- 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 Articles 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 inconversion 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 (¹) 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.

⁽¹⁾ 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).

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.