

- (51) 'ingredient' means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011 or, for products other than food, any substance or product used in the manufacture or preparation of products that is still present in the finished product, even in altered form;
- (52) 'labelling' means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product that are placed on any packaging, document, notice, label, ring or collar that accompanies or refers to that product;
- (53) 'advertising' means any presentation of products to the public, by any means other than a label, that is intended or is likely to influence and shape attitudes, beliefs and behaviours in order to directly or indirectly promote the sale of products;
- (54) 'competent authorities' means competent authorities as defined in point (3) of Article 3 of Regulation (EU) 2017/625;
- (55) 'control authority' means an organic control authority as defined in point (4) of Article 3 of Regulation (EU) 2017/625, or an authority recognised by the Commission or by a third country recognised by the Commission for the purposes of carrying out controls in third countries for the import of organic and in-conversion products into the Union;
- (56) 'control body' means a delegated body as defined in point (5) of Article 3 of Regulation (EU) 2017/625, or a body recognised by the Commission or by a third country recognised by the Commission for the purposes of carrying out controls in third countries for the import of organic and in-conversion products into the Union;
- (57) 'non-compliance' means non-compliance with this Regulation or non-compliance with the delegated or implementing acts adopted in accordance with this Regulation;
- (58) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council ⁽¹⁾ which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive;
- (59) 'produced from GMOs' means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (60) 'produced by GMOs' means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;
- (61) 'food additive' means a food additive as defined in point (a) of Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽²⁾;
- (62) 'feed additives' mean feed additives as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁽³⁾;
- (63) 'engineered nanomaterial' means an engineered nanomaterial as defined in point (f) of Article 3(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽⁴⁾;
- (64) 'equivalence' means meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;
- (65) 'processing aid' means a processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008 for food and in point (h) of Article 2(2) of Regulation (EC) No 1831/2003 for feed;
- (66) 'food enzyme' means a food enzyme as defined in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁽⁵⁾;
- (67) 'ionising radiation' means ionising radiation as defined in point (46) of Article 4 of Council Directive 2013/59/Euratom ⁽⁶⁾;

⁽¹⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽²⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

⁽³⁾ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

⁽⁴⁾ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

⁽⁵⁾ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

⁽⁶⁾ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

- (68) 'prepacked food' means prepacked food as defined in point (e) of Article 2(2) of Regulation (EU) No 1169/2011;
- (69) 'poultry house' means a fixed or mobile building for accommodating flocks of poultry, which includes all surfaces covered by roofs, including a veranda; the house may be subdivided into separate compartments, each accommodating a single flock;
- (70) 'soil-related crop cultivation' means production in living soil or in soil that is mixed or fertilised with materials and products that are allowed in organic production in connection with the subsoil and bedrock;
- (71) 'unprocessed products' means unprocessed products as defined in point (n) of Article 2(1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽¹⁾, irrespective of packaging or labelling operations;
- (72) 'processed products' means processed products as defined in point (o) of Article 2(1) of Regulation (EC) No 852/2004, irrespective of packaging or labelling operations;
- (73) 'processing' means processing as defined in point (m) of Article 2(1) of Regulation (EC) No 852/2004; this includes the use of substances referred to in Articles 24 and 25 of this Regulation but does not include packaging or labelling operations;
- (74) 'integrity of organic or in-conversion products' means the fact that the product does not exhibit non-compliance which:
- (a) in any stage of production, preparation and distribution affects the organic or in-conversion characteristics of the product; or
 - (b) is repetitive or intentional;
- (75) 'pen' means an enclosure that includes a part in which animals are provided with protection from adverse weather conditions.

CHAPTER II

OBJECTIVES AND PRINCIPLES OF ORGANIC PRODUCTION

Article 4

Objectives

Organic production shall pursue the following general objectives:

- (a) contributing to protection of the environment and the climate;
- (b) maintaining the long-term fertility of soils;
- (c) contributing to a high level of biodiversity;
- (d) substantially contributing to a non-toxic environment;
- (e) contributing to high animal welfare standards and, in particular, to meeting the species-specific behavioural needs of animals;
- (f) encouraging short distribution channels and local production in the various areas of the Union;
- (g) encouraging the preservation of rare and native breeds in danger of extinction;
- (h) contributing to the development of the supply of plant genetic material adapted to the specific needs and objectives of organic agriculture;
- (i) contributing to a high level of biodiversity, in particular by using diverse plant genetic material, such as organic heterogeneous material and organic varieties suitable for organic production;
- (j) fostering the development of organic plant breeding activities in order to contribute to favourable economic perspectives of the organic sector.

Article 5

General principles

Organic production is a sustainable management system that is based on the following general principles:

- (a) respect for nature's systems and cycles and the sustainment and enhancement of the state of the soil, the water and the air, of the health of plants and animals, and of the balance between them;
- (b) the preservation of natural landscape elements, such as natural heritage sites;

⁽¹⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

- (c) the responsible use of energy and natural resources, such as water, soil, organic matter and air;
- (d) the production of a wide variety of high-quality food and other agricultural and aquaculture products that respond to consumers' demand for goods that are produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare;
- (e) ensuring the integrity of organic production at all stages of the production, processing and distribution of food and feed;
- (f) the appropriate design and management of biological processes, based on ecological systems and using natural resources which are internal to the management system, using methods that:
 - (i) use living organisms and mechanical production methods;
 - (ii) practice soil-related crop cultivation and land-related livestock production, or practice aquaculture which complies with the principle of the sustainable exploitation of aquatic resources;
 - (iii) exclude the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products;
 - (iv) are based on risk assessment and the use of precautionary measures and preventive measures, where appropriate;
- (g) the restriction of the use of external inputs; where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, the external inputs shall be limited to:
 - (i) inputs from organic production; in the case of plant reproductive material, priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic agriculture;
 - (ii) natural or naturally-derived substances;
 - (iii) low solubility mineral fertilisers;
- (h) the adaptation of the production process, where necessary and within the framework of this Regulation, to take account of the sanitary status, regional differences in the ecological balance, climatic and local conditions, stages of development and specific husbandry practices;
- (i) the exclusion from the whole organic food chain of animal cloning, of rearing artificially induced polyploid animals and of ionising radiation;
- (j) the observance of a high level of animal welfare respecting species-specific needs.

Article 6

Specific principles applicable to agricultural activities and aquaculture

As regards agricultural activities and aquaculture, organic production shall, in particular, be based on the following specific principles:

- (a) the maintenance and enhancement of soil life and natural soil fertility, soil stability, soil water retention and soil biodiversity, preventing and combating loss of soil organic matter, soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem;
- (b) the limitation of the use of non-renewable resources and external inputs to a minimum;
- (c) the recycling of waste and by-products of plant and animal origin as input in plant and livestock production;
- (d) the maintenance of plant health by preventive measures, in particular the choice of appropriate species, varieties or heterogeneous material resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests;
- (e) the use of seeds and animals with a high degree of genetic diversity, disease resistance and longevity;
- (f) in the choosing of plant varieties, having regard to the particularities of the specific organic production systems, focussing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect for the natural crossing barriers;

- (g) the use of organic plant reproductive material, such as plant reproductive material of organic heterogeneous material and of organic varieties suitable for organic production;
- (h) the production of organic varieties through natural reproductive ability and focussing on containment within natural crossing barriers;
- (i) without prejudice to Article 14 of Regulation (EC) No 2100/94 and to the national plant variety rights granted under Member States' national law, the possibility for farmers to use plant reproductive material obtained from their own farms in order to foster genetic resources adapted to the special conditions of organic production;
- (j) in the choosing of animal breeds, having regard to a high degree of genetic diversity, the capacity of animals to adapt to local conditions, their breeding value, their longevity, their vitality and their resistance to disease or health problems;
- (k) the practice of site-adapted and land-related livestock production;
- (l) the application of animal husbandry practices which enhance the immune system and strengthen the natural defence against diseases, including regular exercise and access to open air areas and pastures;
- (m) the feeding of livestock with organic feed composed of agricultural ingredients resulting from organic production and of natural non-agricultural substances;
- (n) the production of organic livestock products derived from animals that have been raised on organic holdings throughout their lives since birth or hatching;
- (o) the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems;
- (p) the feeding of aquatic organisms with feed from sustainably exploited fisheries in accordance with Regulation (EU) No 1380/2013 or with organic feed composed of agricultural ingredients resulting from organic production, including organic aquaculture, and of natural non-agricultural substances;
- (q) avoiding any endangerment of species of conservation interest that might arise from organic production.

Article 7

Specific principles applicable to the processing of organic food

The production of processed organic food shall be based, in particular, on the following specific principles:

- (a) the production of organic food from organic agricultural ingredients;
- (b) the restriction of the use of food additives, of non-organic ingredients with mainly technological and sensory functions, and of micronutrients and processing aids, so that they are used to a minimum extent and only in cases of essential technological need or for particular nutritional purposes;
- (c) the exclusion of substances and processing methods that might be misleading as regards the true nature of the product;
- (d) the processing of organic food with care, preferably through the use of biological, mechanical and physical methods;
- (e) the exclusion of food containing, or consisting of, engineered nanomaterials.

Article 8

Specific principles applicable to the processing of organic feed

The production of processed organic feed shall be based, in particular, on the following specific principles:

- (a) the production of organic feed from organic feed materials;
- (b) the restriction of the use of feed additives and processing aids, so that they are used to a minimum extent and only in cases of essential technological or zootechnical needs or for particular nutritional purposes;

- (c) the exclusion of substances and processing methods that might be misleading as regards the true nature of the product;
- (d) the processing of organic feed with care, preferably through the use of biological, mechanical and physical methods.

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.

⁽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).

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 ⁽¹⁾, 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).

⁽¹⁾ 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).

*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 ⁽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.

CHAPTER IV

LABELLING

Article 30

Use of terms referring to organic production

1. For the purposes of this Regulation, a product shall be regarded as bearing terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials used for its production are described in terms suggesting to the purchaser that the product, ingredients or feed materials have been produced in accordance with this Regulation. In particular, the terms listed in Annex IV and their derivatives and diminutives, such as 'bio' and 'eco', whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation.

2. For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation.

Furthermore, no terms, including terms used in trademarks or company names, or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation.

3. Products that have been produced during the conversion period shall not be labelled or advertised as organic products or as in-conversion products.

However, plant reproductive material, food products of plant origin and feed products of plant origin that have been produced during the conversion period, which comply with Article 10(4), may be labelled and advertised as in-conversion products by using the term 'in-conversion' or a corresponding term, together with the terms referred to in paragraph 1.

4. The terms referred to in paragraph 1 and 3 shall not be used for a product for which Union law requires the labelling or advertising to state that the product contains GMOs, consists of GMOs or is produced from GMOs.

5. For processed food, the terms referred to in paragraph 1 may be used:

(a) in the sales description, and in the list of ingredients where such a list is mandatory pursuant to Union legislation, provided that:

(i) the processed food complies with the production rules set out in Part IV of Annex II and with the rules laid down in accordance with Article 16(3);

(ii) at least 95 % of the agricultural ingredients of the product by weight are organic; and

(iii) in the case of flavourings, they are only used for natural flavouring substances and natural flavouring preparations labelled in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 and all of the flavouring components and carriers of flavouring components in the flavouring concerned are organic;

(b) only in the list of ingredients, provided that:

(i) less than 95 % of the agricultural ingredients of the product by weight are organic, and provided that those ingredients comply with the production rules set out in this Regulation; and

(ii) the processed food complies with the production rules set out in points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3);

(c) in the sales description and in the list of ingredients, provided that:

(i) the main ingredient is a product of hunting or fishing;

(ii) the term referred to in paragraph 1 is clearly related in the sales description to another ingredient which is organic and different from the main ingredient;

(iii) all other agricultural ingredients are organic; and

(iv) the food complies with points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3).

The list of ingredients referred to in points (a), (b) and (c) of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients.

The list of ingredients referred to in points (b) and (c) of the first subparagraph shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of agricultural ingredients.

The terms referred to in paragraph 1, when used in the list of ingredients referred to in points (a), (b), and (c) of the first subparagraph of this paragraph, and the indication of the percentage referred to in the third subparagraph of this paragraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients.

6. For processed feed, the terms referred to in paragraph 1 may be used in the sales description and in the list of ingredients, provided that:

- (a) the processed feed complies with the production rules set out in Parts II, III and V of Annex II and with the specific rules laid down in accordance with Article 16(3);
- (b) all of the ingredients of agricultural origin that are contained in the processed feed are organic; and
- (c) at least 95 % of the dry matter of the product are organic.

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

- (a) this Article by adding further rules on the labelling of products listed in Annex I, or by amending those added rules; and
- (b) the list of terms set out in Annex IV, taking into account linguistic developments within the Member States.

8. The Commission may adopt implementing acts to set detailed requirements for the application of paragraph 3 of this Article.

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

Article 31

Labelling of products and substances used in crop production

Notwithstanding the scope of this Regulation as set out in Article 2(1), products and substances used in plant protection products or as fertilisers, soil conditioners or nutrients that have been authorised in accordance with Articles 9 and 24 may bear a reference indicating that those products or substances have been authorised for use in organic production in accordance with this Regulation.

Article 32

Compulsory indications

1. Where products bear terms as referred to in Article 30(1), including products labelled as in-conversion products in accordance with Article 30(3):

- (a) the code number of the control authority or control body to which the operator that carried out the last production or preparation operation is subject shall also appear in the labelling; and
- (b) in the case of prepacked food, the organic production logo of the European Union referred to in Article 33 shall also appear on the packaging, except in cases referred to in Article 30(3) and points (b) and (c) of Article 30(5).

2. Where the organic production logo of the European Union is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed shall appear in the same visual field as the logo and shall take one of the following forms, as appropriate:

- (a) 'EU Agriculture', where the agricultural raw material has been farmed in the Union;
- (b) 'non-EU Agriculture', where the agricultural raw material has been farmed in third countries;
- (c) 'EU/non-EU Agriculture', where a part of the agricultural raw materials has been farmed in the Union and a part of it has been farmed in a third country.

For the purposes of the first subparagraph, the word 'Agriculture' may be replaced by 'Aquaculture' where appropriate and the words 'EU' and 'non-EU' may be replaced or supplemented by the name of a country, or by the name of a country and a region, if all of the agricultural raw materials of which the product is composed have been farmed in that country and, if applicable, in that region.

For the indication of the place where the agricultural raw materials of which the product is composed have been farmed, as referred to in the first and third subparagraphs, small quantities by weight of ingredients may be disregarded, provided that the total quantity of the disregarded ingredients does not exceed 5 % of the total quantity by weight of agricultural raw materials.

The words 'EU' or 'non-EU' shall not appear in a colour, size and style of lettering that is more prominent than the name of the product.

3. The indications referred to in paragraphs 1 and 2 of this Article and in Article 33(3) shall be marked in a conspicuous place in such a way as to be easily visible, and shall be clearly legible and indelible.

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraph 2 of this Article and Article 33(3) by adding further rules on labelling, or by amending those added rules.

5. The Commission shall adopt implementing acts relating to:

- (a) practical arrangements for the use, presentation, composition and size of the indications referred to in point (a) of paragraph 1 and in paragraph 2 of this Article and in Article 33(3);
- (b) the assignment of code numbers to control authorities and control bodies;
- (c) the indication of the place where the agricultural raw materials were farmed, in accordance with paragraph 2 of this Article and with Article 33(3).

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

Article 33

Organic production logo of the European Union

1. The organic production logo of the European Union may be used in the labelling, presentation and advertising of products which comply with this Regulation.

The organic production logo of the European Union may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that such use is not liable to mislead the consumer as regards the organic production of specific products, and provided that the logo is reproduced in accordance with the rules set out in Annex V. In such case, the requirements of Article 32(2) and point 1.7 of Annex V shall not apply.

The organic production logo of the European Union shall not be used for processed food as referred to in points (b) and (c) of Article 30(5) and for in-conversion products as referred to in Article 30(3).

2. Except where used in accordance with the second subparagraph of paragraph 1, the organic production logo of the European Union is an official attestation in accordance with Articles 86 and 91 of Regulation (EU) 2017/625.

3. The use of the organic production logo of the European Union shall be optional for products imported from third countries. Where that logo appears in the labelling of such products, the indication referred to in Article 32(2) shall also appear in the labelling.

4. The organic production logo of the European Union shall follow the model set out in Annex V, and shall comply with the rules set out in that Annex.

5. National logos and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation.

6. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex V as regards the organic production logo of the European Union and the rules relating thereto.

CHAPTER V

CERTIFICATION

Article 34

Certification system

1. Prior to placing any products on the market as 'organic' or as 'in-conversion' or prior to the conversion period, operators and groups of operators referred to in Article 36 which produce, prepare, distribute or store organic or in-conversion products, which import such products from a third country or export such products to a third country, or which place such products on the market, shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system.

Where the competent authorities have conferred their responsibilities or delegated certain official control tasks or certain tasks related to other official activities to more than one control authority or control body, the operators or groups of operators shall indicate in the notification referred to in the first subparagraph which control authority or control body verifies whether their activity complies with this Regulation and provides the certificate referred to in Article 35(1).

2. Operators that sell prepacked organic products directly to the final consumer or user shall be exempted from the notification obligation referred to in paragraph 1 of this Article and from the obligation to be in the possession of a certificate referred to in Article 35(2) provided that they 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 another operator.

3. Where operators or groups of operators subcontract any of their activities to third parties, both the operators or groups of operators and the third parties to whom those activities have been subcontracted shall comply with paragraph 1, unless the operator or group of operators has declared in the notification referred to in paragraph 1 that it remains responsible as regards organic production and that it has not transferred that responsibility to the subcontractor. In such cases, the competent authority, or, where appropriate, the control authority or control body, shall verify that the subcontracted activities comply with this Regulation, in the context of the control it carries out on the operators or groups of operators that have subcontracted their activities.

4. Member States may designate an authority or approve a body which is to receive the notifications referred to in paragraph 1.

5. Operators, groups of operators and subcontractors shall keep records in accordance with this Regulation on the different activities they engage in.

6. Member States shall keep updated lists containing the names and addresses of operators and groups of operators that have notified their activities in accordance with paragraph 1 and shall make public in an appropriate manner, including by means of links to a single internet website, a comprehensive list of this data, together with the information relating to the certificates provided to those operators and groups of operators in accordance with Article 35(1). When doing so, Member States shall comply with the requirements for the protection of personal data under Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽¹⁾.

7. Member States shall ensure that any operator or group of operators that complies with this Regulation and, in cases where a fee is collected in accordance with Articles 78 and 80 of Regulation (EU) 2017/625, that pays a reasonable fee covering the cost of controls is entitled to be covered by the control system. Member States shall ensure that any fees that may be collected are made public.

8. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex II as regards the requirements for keeping records.

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

- (a) the format and technical means of the notification referred to in paragraph 1;
- (b) the arrangements for the publication of the lists referred to in paragraph 6; and
- (c) the procedures and the arrangements for publication of the fees referred to in paragraph 7.

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

Article 35

Certificate

1. Competent authorities, or, where appropriate, control authorities or control bodies, shall provide a certificate to any operator or group of operators that has notified its activity in accordance with Article 34(1) and complies with this Regulation. The certificate shall:

- (a) be issued in electronic form wherever possible;
- (b) allow at least the identification of the operator or group of operators including the list of the members, the category of products covered by the certificate and its period of validity;
- (c) certify that the notified activity complies with this Regulation; and
- (d) be issued in accordance with the model set out in Annex VI.

2. Without prejudice to paragraph 8 of this Article and to Article 34(2), operators and groups of operators shall not place products referred to in Article 2(1) on the market as organic products or in-conversion products unless they are already in possession of a certificate as referred to in paragraph 1 of this Article.

⁽¹⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).