the first subparagraph, it may set stricter limits than those set in the first subparagraph.

Member States shall inform the Commission and the other Member States of any decision to exempt operators pursuant to the first subparagraph and of the limits up to which such operators are exempted.

9. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending the model of the certificate set out in Annex VI.

10. The Commission shall adopt implementing acts to provide details and specifications regarding the form of the certificate referred to in paragraph 1 and the technical means by which it is issued.

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

#### *Article 36*

#### **Group of operators**

1. Each group of operators shall:

- (a) only be composed of members 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;
- (b) only be composed of members:
  - (i) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000 or whose standard output of organic production is not more than EUR 15 000 per year; or
  - (ii) who have each holdings of maximum:
    - five hectares,

- 0,5 hectares, in the case of greenhouses, or
  - 15 hectares, exclusively in the case of permanent grassland;
- (c) be established in a Member State or a third country;
- (d) have legal personality;
- (e) only be composed of members whose production activities take place in geographical proximity to each other;
- (f) set up a joint marketing system for the products produced by the group; and
- (g) establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group.
2. Competent authorities, or, where appropriate, control authorities or control bodies, shall withdraw the certificate referred to in Article 35 for the whole group where deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators, affect the integrity of organic and in-conversion products.
3. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 1 and 2 of this Article by adding provisions, or by amending those added provisions, in particular as regards:
- (a) the responsibilities of the individual members of a group of operators;
  - (b) the criteria to determine the geographical proximity of the members of the group, such as the sharing of facilities or sites;
  - (c) the set-up and functioning of the system for internal controls, including the scope, content and frequency of the controls to be carried out and the criteria to identify deficiencies in the set-up or functioning of the system for internal controls.
4. The Commission may adopt implementing acts laying down specific rules concerning:
- (a) the composition and dimension of a group of operators;
  - (b) the documents and record-keeping systems, the system for internal traceability and the list of operators;
  - (c) the exchange of information between a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission.
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

#### CHAPTER VI

#### OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES

##### *Article 37*

#### **Relationship with Regulation (EU) 2017/625 and additional rules for official controls and other official activities in relation to organic production and labelling of organic products**

The specific rules of this Chapter shall apply, in addition to the rules laid down in Regulation (EU) 2017/625, save as otherwise provided for in Article 40(2) of this Regulation, and in addition to Article 29 of this Regulation, save as otherwise provided for in Article 41(1) of this Regulation, to the official controls and other official activities performed to verify throughout the entire process at all stages of production, preparation and distribution that the products referred to in Article 2(1) of this Regulation have been produced in compliance with this Regulation.

##### *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).

#### 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).



*Article 45***Import of organic and in-conversion products**

1. A product may be imported from a third country for the purpose of placing that product on the market within the Union as an organic product or as an in-conversion product, provided that the following three conditions are met:

- (a) the product is a product as referred to in Article 2(1);
- (b) one of the following applies:
  - (i) the product complies with Chapters II, III and IV of this Regulation, and all operators and groups of operators referred to in Article 36, including exporters in the third country concerned, have been subject to controls by control authorities or control bodies recognised in accordance with Article 46, and those authorities or bodies have provided all such operators, groups of operators and exporters with a certificate confirming that they comply with this Regulation;
  - (ii) in cases where the product comes from a third country which is recognised in accordance with Article 47, that product complies with the conditions laid down in the relevant trade agreement; or
  - (iii) in cases where the product comes from a third country which is recognised in accordance with Article 48, that product complies with the equivalent production and control rules of that third country and is imported with a certificate of inspection confirming this compliance that was issued by the competent authorities, control authorities or control bodies of that third country; and
- (c) the operators in third countries are able at any time to provide the importers and the national authorities in the Union and in those third countries with information allowing the identification of the operators that are their suppliers and the control authorities or control bodies of those suppliers, with a view to ensuring the traceability of the organic or in-conversion product concerned. That information shall also be made available to the control authorities or control bodies of the importers.

2. The Commission may, in accordance with the procedure set out in Article 24(9), grant specific authorisations for the use of products and substances in third countries and in the outermost regions of the Union, taking into account differences in the ecological balance in plant or animal production, specific climatic conditions, traditions and local conditions in those areas. Such specific authorisations may be granted for a renewable period of two years and shall be subject to the principles laid down in Chapter II and to the criteria set out in Article 24(3) and (6).

3. When providing for the criteria for determining whether a situation qualifies as catastrophic circumstances, and when laying down specific rules on how to deal with such circumstances in accordance with Article 22, the Commission shall take into account differences in the ecological balance, climate and local conditions in third countries and in the outermost regions of the Union.

4. The Commission shall adopt implementing acts to lay down specific rules concerning the content of the certificates referred to in point (b) of paragraph 1, the procedure to be followed for their issuance, their verification and the technical means by which the certificate is issued, in particular as regards the role of competent authorities, control authorities and control bodies, ensuring the traceability and compliance of imported products intended to be placed on the Union market as organic products or as in-conversion products as referred to in paragraph 1.

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

5. Compliance with the conditions and measures for the import of organic products and in-conversion products referred to in paragraph 1 into the Union shall be ascertained at border control posts, in accordance with Article 47(1) of Regulation (EU) 2017/625. The frequency of the physical checks referred to in Article 49(2) of that Regulation shall depend on the likelihood of non-compliance as defined in point (57) of Article 3 of this Regulation.

*Article 46***Recognition of control authorities and control bodies**

1. The Commission may adopt implementing acts to recognise control authorities and control bodies that are competent to carry out controls and to issue organic certificates in third countries, to withdraw the recognition of such control authorities and control bodies, and to establish a list of recognised control authorities and control bodies.

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

2. Control authorities or control bodies shall be recognised in accordance with paragraph 1 of this Article for the control of import of the categories of products listed in Article 35(7) if they fulfil the following criteria:

- (a) they are legally established in one Member State or third country;
- (b) they have the capacity to carry out controls to ensure that the conditions set out in points (a), (b)(i) and (c) of Article 45(1) and in this Article are met in relation to organic products and in-conversion products intended for import into the Union;
- (c) they offer adequate guarantees of objectivity and impartiality and are free from any conflict of interest as regards the exercise of their control tasks;
- (d) in the case of control bodies, they are accredited under the relevant 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*;
- (e) they have the expertise, equipment and infrastructure required to carry out control tasks, and have a sufficient number of suitable qualified and experienced staff; and
- (f) they meet any additional criteria that may be laid down in a delegated act adopted pursuant to paragraph 7.

3. The accreditation referred to in point (d) of paragraph 2 may only be granted by:

- (a) a national accreditation body in the Union in accordance with Regulation (EC) No 765/2008; or
- (b) an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.

4. Control authorities and control bodies shall submit a request for recognition to the Commission. Such request shall consist of a technical dossier containing all information that is necessary to ensure that the criteria set out in paragraph 2 are met.

The control authorities shall provide the latest assessment report issued by the competent authority, and the control bodies shall provide the accreditation certificate issued by the accreditation body. Where appropriate, control authorities or control bodies shall also provide latest reports on the regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities.

5. Based on the information referred to under paragraph 4 and on any other relevant information relating to the control authority or control body, the Commission shall ensure appropriate supervision of the recognised control authorities and control bodies by regularly reviewing their performance and recognition. For the purposes of that supervision, the Commission may request additional information from the accreditation bodies or the competent authorities, as appropriate.

6. The nature of the supervision referred to in paragraph 5 shall be determined on the basis of an assessment of the likelihood of non-compliance, taking into account, in particular, the activity of the control authority or control body, the type of products and operators under its control and the changes in the production rules and control measures.

The recognition of control authorities or of control bodies referred to in paragraph 1 shall in particular be withdrawn without delay, in accordance with the procedure referred to in that paragraph, where serious or repetitive infringements as regards the certification or the controls and actions laid down in accordance with paragraph 8 have been detected and where the control authority or control body concerned has failed to take appropriate and timely remedial action in reaction to a request by the Commission within a period determined by the Commission. Such period shall be determined in accordance with the severity of the problem and in general shall not be less than 30 days.

7. The Commission is empowered to adopt delegated acts in accordance with Article 54:

- (a) amending paragraph 2 of this Article by adding further criteria to those laid down therein for the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article and for the withdrawal of such recognition, or by amending those added criteria;
- (b) supplementing this Regulation as regards:
  - (i) the exercise of the supervision of the control authorities and control bodies recognised by the Commission in accordance with paragraph 1, including on-the-spot examinations; and
  - (ii) the controls and other actions to be performed by those control authorities and control bodies.

8. The Commission may adopt implementing acts to ensure the application of the measures to be taken in relation to cases of suspected or established non-compliance, in particular those affecting the integrity of organic or in-conversion products imported under the recognition provided for in this Article. Such measures may consist in particular in the verification of the integrity of organic or in-conversion products before placing the products on the market within the Union and, where appropriate, in the suspension of the authorisation for the placing on the market of such products within the Union as organic products or in-conversion products.

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

9. On duly justified imperative grounds of urgency relating to unfair practices or practices which are incompatible with the principles and rules on organic production, the protection of consumers' confidence or the protection of fair competition between operators, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 55(3) to take the measures referred to in paragraph 8 of this Article or to decide on the withdrawal of the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article.

#### Article 47

##### **Equivalence under a trade agreement**

A recognised third country referred to in point (b)(ii) of Article 45(1) is a third country which the Union has recognised under a trade agreement as having a system of production meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity as those of the Union.

#### Article 48

##### **Equivalence under Regulation (EC) No 834/2007**

1. A recognised third country referred to in point (b)(iii) of Article 45(1) is a third country which has been recognised for the purposes of equivalence under Article 33(2) of Regulation (EC) No 834/2007, including those recognised under the transitional measure provided for in Article 58 of this Regulation.

That recognition shall expire on 31 December 2025.

2. On the basis of annual reports to be sent to the Commission, by 31 March of each year, by the third countries referred to in paragraph 1 regarding the implementation and enforcement of the control measures established by them, and in the light of any other information received, the Commission shall ensure appropriate supervision of the recognised third countries by regularly reviewing their recognition. For this purpose, the Commission may request the assistance of Member States. The nature of the supervision shall be determined on the basis of an assessment of the likelihood of non-compliance, taking into account in particular the volume of exports to the Union from the third country concerned, the results of the monitoring and supervisory activities carried out by the competent authority and the results of previous controls. The Commission shall regularly report to the European Parliament and the Council on the outcome of its review.

3. The Commission shall, by means of an implementing act, establish a list of the third countries referred to in paragraph 1 and may amend that list by means of implementing acts.

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

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards the information to be sent by the third countries listed in accordance with paragraph 3 of this Article which is necessary for the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.

5. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those affecting the integrity of organic or in-conversion products imported from third countries referred to in this Article. Such measures may consist in particular in the verification of the integrity of organic or in-conversion products before placing the products on the market within the Union and, where appropriate, in the suspension of the authorisation for the placing on the market of such products within the Union as organic products or in-conversion products.

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

*Article 49***Report from the Commission on the application of Articles 47 and 48**

By 31 December 2021, the Commission shall present a report to the European Parliament and the Council on the state of application of Articles 47 and 48, in particular as regards the recognition of third countries for the purpose of equivalence.

## CHAPTER VIII

## GENERAL PROVISIONS

## SECTION 1

***Free movement of organic and in-conversion products****Article 50***Non-prohibition and non-restriction of the marketing of organic and in-conversion products**

Competent authorities, control authorities and control bodies shall not, on grounds that relate to the production, labelling or presentation of the products, prohibit or restrict the marketing of organic or in-conversion products subject to control by another competent authority, control authority or control body located in another Member State where those products comply with this Regulation. In particular, no official controls and other official activities other than those under Regulation (EU) 2017/625 shall be performed and no fees for official controls and other official activities other than those provided for in Chapter VI of that Regulation shall be collected.

## SECTION 2

***Information, reporting and related derogations****Article 51***Information relating to the organic sector and trade**

1. Each year Member States shall transmit to the Commission the information necessary for the implementation and monitoring of the application of this Regulation. As far as possible, such information shall be based on established sources of data. The Commission shall take into account the data needs and synergies between potential data sources, in particular their use for statistical purposes where appropriate.

2. The Commission shall adopt implementing acts as regards the system to be used for transmitting the information referred to in paragraph 1, the details of information to be transmitted, and the date by which that information is to be transmitted.

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

*Article 52***Information relating to the competent authorities, control authorities and control bodies**

1. Member States shall keep a regularly updated list of:

- (a) the names and addresses of the competent authorities; and
- (b) the names, addresses and code numbers of the control authorities and control bodies.

Member States shall transmit those lists, and any change thereof, to the Commission and make them public, except where such transmission and publication has already taken place in accordance with Article 4(4) of Regulation (EU) 2017/625.

2. Based on the information provided for under paragraph 1, the Commission shall regularly publish on the internet an updated list of control authorities and control bodies referred to in point (b) of paragraph 1.

*Article 53***Derogations, authorisations and report**

1. The derogations from the use of organic plant reproductive material and from the use of organic animals provided in points 1.8.5 of Part I of Annex II and points 1.3.4.3 and 1.3.4.4 of Part II of Annex II, with the exception of point 1.3.4.4.2 of Part II of Annex II, shall expire on 31 December 2035.

2. From 1 January 2028, based on the conclusions as regards availability of organic plant reproductive material and animals presented in the report provided for in paragraph 7 of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 54 amending this Regulation by:

- (a) ending the derogations referred to in point 1.8.5 of Part I of Annex II and in points 1.3.4.3 and 1.3.4.4 of Part II of Annex II, with the exception of point 1.3.4.4.2 of Part II of Annex II, at an earlier date than 31 December 2035 or extending them beyond that date; or
- (b) ending the derogation referred to in point 1.3.4.4.2 of Part II of Annex II.

3. From 1 January 2026, the Commission shall be empowered to adopt delegated acts in accordance with Article 54 amending point (b) of Article 26(2) to extend the scope of the information system referred to in Article 26(2) to pullets and point 1.3.4.3 of Part II of Annex II to base the derogations concerning pullets on the data collected in accordance with this system.

4. From 1 January 2025, the Commission shall be empowered to adopt delegated acts in accordance with Article 54, based on the information as regards availability of organic protein feed for poultry and porcine animals made available by Member States in accordance with paragraph 6 of this Article or presented in the report referred to in paragraph 7 of this Article, ending the authorisations to use non-organic protein feed in the nutrition of poultry and porcine animals referred to in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II at an earlier date than 31 December 2025 or extending them beyond that date.

5. When extending the derogations or authorisations referred to in paragraphs 2, 3 and 4, the Commission shall do so only for as long as it has information, in particular information provided by Member States in accordance with paragraph 6, that confirms the unavailability on the Union market of the plant reproductive material, animal or feed concerned.

6. By 30 June of each year, Member States shall make available to the Commission and to the other Member States:

- (a) information provided in the database referred to in Article 26(1) and in the systems referred to in Article 26(2) and, if relevant, in the systems referred to in Article 26(3);
- (b) information on the derogations granted in accordance with point 1.8.5 of Part I of Annex II and points 1.3.4.3 and 1.3.4.4 of Part II of Annex II; and
- (c) information on the availability on the Union market of organic protein feed for poultry and porcine animals and on the authorisations granted in accordance with points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II.

7. By 31 December 2025, the Commission shall present a report to the European Parliament and the Council on the availability on the Union market of and, if relevant, on the causes of limited access to:

- (a) organic plant reproductive material;
- (b) organic animals covered by the derogations referred to in points 1.3.4.3 and 1.3.4.4 of Part II of Annex II;
- (c) organic protein feed intended for the nutrition of poultry and porcine animals subject to the authorisations referred to in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II.

In drawing up that report, the Commission shall take into account, in particular, the data collected in accordance with Article 26 and the information relating to the derogations and the authorisations referred to in paragraph 6 of this Article.

## CHAPTER IX

### PROCEDURAL, TRANSITIONAL AND FINAL PROVISIONS

#### SECTION 1

#### *Procedural provisions*

#### *Article 54*

#### **Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) shall be conferred on the Commission for a period of five years from 1 January 2021. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 55

##### **Committee procedure**

1. The Commission shall be assisted by a committee called the 'Organic Production Committee'. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

4. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

#### SECTION 2

##### **Repeal and transitional and final provisions**

#### Article 56

##### **Repeal**

Regulation (EC) No 834/2007 is repealed.

However, that Regulation shall continue to apply for the purpose of completing the examination of pending applications from third countries, as provided for in Article 58 of this Regulation.

References to the repealed Regulation shall be construed as references to this Regulation.



*Article 57***Transitional measures relating to control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007**

1. The recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007 shall expire by 31 December 2023 at the latest.
2. The Commission shall, by means of an implementing act, establish a list of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007, and may amend that list by means of implementing acts.

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

3. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards the information to be sent by the control authorities and control bodies referred to in paragraph 2 of this Article which is necessary for the purpose of the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.

*Article 58***Transitional measures relating to applications from third countries submitted under Article 33(2) of Regulation (EC) No 834/2007**

1. The Commission shall complete the examination of applications from third countries which have been submitted under Article 33(2) of Regulation (EC) No 834/2007 and which are pending on 17 June 2018. That Regulation shall apply to the examination of such applications.
2. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by laying down the procedural rules necessary for the examination of the applications referred to in paragraph 1 of this Article, including on the information to be submitted by third countries.

*Article 59***Transitional measures relating to the first recognition of control authorities and control bodies**

By way of derogation from the date of application referred to in the second paragraph of Article 61, Article 46 shall apply from 17 June 2018 insofar as necessary in order to allow a timely recognition of control authorities and control bodies.

*Article 60***Transitional measures for stocks of organic products produced in accordance with Regulation (EC) No 834/2007**

Products produced in accordance with Regulation (EC) No 834/2007 before 1 January 2021 may be placed on the market after that date until stocks are exhausted.

*Article 61***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 2021.

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

Done at Strasbourg, 30 May 2018.

*For the European Parliament*  
*The President*  
A. TAJANI

*For the Council*  
*The President*  
L. PAVLOVA

## ANNEX I

**OTHER PRODUCTS REFERRED TO IN ARTICLE 2(1)**

- Yeasts used as food or feed,
  - maté, sweetcorn, vine leaves, palm hearts, hop shoots, and other similar edible parts of plants and products produced therefrom,
  - sea salt and other salts for food and feed,
  - silkworm cocoon suitable for reeling,
  - natural gums and resins,
  - beeswax,
  - essential oils,
  - cork stoppers of natural cork, not agglomerated, and without any binding substances,
  - cotton, not carded or combed,
  - wool, not carded or combed,
  - raw hides and untreated skins,
  - plant-based traditional herbal preparations.
-

## ANNEX II

## DETAILED PRODUCTION RULES REFERRED TO IN CHAPTER III

**Part I: Plant production rules**

In addition to the production rules laid down in Articles 9 to 12, the rules set out in this Part shall apply to organic plant production.

1. General requirements
- 1.1. Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock.
- 1.2. Hydroponic production, which is a method of growing plants which do not naturally grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.
- 1.3. By way of derogation from point 1.1, the production of sprouts by moistening of seeds and the obtaining of chicory heads including by dipping in clear water shall be allowed.
- 1.4. By way of derogation from point 1.1, the following practices shall be allowed:
  - (a) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer;
  - (b) growing seedlings or transplants in containers for further transplanting.
- 1.5. By way of derogation from point 1.1, growing crops in demarcated beds shall only be allowed for the surfaces that have been certified as organic for that practice before 28 June 2017 in Finland, Sweden and Denmark. No extension of those surfaces shall be permitted.

That derogation shall expire on 31 December 2030.

By 31 December 2025, the Commission shall present a report to the European Parliament and the Council on the use of demarcated beds in organic agriculture. That report may be accompanied, where appropriate, by a legislative proposal on the use of demarcated beds in organic agriculture.

- 1.6. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.
- 1.7. Conversion
- 1.7.1. For plants and plant products to be considered as organic products, the production rules laid down in this Regulation shall have been applied with respect to the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, during a period of at least two years before its use as organic feed, or, in the case of perennial crops other than forage, during a period of at least three years before the first harvest of organic products.
- 1.7.2. Where the land or one or more parcels thereof have been contaminated with products or substances not authorised for use in organic production, the competent authority may decide to extend the conversion period for the land or parcels concerned beyond the period referred to in point 1.7.1.
- 1.7.3. In the case of treatment with a product or a substance not authorised for use in organic production, the competent authority shall require a new conversion period in accordance with point 1.7.1.

That period may be shortened in the following two cases:

- (a) treatment with a product or a substance not authorised for use in organic production as part of a compulsory control measure for pests or weeds, including quarantine organisms or invasive species, imposed by the competent authority of the Member State concerned;
- (b) treatment with a product or a substance not authorised for use in organic production as part of scientific tests approved by the competent authority of the Member State concerned.

- 1.7.4. In the cases referred to in points 1.7.2 and 1.7.3, the length of the conversion period shall be fixed taking into account the following requirements:
- (a) the process of degradation of the product or substance concerned must guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;
  - (b) the harvest following the treatment may not be placed on the market as organic or in-conversion products.
- 1.7.4.1. Member States shall inform the Commission and the other Member States of any decision taken by them which lays down compulsory measures related to treatment with a product or a substance not authorised for use in organic production.
- 1.7.4.2. In the case of treatment with a product or a substance which is not authorised for use in organic production, point 1.7.5(b) shall not apply.
- 1.7.5. In the case of land associated with organic livestock production:
- (a) the conversion rules shall apply to the whole area of the production unit on which animal feed is produced;
  - (b) notwithstanding point (a), the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.
- 1.8. Origin of plants including plant reproductive material
- 1.8.1. For the production of plants and plant products other than plant reproductive material, only organic plant reproductive material shall be used.
- 1.8.2. To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.
- 1.8.3. When choosing organic plant reproductive material, operators shall give preference to organic plant reproductive material suitable for organic agriculture.
- 1.8.4. For the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.
- All multiplication practices except meristem culture shall be carried out under certified organic management.
- 1.8.5. Use of in-conversion and non-organic plant reproductive material
- 1.8.5.1. By way of derogation from point 1.8.1, where the data collected in the database referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) shows that the qualitative or quantitative needs of the operator regarding relevant organic plant reproductive material, excluding seedlings, are not met, competent authorities may authorise the use of in-conversion or non-organic plant reproductive material under the conditions laid down in points 1.8.5.3, 1.8.5.4 and 1.8.5.5.
- Prior to requesting any such derogation, the operator shall consult the database referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) in order to verify whether his or her request is justified.
- 1.8.5.2. Control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators in third countries to use in-conversion or non-organic plant reproductive material in an organic production unit when organic plant reproductive material is not available in sufficient quality or quantity in the territory of the third country in which the operator is located, under the conditions laid down under points 1.8.5.3, 1.8.5.4 and 1.8.5.5.
- 1.8.5.3. Non-organic plant reproductive material shall not be treated with plant protection products other than those authorised for the treatment of seed in accordance with Article 24(1) of this Regulation, unless chemical treatment has been prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authority of the Member State concerned for all varieties of a given species in the area in which the plant reproductive material is to be used.
- 1.8.5.4. The authorisation to use in-conversion or non-organic plant reproductive material shall be obtained before the sowing of the crop.

- 1.8.5.5. The authorisation to use in-conversion or non-organic plant reproductive material shall be granted only to individual users for one season at a time, and the competent authority responsible for authorisations shall list the quantities of the authorised plant reproductive material.
- 1.9. Soil management and fertilisation
- 1.9.1. In organic plant production, tillage and cultivation practices shall be used that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.
- 1.9.2. The fertility and biological activity of the soil shall be maintained and increased:
- (a) except in the case of grassland or perennial forage, by the use of multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops;
  - (b) in the case of greenhouses or perennial crops other than forage, by the use of short-term green manure crops and legumes as well as the use of plant diversity; and
  - (c) in all cases, by the application of livestock manure or organic matter, both preferably composted, from organic production.
- 1.9.3. Where the nutritional needs of plants cannot be met by the measures provided for in points 1.9.1 and 1.9.2, only fertilisers and soil conditioners that have been authorised pursuant to Article 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records of the use of those products.
- 1.9.4. The total amount of livestock manure, as defined in Directive 91/676/EEC, used in the in-conversion and organic production units shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrement, including poultry manure, composted farmyard manure and liquid animal excrement.
- 1.9.5. Operators of agricultural holdings may establish written cooperation agreements exclusively with operators of other agricultural holdings and undertakings which comply with the organic production rules, for the purpose of spreading surplus manure from organic production units. The maximum limit referred to in point 1.9.4 shall be calculated on the basis of all of the organic production units involved in such cooperation.
- 1.9.6. Preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.
- 1.9.7. For compost activation, appropriate plant-based preparations and preparations of micro-organisms may be used.
- 1.9.8. Mineral nitrogen fertilisers shall not be used.
- 1.9.9. Biodynamic preparations may be used.
- 1.10. Pest and weed management
- 1.10.1. The prevention of damage caused by pests and weeds shall rely primarily on the protection by:
- natural enemies,
  - the choice of species, varieties and heterogeneous material,
  - crop rotation,
  - cultivation techniques such as biofumigation, mechanical and physical methods, and
  - thermal processes such as solarisation and, in the case of protected crops, shallow steam treatment of the soil (to a maximum depth of 10 cm).
- 1.10.2. Where plants cannot adequately be protected from pests by measures provided for in point 1.10.1 or in the case of an established threat to a crop, only products and substances authorised pursuant to Articles 9 and 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records proving the need for the use of such products.
- 1.10.3. In relation to products and substances used in traps or in dispensers of products and substances other than pheromones, the traps or dispensers shall prevent the products and substances from being released into the environment and shall prevent contact between the products and substances and the crops being cultivated. All traps, including pheromone traps, shall be collected after use and shall be safely disposed of.

1.11. Products used for cleaning and disinfection

Only those products for cleaning and disinfection in plant production authorised pursuant to Article 24 for use in organic production shall be used for that purpose.

1.12. Record-keeping obligation

Operators shall keep records regarding the parcels concerned and the amount of the harvest.

1.13. Preparation of unprocessed products

If preparation operations other than processing are carried out on plants, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply *mutatis mutandis* to such operations.

2. Detailed rules for specific plants and plant products

2.1. Rules on mushroom production

For the production of mushrooms, substrates may be used if they are composed only of the following components:

(a) farmyard manure and animal excrement:

(i) either from organic production units or from in-conversion units in their second year of conversion; or

(ii) referred to in point 1.9.3, only when the product referred to in point (i) is not available, provided that that farmyard manure and animal excrement do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;

(b) products of agricultural origin, other than those referred to in point (a), from organic production units;

(c) peat, not treated with chemical products;

(d) wood, not treated with chemical products after felling;

(e) mineral products referred to in point 1.9.3, water and soil.

2.2. Rules concerning the collection of wild plants

The collection of wild plants and parts thereof growing naturally in natural areas, forests and agricultural areas is considered as organic production, provided that:

(a) for a period of at least three years before the collection, those areas were not treated with products or substances other than those authorised pursuant to Articles 9 and 24 for use in organic production;

(b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

## Part II: Livestock production rules

In addition to the production rules laid down in Articles 9, 10, 11 and 14, the rules laid down in this Part shall apply to organic livestock production.

1. General requirements

1.1. Except in the case of beekeeping, landless livestock production, where the farmer intending to produce organic livestock does not manage agricultural land and has not established a written cooperation agreement with a farmer as regards the use of organic production units or in-conversion production units for that livestock, shall be prohibited.

1.2. Conversion

1.2.1. In the case of simultaneous start of conversion of the production unit, including pasturage or any land used for animal feed, and of the animals existing on this production unit at the beginning of the conversion period of this production unit as referred to in points 1.7.1 and 1.7.5(b) of Part I, animals and animal products may be considered organic at the end of the conversion period of the production unit, even if the conversion period laid down in point 1.2.2 of this Part for the type of animal concerned is longer than the conversion period for the production unit.

By derogation from point 1.4.3.1, in the case of such simultaneous conversion and during the conversion period of the production unit, animals present in this production unit since the beginning of the conversion period may be fed with in-conversion feed produced on the in-conversion production unit during the first year of conversion and/or with feed in accordance with point 1.4.3.1 and/or with organic feed.