

Regulation (EU) 2018/848 of the European Parliament and of the
Council of 30 May 2018 on organic production and labelling of
organic products and repealing Council Regulation (EC) No 834/2007

CHAPTER III

PRODUCTION RULES

Article 9

General production rules

- 1 Operators shall comply with the general production rules laid down in this Article.
- 2 The entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production.
- 3 For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, provided that their use in non-organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law.

The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that Regulation:

- a safeners, synergists and co-formulants as components of plant protection products;
- b adjuvants that are to be mixed with plant protection products.

The use in organic production of products and substances for purposes other than those covered by this Regulation shall be allowed, provided that their use complies with the principles laid down in Chapter II.

- 4 Ionising radiation shall not be used in the treatment of organic food or feed, and in the treatment of raw materials used in organic food or feed.
- 5 The use of animal cloning, and the rearing of artificially induced polyploid animals, shall be prohibited.
- 6 Preventive and precautionary measures shall be taken, where appropriate, at every stage of production, preparation and distribution.
- 7 Notwithstanding paragraph 2, a holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that for the non-organic production units:
 - a as regards livestock, different species are involved;
 - b as regards plants, different varieties that can be easily differentiated are involved.

As regards algae and aquaculture animals, the same species may be involved, provided that there is a clear and effective separation between the production sites or units.

8 By way of derogation from point (b) of paragraph 7, in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated, or the same varieties, may be involved, provided that the production in question is within the context of a conversion plan, and provided that the conversion of the last part of the area related to the production in question to organic production begins as soon as possible and is completed within a maximum of five years.

In such cases:

- a the farmer shall notify the competent authority, or, where appropriate, the control authority or the control body, of the start of harvest of each of the products concerned at least 48 hours in advance;
- b upon completion of the harvest, the farmer shall inform the competent authority, or, where appropriate, the control authority or the control body, of the exact quantities harvested from the units concerned and of the measures taken to separate the products;
- c the conversion plan and the measures to be taken to ensure the effective and clear separation shall be confirmed each year by the competent authority, or, where appropriate, by the control authority or the control body, after the start of the conversion plan.

9 The requirements concerning different species and varieties, laid down in points (a) and (b) of paragraph 7, shall not apply in the case of research and educational centres, plant nurseries, seed multipliers and breeding operations.

10 Where, in the cases referred to in paragraphs 7, 8 and 9, not all production units of a holding are managed under organic production rules, the operators shall:

- a keep the products used for the organic and in-conversion production units separate from those used for the non-organic production units;
- b keep the products produced by the organic, in-conversion and non-organic production units separate from each other;
- c keep adequate records to show the effective separation of the production units and of the products.

11 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraph 7 of this Article by adding further rules on the splitting of a holding into organic, in-conversion and non-organic production units, in particular in relation to products listed in Annex I, or by amending those added rules.

Article 10

Conversion

1 Farmers and operators that produce algae or aquaculture animals shall comply with a conversion period. During the whole conversion period they shall apply all rules on organic production laid down in this Regulation, in particular the applicable rules on conversion set out in this Article and in Annex II.

2 The conversion period shall start at the earliest when the farmer or the operator that produces algae or aquaculture animals has notified the activity to the competent authorities, in accordance with Article 34(1), in the Member State in which the activity is carried out and in which that farmer or operator's holding is subject to the control system.

3 No previous period may be retroactively recognised as being part of the conversion period, except where:

- a the operator's land parcels were subject to measures which were defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 for the purpose of ensuring that no products or substances other than those authorised for use in organic production have been used on those land parcels; or
- b the operator can provide proof that the land parcels were natural or agricultural areas that, for a period of at least three years, have not been treated with products or substances that are not authorised for use in organic production.

4 Products produced during the conversion period shall not be marketed as organic products or as in-conversion products.

However, the following products produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products:

- a plant reproductive material, provided that a conversion period of at least 12 months has been complied with;
- b food products of plant origin and feed products of plant origin, provided that the product contains only one agricultural crop ingredient, and provided that a conversion period of at least 12 months before the harvest has been complied with.

5 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.2.2 of Part II of Annex II by adding conversion rules for species other than those regulated in Part II of Annex II on 17 June 2018, or by amending those added rules.

6 The Commission shall, where appropriate, adopt implementing acts specifying the documents to be supplied for the purpose of the retroactive recognition of a previous period in accordance with paragraph 3 of this Article.

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

Article 11

Prohibition of the use of GMOs

1 GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms or animals in organic production.

2 For the purposes of the prohibition laid down in paragraph 1, with regard to GMOs and products produced from GMOs for food and feed, operators may rely on the labels of a product that have been affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽¹⁾ or Regulation (EC) No 1830/2003 of the European Parliament and of the Council⁽²⁾ or any accompanying document provided pursuant thereto.

3 Operators may assume that no GMOs and no products produced from GMOs have been used in the manufacture of purchased food and feed where such products do not have a label affixed or provided, or are not accompanied by a document provided, pursuant to the legal acts referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those legal acts.

4 For the purposes of the prohibition laid down in paragraph 1, with regard to products not covered by paragraphs 2 and 3, operators using non-organic products purchased from third

parties shall require the vendor to confirm that those products are not produced from GMOs or produced by GMOs.

Article 12

Plant production rules

1 Operators that produce plants or plant products shall comply, in particular, with the detailed rules set out in Part I of Annex II.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

- a points 1.3 and 1.4 of Part I of Annex II as regards derogations;
- b point 1.8.5 of Part I of Annex II as regards the use of in-conversion and non-organic plant reproductive material;
- c point 1.9.5 of Part I of Annex II by adding further provisions concerning agreements between operators of agricultural holdings, or by amending those added provisions;
- d point 1.10.1 of Part I of Annex II by adding further pest- and weed-management measures, or by amending those added measures;
- e Part I of Annex II by adding further detailed rules and cultivation practices for specific plants and plant products, including rules for sprouted seeds, or by amending those added rules.

Article 13

Specific provisions for the marketing of plant reproductive material of organic heterogeneous material

1 Plant reproductive material of organic heterogeneous material may be marketed without complying with the requirements for registration and without complying with the certification categories of pre-basic, basic and certified material or with the requirements for other categories, which are set out in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC or acts adopted pursuant to those Directives.

2 Plant reproductive material of organic heterogeneous material as referred to in paragraph 1 may be marketed following a notification of the organic heterogeneous material by the supplier to the responsible official bodies referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, made by means of a dossier containing:

- a the contact details of the applicant;
- b the species and denomination of the organic heterogeneous material;
- c the description of the main agronomic and phenotypic characteristics that are common to that plant grouping, including breeding methods, any available results from tests on those characteristics, the country of production and the parental material used;
- d a declaration by the applicant concerning the truth of the elements in points (a), (b) and (c); and
- e a representative sample.

That notification shall be sent by registered letter, or by any other means of communication accepted by the official bodies, with confirmation of receipt requested.

Three months after the date shown on the return receipt, provided that no additional information was requested or that no formal refusal for reasons of incompleteness of the dossier or non-compliance as defined in Article 3(57) was communicated to the supplier, the responsible official body shall be deemed to have acknowledged the notification and its content.

After having expressly or implicitly acknowledged the notification, the responsible official body may proceed to the listing of the notified organic heterogeneous material. That listing shall be free of charge to the supplier.

The listing of any organic heterogeneous material shall be communicated to the competent authorities of the other Member States and to the Commission.

Such organic heterogeneous material shall fulfil the requirements laid down in the delegated acts adopted in accordance with paragraph 3.

3 The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by setting out rules governing the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species, as regards:

- a the description of the organic heterogeneous material, including the relevant breeding and production methods and parental material used;
- b the minimum quality requirements for seeds lots, including identity, specific purity, germination rates and sanitary quality;
- c labelling and packaging;
- d information and samples of production to be kept by the professional operators;
- e where applicable, maintenance of the organic heterogeneous material.

Article 14

Livestock production rules

1 Livestock operators shall comply, in particular, with the detailed production rules set out in Part II of Annex II and in any implementing acts referred to in paragraph 3 of this Article.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

- a points 1.3.4.2, 1.3.4.4.2 and 1.3.4.4.3 of Part II of Annex II by reducing the percentages as regards the origin of animals, once sufficient availability on the Union market of organic animals has been established;
- b point 1.6.6 of Part II of Annex II as regards the limit on organic nitrogen linked to the total stocking density;
- c point 1.9.6.2(b) of Part II of Annex II as regards the feeding of bee colonies;
- d points 1.9.6.3(b) and (e) of Part II of Annex II as regards the acceptable treatments for the disinfection of apiaries and the methods and treatments to fight against *Varroa destructor*;
- e Part II of Annex II by adding detailed rules on livestock production for species other than species regulated in that Part on 17 June 2018, or by amending those added rules, as regards:
 - (i) derogations as regards the origin of animals;
 - (ii) nutrition;

- (iii) housing and husbandry practices;
- (iv) health care;
- (v) animal welfare.

3 The Commission shall, where appropriate, adopt implementing acts regarding Part II of Annex II providing rules on:

- a the minimum period to be complied with for feeding of suckling animals with maternal milk, referred to in point 1.4.1(g);
- b the stocking density and the minimum surface for indoor and outdoor areas that are to be complied with for specific livestock species to ensure that the developmental, physiological and ethological needs of animals are met in accordance with points 1.6.3, 1.6.4 and 1.7.2,
- c the characteristics of and technical requirements for the minimum surface for indoor and outdoor areas;
- d the characteristics of and technical requirements for buildings and pens for all livestock species other than bees, to ensure that the developmental, physiological and ethological needs of animals are met in accordance with point 1.7.2;
- e requirements for vegetation and the characteristics of protected facilities and open air areas.

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

Article 15

Production rules for algae and aquaculture animals

1 Operators that produce algae and aquaculture animals shall comply, in particular, with the detailed production rules set out in Part III of Annex II and in any implementing acts referred to in paragraph 3 of this Article.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

- a point 3.1.3.3 of Part III of Annex II as regards feed for carnivorous aquaculture animals;
- b point 3.1.3.4 of Part III of Annex II by adding further specific rules on feed for certain aquaculture animals, or by amending those added rules;
- c point 3.1.4.2 of Part III of Annex II as regards veterinary treatments for aquaculture animals;
- d Part III of Annex II by adding further detailed conditions per species for broodstock management, breeding and juvenile production, or by amending those added detailed conditions.

3 The Commission shall, where appropriate, adopt implementing acts laying down detailed rules per species or per group of species on the stocking density, and on the specific characteristics for production systems and containment systems, in order to ensure that the species-specific needs are met.

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

4 For the purpose of this Article and of Part III of Annex II, ‘stocking density’ means the live weight of aquaculture animals per cubic metre of water at any time during the grow-out phase and, in the case of flatfish and shrimp, the weight per square metre of surface.

Article 16

Production rules for processed food

1 Operators that produce processed food shall comply, in particular, with the detailed production rules set out in Part IV of Annex II and in any implementing acts referred to in paragraph 3 of this Article.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

- a point 1.4 of Part IV of Annex II as regards precautionary measures and preventive measures to be taken by operators;
- b point 2.2.2 of Part IV of Annex II as regards the types and composition of products and substances that are allowed for use in processed food, as well as conditions under which they may be used;
- c point 2.2.4 of Part IV of Annex II as regards the calculation of the percentage of agricultural ingredients referred to in points (a)(ii) and (b)(i) of Article 30(5), including the food additives authorised pursuant to Article 24 for use in organic production that are considered as agricultural ingredients for the purpose of such calculations.

Those delegated acts shall not include the possibility of using flavouring substances or flavouring preparations which are neither natural, within the meaning of Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council⁽³⁾, nor organic.

3 The Commission may adopt implementing acts laying down the techniques authorised in the processing of food products.

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

Article 17

Production rules for processed feed

1 Operators that produce processed feed shall comply, in particular, with the detailed production rules set out in Part V of Annex II and in any implementing acts referred to in paragraph 3 of this Article.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.4 of Part V of Annex II by adding further precautionary and preventive measures to be taken by operators, or by amending those added measures.

3 The Commission may adopt implementing acts laying down the techniques authorised for use in the processing of feed products.

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

Article 18

Production rules for wine

1 Operators that produce products of the wine sector shall comply, in particular, with the detailed production rules set out in Part VI of Annex II.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

- a point 3.2 of Part VI of Annex II by adding further oenological practices, processes and treatments that are prohibited, or by amending those added elements;
- b point 3.3. of Part VI of Annex II.

Article 19

Production rules for yeast used as food or feed

1 Operators that produce yeast to be used as food or feed shall comply, in particular, with the detailed production rules set out in Part VII of Annex II.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.3 of Part VII of Annex II by adding further detailed yeast production rules, or by amending those added rules.

Article 20

Absence of certain production rules for specific livestock species and species of aquaculture animals

Pending the adoption of:

- (a) additional general rules for other livestock species than those regulated in point 1.9 of Part II of Annex II in accordance with point (e) of Article 14(2);
- (b) the implementing acts referred to in Article 14(3) for livestock species; or
- (c) the implementing acts referred to in Article 15(3) for species or group of species of aquaculture animals;

a Member State may apply detailed national production rules for specific species or groups of species of animals in relation to the elements to be covered by the measures referred to in points (a), (b) and (c), provided that those national rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation.

Article 21

Production rules for products not falling within the categories of products referred to in Articles 12 to 19

1 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex II by adding detailed production rules, as well as rules on the obligation to convert, for products that do not fall within the categories of products referred to in Articles 12 to 19, or by amending those added rules.

Those delegated acts shall be based on the objectives and principles of organic production laid down in Chapter II and shall comply with the general production rules laid down in Articles 9, 10 and 11 as well as existing detailed production rules laid down for similar products in Annex II. They shall lay down requirements concerning, in particular, the treatments, practices and inputs that are allowed or prohibited, or conversion periods for the products concerned.

- 2 In the absence of the detailed production rules referred to in paragraph 1:
- a operators shall, as regards products referred to in paragraph 1, comply with the principles laid down in Articles 5 and 6, *mutatis mutandis* with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11;
 - b a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation.

Article 22

Adoption of exceptional production rules

1 The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by laying down:

- a the criteria to determine whether a situation qualifies as catastrophic circumstances deriving from an ‘adverse climatic event’, ‘animal diseases’, an ‘environmental incident’, a ‘natural disaster’ or a ‘catastrophic event’, as defined in points (h), (i), (j), (k) and (l) of Article 2(1) of Regulation (EU) No 1305/2013, respectively, as well as any comparable situation;
- b specific rules, including possible derogations from this Regulation, on how Member States are to deal with such catastrophic circumstances if they decide to apply this Article; and
- c specific rules on monitoring and reporting in such cases.

Those criteria and rules shall be subject to the principles of organic production laid down in Chapter II.

2 Where a Member State has formally recognised an event as a natural disaster as referred to in Article 18(3) or Article 24(3) of Regulation (EU) No 1305/2013, and that event makes it impossible to comply with the production rules laid down in this Regulation, that Member State may grant derogations from the production rules for a limited period until organic

production can be re-established, subject to the principles laid down in Chapter II and to any delegated act adopted in accordance with paragraph 1.

3 Member States may adopt measures in accordance with the delegated act referred to in paragraph 1 to allow organic production to continue or recommence in the event of catastrophic circumstances.

Article 23

Collection, packaging, transport and storage

1 Operators shall ensure that organic products and in-conversion products are collected, packaged, transported and stored in accordance with the rules set out in Annex III.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending:

- a Section 2 of Annex III;
- b Sections 3, 4 and 6 of Annex III by adding further special rules for the transport and reception of the products concerned, or by amending those added rules.

Article 24

Authorisation of products and substances for use in organic production

1 The Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

- a as active substances to be used in plant protection products;
- b as fertilisers, soil conditioners and nutrients;
- c as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin;
- d as feed additives and processing aids;
- e as products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production;
- f as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding;
- g as products for cleaning and disinfection in processing and storage facilities.

2 In addition to products and substances authorised in accordance with paragraph 1, the Commission may authorise certain products and substances for use in the production of processed organic food and of yeast used as food or feed, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

- a as food additives and processing aids;
- b as non-organic agricultural ingredients to be used for the production of processed organic food;
- c as processing aids for the production of yeast and yeast products.

3 The authorisation of the products and substances referred to in paragraph 1 for use in organic production shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole:

- a they are essential for sustained production and for the use for which they are intended;

- b all of the products and substances concerned are of plant, algal, animal, microbial or mineral origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available;
- c in the case of products referred to in point (a) of paragraph 1:
 - (i) their use is essential for the control of a pest for which other biological, physical or breeding alternatives, cultivation practices or other effective management practices are not available;
 - (ii) if such products are not of plant, algal, animal, microbial or mineral origin and are not identical to their natural form, their conditions for use preclude any direct contact with the edible parts of the crop;
- d in the case of products referred to in point (b) of paragraph 1, their use is essential for building or maintaining the fertility of the soil or to fulfil specific nutritional requirements of crops, or for specific soil-conditioning purposes;
- e in the case of products referred to in points (c) and (d) of paragraph 1:
 - (i) their use is necessary to maintain animal health, animal welfare and vitality and contributes to an appropriate diet fulfilling the physiological and behavioural needs of the species concerned or their use is necessary to produce or preserve feed because the production or preservation of feed is not possible without having recourse to such substances;
 - (ii) feed of mineral origin, trace elements, vitamins or provitamins are of natural origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available;
 - (iii) the use of non-organic feed material of plant or animal origin is necessary because feed material of plant or animal origin produced in accordance with organic production rules is not available in sufficient quantity;
 - (iv) the use of non-organic spices, herbs and molasses is necessary because such products are not available in organic form; they have to be produced or prepared without chemical solvents and their use is limited to 1 % of the feed ration for a given species, calculated annually as a percentage of the dry matter of feed from agricultural origin.

4 The authorisation of the products and substances referred to in paragraph 2 for use in the production of processed organic food or for the production of yeast used as food or feed shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole:

- a alternative products or substances authorised in accordance with this Article or techniques compliant with this Regulation are not available;
- b it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of Union legislation without having recourse to those products and substances;
- c they are to be found in nature and may only have undergone mechanical, physical, biological, enzymatic or microbial processes, except in cases where products or substances from such sources are not available in sufficient quantities or qualities;
- d the organic ingredient is not available in sufficient quantity.

5 The authorisation of the use of chemically synthesised products and substances, in accordance with paragraphs 1 and 2 of this Article, shall be strictly limited to cases where the

use of external inputs referred to in point (g) of Article 5 would contribute to unacceptable impacts on the environment.

6 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 3 and 4 of this Article by adding further criteria for the authorisation of products and substances referred to in paragraphs 1 and 2 of this Article for use in organic production in general, and in the production of processed organic food in particular, as well as further criteria for the withdrawal of such authorisations, or by amending those added criteria.

7 Where a Member State considers that a product or substance should be added to or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 2, or that the specifications of use referred to in the production rules should be amended, it shall ensure that a dossier giving the reasons for the inclusion, withdrawal or other amendments is officially sent to the Commission and to the other Member States and is made publicly available, subject to Union and national legislation on data protection.

The Commission shall publish any requests referred to in this paragraph.

8 The Commission shall regularly review the lists referred to in this Article.

The list of non-organic ingredients referred to in point (b) of paragraph 2 shall be reviewed at least once a year.

9 The Commission shall adopt implementing acts concerning the authorisation or withdrawal of authorisation of products and substances in accordance with paragraphs 1 and 2 that may be used in organic production in general and in the production of processed organic food in particular, and establishing the procedures to be followed for such authorisations and the lists of such products and substances and, where appropriate, their description, compositional requirements and conditions for use.

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

Article 25

Authorisation of non-organic agricultural ingredients for processed organic food by Member States

1 Where it is necessary in order to ensure access to certain agricultural ingredients, and where such ingredients are not available in organic form in sufficient quantity, a Member State may, at the request of an operator, provisionally authorise the use of non-organic agricultural ingredients for the production of processed organic food on its territory for a period of maximum six months. That authorisation shall apply to all operators in that Member State.

2 The Member State shall immediately notify the Commission and the other Member States, via a computer system that enables the electronic exchange of documents and information made available by the Commission, of any authorisation granted for its territory in accordance with paragraph 1.

3 The Member State may prolong the authorisation provided for in paragraph 1 two times for a maximum of six months each, provided that no other Member State has objected by indicating, via the system referred to in paragraph 2, that such ingredients are available in organic form in sufficient quantity.

4 A control authority or a control body recognised in accordance with Article 46(1) may grant a provisional authorisation, as referred to in paragraph 1 of this Article, for a maximum

of six months to operators in third countries that request such an authorisation and that are subject to controls by that control authority or control body, provided that the conditions of that paragraph are fulfilled in the third country concerned. The authorisation may be prolonged for a maximum of two times six months each.

5 Where, after two prolongations of a provisional authorisation, a Member State considers, on the basis of objective information, that the availability of such ingredients in organic form remains insufficient to meet the qualitative and quantitative needs of operators, it may make a request to the Commission in accordance with Article 24(7).

Article 26

Collection of data concerning the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles

1 Each Member State shall ensure that a regularly updated database is established for the listing of the organic and in-conversion plant reproductive material, excluding seedlings but including seed potatoes, which is available on its territory.

2 Member States shall have in place systems that allow operators that market organic or in-conversion plant reproductive material, organic animals or organic aquaculture juveniles, and that are able to supply them in sufficient quantities and within a reasonable period, to make public on a voluntary basis, free of charge, together with their names and contact details, information on the following:

- a the organic and in-conversion plant reproductive material, such as plant reproductive material of organic heterogeneous material or of organic varieties suitable for organic production, excluding seedlings but including seed potatoes, which is available; the quantity in weight of that material; and the period of the year of its availability; such material shall be listed using at least the Latin scientific name;
- b the organic animals for which derogation may be provided in accordance with point 1.3.4.4 of Part II of Annex II; the number of available animals categorised by sex; information, if relevant, relating to the different species of animals as regards the breeds and strains available; the races of the animals; the age of the animals; and any other relevant information;
- c the organic aquaculture juveniles available on the holding and their health status in accordance with Council Directive 2006/88/EC⁽⁴⁾ and the production capacity for each aquaculture species.

3 Member States may also set up systems which allow operators that market breeds and strains adapted to organic production in accordance with point 1.3.3 of Part II of Annex II or organic pullets and that are able to supply those animals in sufficient quantities and within a reasonable period to make public the relevant information on a voluntary basis, free of charge, together with names and contact details.

4 Operators that opt to include information on plant reproductive material, animals or aquaculture juveniles in the systems referred to in paragraphs 2 and 3 shall ensure that the information is updated regularly, and shall ensure that the information is withdrawn from the lists once the plant reproductive material, animals or aquaculture juveniles are no longer available.

5 For the purpose of paragraphs 1, 2 and 3, Member States may continue to use relevant information systems that are already in existence.

6 The Commission shall make public the link to each of the national databases or systems on a dedicated website of the Commission, in order to allow users to have access to such databases or systems throughout the Union.

- 7 The Commission may adopt implementing acts providing:
- a technical details for establishing and maintaining the databases referred to in paragraph 1 and the systems referred to in paragraph 2;
 - b specifications as regards the collection of information referred to in paragraph 1 and 2;
 - c specifications as regards the arrangements for participation in the databases referred to in paragraph 1 and in the systems referred to in paragraphs 2 and 3; and
 - d details as regards the information to be provided by Member States in accordance with Article 53(6).

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

Article 27

Obligations and actions in the event of suspicion of non-compliance

Where an operator suspects that a product it has produced, prepared, imported or has received from another operator does not comply with this Regulation, that operator shall, subject to Article 28(2):

- (a) identify and separate the product concerned;
- (b) check whether the suspicion can be substantiated;
- (c) not place the product concerned on the market as an organic or in-conversion product and not use it in organic production, unless the suspicion can be eliminated;
- (d) where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available elements, where appropriate;
- (e) fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in verifying and identifying the reasons for the suspected non-compliance.

Article 28

Precautionary measures to avoid the presence of non-authorised products and substances

1 In order to avoid contamination with products or substances that are not authorised in accordance with the first subparagraph of Article 9(3) for use in organic production, operators shall take the following precautionary measures at every stage of production, preparation and distribution:

- a put in place and maintain measures that are proportionate and appropriate to identify the risks of contamination of organic production and products with non-authorised products or substances, including systematic identification of critical procedural steps;

- b put in place and maintain measures that are proportionate and appropriate to avoid risks of contamination of organic production and products with non-authorised products or substances;
- c regularly review and adjust such measures; and
- d comply with other relevant requirements of this Regulation that ensure the separation of organic, in-conversion and non-organic products.

2 Where an operator suspects, due to the presence of a product or substance that is not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production in a product that is intended to be used or marketed as an organic or in-conversion product, that the latter product does not comply with this Regulation, the operator shall:

- a identify and separate the product concerned;
- b check whether the suspicion can be substantiated;
- c not place the product concerned on the market as an organic or in-conversion product and not use it in organic production unless the suspicion can be eliminated;
- d where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant competent authority, or, where appropriate, the relevant control authority or control body, and provide it with available elements, where appropriate;
- e fully cooperate with the relevant competent authority, or, where appropriate, with the relevant control authority or control body, in identifying and verifying the reasons for the presence of non-authorised products or substances.

3 The Commission may adopt implementing acts laying down uniform rules to specify:

- a the procedural steps to be followed by operators in accordance with points (a) to (e) of paragraph 2 and the relevant documents to be provided by them;
- b the proportionate and appropriate measures to be adopted and reviewed by operators to identify and avoid risks of contamination in accordance with points (a), (b) and (c) of paragraph 1.

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

Article 29

Measures to be taken in the event of the presence of non-authorised products or substances

1 Where the competent authority, or, where appropriate, the control authority or control body, receives substantiated information about the presence of products or substances that are not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production, or has been informed by an operator in accordance with point (d) of Article 28(2), or detects such products or substances in an organic or an in-conversion product:

- a it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to determining the source and the cause in order to verify compliance with the first subparagraph of Article 9(3) and with Article 28(1); 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).

2 The product concerned shall not be marketed as an organic or in-conversion product or used in organic production where the competent authority, or, where appropriate, the control authority or control body, has established that the operator concerned:

- a has used products or substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production;
- b has not taken the precautionary measures referred to in Article 28(1); or
- c has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

3 The operator concerned shall be given an opportunity to comment on the results of the investigation referred to in point (a) of paragraph 1. The competent authority, or, where appropriate, the control authority or control body, shall keep records of the investigation it has carried out.

Where required, the operator concerned shall take such corrective measures as necessary to avoid future contamination.

4 By 31 December 2024, the Commission shall present a report to the European Parliament and the Council on the implementation of this Article, on the presence of products and substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production and on the assessment of the national rules referred to in paragraph 5 of this Article. That report may be accompanied, where appropriate, by a legislative proposal for further harmonisation.

5 Member States having in place rules providing for products that contain more than a certain level of products or substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production not to be marketed as organic products may continue to apply those rules, provided that those rules do not prohibit, restrict or impede the placing on the market of products produced in other Member States as organic products, where those products were produced in compliance with this Regulation. Member States that make use of this paragraph shall inform the Commission without delay.

6 The competent authorities shall document the results of the investigations referred to in paragraph 1, as well as any measures they have taken for the purpose of formulating best practices and further measures to avoid the presence of products and substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production.

Member States shall make such information available to the other Member States and to the Commission via a computer system that enables the electronic exchange of documents and information made available by the Commission.

7 Member States may take appropriate measures on their territory to avoid the unintended presence in organic agriculture of products and substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production. Such measures shall not prohibit, restrict or impede the placing on the market of products produced in other Member States as organic or in-conversion products, where those products were produced in compliance with this Regulation. Member States that make use of this paragraph shall inform the Commission and the other Member States without delay.

8 The Commission shall adopt implementing acts laying down uniform rules to specify:

- a the methodology to be applied by competent authorities, or, where appropriate, by control authorities or control bodies, for the detection and evaluation of the presence of products and substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production;

- b the details and format of the information to be made available by Member States to the Commission and other Member States in accordance with paragraph 6 of this Article.

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

9 By 31 March of each year, Member States shall electronically transmit to the Commission relevant information about cases involving contamination with non-authorised products or substances in the previous year, including information collected at border control posts, concerning the nature of contamination detected, and in particular the cause, the source and the level of contamination as well as the volume and nature of products contaminated. This information shall be collected by the Commission through the computer system made available by the Commission and shall be used to facilitate the formulation of best practices for avoiding contamination.

Status: This is the original version (as it was originally adopted).

- (1) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([OJ L 268, 18.10.2003, p. 1](#)).
- (2) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([OJ L 268, 18.10.2003, p. 24](#)).
- (3) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ([OJ L 354, 31.12.2008, p. 34](#)).
- (4) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ([OJ L 328, 24.11.2006, p. 14](#)).