

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

CHAPTER I

**SUBJECT MATTER, SCOPE AND DEFINITIONS**

*Article 1*

**Subject matter**

This Regulation establishes the principles of organic production and lays down the rules concerning organic production, related certification and the use of indications referring to organic production in labelling and advertising, as well as rules on controls additional to those laid down in Regulation (EU) 2017/625.

*Article 2*

**Scope**

1 This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:

- a live or unprocessed agricultural products, including seeds and other plant reproductive material;
- b processed agricultural products for use as food;
- c feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

2 This Regulation applies to any operator involved, at any stage of production, preparation and distribution, in activities relating to the products referred to in paragraph 1.

3 Mass catering operations carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 are not subject to this Regulation except as set out in this paragraph.

Member States may apply national rules or, in the absence thereof, private standards, on the production, labelling and control of products originating from mass catering operations. The organic production logo of the European Union shall not be used in the labelling, the presentation or the advertising of such products, and shall not be used to advertise the mass caterer.

4 Except where otherwise provided, this Regulation applies without prejudice to related Union legislation, in particular, legislation in the fields of safety of the food chain, animal health and welfare, plant health and plant reproductive material.

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5 This Regulation applies without prejudice to other specific Union law relating to the placing of products on the market and, in particular, to Regulation (EU) No 1308/2013 of the European Parliament and of the Council<sup>(1)</sup> and to Regulation (EU) No 1169/2011.

6 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending the list of products set out in Annex I by adding further products to the list, or by amending those added entries. Only products which are closely linked to agricultural products shall be eligible for inclusion in that list.

### Article 3

#### Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) ‘organic production’ means the use, including during the conversion period referred to in Article 10, of production methods that comply with this Regulation at all stages of production, preparation and distribution;
- (2) ‘organic product’ means a product resulting from organic production, other than a product produced during the conversion period referred to in Article 10. The products of hunting or fishing of wild animals are not considered as organic products;
- (3) ‘agricultural raw material’ means an agricultural product that has not been subjected to any operation of preservation or processing;
- (4) ‘preventive measures’ means measures that are to be taken by operators at every stage of production, preparation and distribution in order to ensure the preservation of biodiversity and soil quality, measures for the prevention and control of pests and diseases and measures that are to be taken to avoid negative effects on the environment, animal health and plant health;
- (5) ‘precautionary measures’ means measures that are to be taken by operators at every stage of production, preparation, and distribution to avoid contamination with products or substances that are not authorised for use in organic production in accordance with this Regulation, and to avoid the commingling of organic products with non-organic products;
- (6) ‘conversion’ means the transition from non-organic to organic production within a given period, during which the provisions of this Regulation concerning organic production apply;
- (7) ‘in-conversion product’ means a product that is produced during the conversion period referred to in Article 10;
- (8) ‘holding’ means all the production units operated under single management for the purpose of producing live or unprocessed agricultural products, including products originating from aquaculture and beekeeping, referred to in point (a) of Article 2(1) or products listed in Annex I other than essential oils and yeast;
- (9) ‘production unit’ means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs managed as described in point (10), point (11) or point (12);

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- (10) ‘organic production unit’ means a production unit, excluding during the conversion period referred to in Article 10, which is managed in compliance with the requirements applicable to organic production;
- (11) ‘in-conversion production unit’ means a production unit, during the conversion period referred to in Article 10, which is managed in compliance with the requirements applicable to organic production; it may be constituted of land parcels or other assets for which the conversion period referred to in Article 10 starts at different moments in time;
- (12) ‘non-organic production unit’ means a production unit which is not managed in compliance with the requirements applicable to organic production;
- (13) ‘operator’ means the natural or legal person responsible for ensuring that this Regulation is complied with at every stage of production, preparation and distribution that are under that person’s control;
- (14) ‘farmer’ means a natural or legal person, or a group of natural or legal persons, regardless of the legal status of that group and its members under national law, who exercises an agricultural activity;
- (15) ‘agricultural area’ means agricultural area as defined in point (e) of Article 4(1) of Regulation (EU) No 1307/2013;
- (16) ‘plants’ means plants as defined in point (5) of Article 3 of Regulation (EC) No 1107/2009;
- (17) ‘plant reproductive material’ means plants and all parts of plants, including seeds, at any stage of growth that are capable of, and intended for, producing entire plants;
- (18) ‘organic heterogeneous material’ means a plant grouping within a single botanical taxon of the lowest known rank which:
- (a) presents common phenotypic characteristics;
  - (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;
  - (c) is not a variety within the meaning of Article 5(2) of Council Regulation (EC) No 2100/94<sup>(2)</sup>;
  - (d) is not a mixture of varieties; and
  - (e) has been produced in accordance with this Regulation;
- (19) ‘organic variety suitable for organic production’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94 which:
- (a) is characterised by a high level of genetic and phenotypical diversity between individual reproductive units; and
  - (b) results from organic breeding activities referred to in point 1.8.4 of Part I of Annex II to this Regulation;
- (20) ‘mother plant’ means an identified plant from which plant reproductive material is taken for the reproduction of new plants;

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- (21) ‘generation’ means a group of plants constituting a single step in the line of descent of plants;
- (22) ‘plant production’ means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
- (23) ‘plant products’ means plant products as defined in point (6) of Article 3 of Regulation (EC) No 1107/2009;
- (24) ‘pest’ means a pest as defined in Article 1(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council<sup>(3)</sup>;
- (25) ‘biodynamic preparations’ means mixtures traditionally used in biodynamic farming;
- (26) ‘plant protection products’ means the products referred to in Article 2 of Regulation (EC) No 1107/2009;
- (27) ‘livestock production’ means the production of domestic or domesticated terrestrial animals, including insects;
- (28) ‘veranda’ means an additional, roofed, uninsulated, outdoor part of a building intended for poultry, the longest side usually being equipped with wire fencing or netting, with an outdoor climate, natural and, where necessary, artificial illumination, and a littered floor;
- (29) ‘pullets’ means young animals of the *Gallus gallus* species that are of an age of less than 18 weeks;
- (30) ‘laying hens’ means animals of the *Gallus gallus* species that are intended for the production of eggs for consumption and that are of an age of at least 18 weeks;
- (31) ‘usable area’ means usable area as defined in point (d) of Article 2(2) of Council Directive 1999/74/EC<sup>(4)</sup>;
- (32) ‘aquaculture’ means aquaculture as defined in point (25) of Article 4(1) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council<sup>(5)</sup>;
- (33) ‘aquaculture products’ means aquaculture products as defined in point (34) of Article 4(1) of Regulation (EU) No 1380/2013;
- (34) ‘closed recirculation aquaculture facility’ means a facility on land or in a vessel where aquaculture takes place within an enclosed environment involving the recirculation of water and which depends on permanent external energy input to stabilise the environment for the aquaculture animals;
- (35) ‘energy from renewable sources’ means energy from renewable non-fossil sources such as wind, solar, geothermal, wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;
- (36) ‘hatchery’ means a place for the breeding, hatching and rearing through the early life stages of aquaculture animals, in particular finfish and shellfish;
- (37) ‘nursery’ means a place where an intermediate aquaculture production system is applied between the hatchery and grow-out stages. The nursery stage is completed within the first third of the production cycle, with the exception of species undergoing a smoltification process;

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- (38) ‘water pollution’ means pollution as defined in point (33) of Article 2 of Directive 2000/60/EC and in point (8) of Article 3 of Directive 2008/56/EC of the European Parliament and of the Council<sup>(6)</sup>, in the waters to which each of those Directives applies;
- (39) ‘polyculture’ means the rearing in aquaculture of two or more species, usually from different trophic levels, in the same culture unit;
- (40) ‘production cycle’ means the lifespan of an aquaculture animal or alga, from the earliest life stage (fertilised eggs, in the case of aquaculture animals) to harvesting;
- (41) ‘locally grown species’ means aquaculture species which are neither alien nor locally absent species within the meaning of points (6) and (7), respectively, of Article 3 of Council Regulation (EC) No 708/2007<sup>(7)</sup>, as well as the species listed in Annex IV to that Regulation;
- (42) ‘veterinary treatment’ means all courses of a curative or preventive treatment against an occurrence of a specific disease;
- (43) ‘veterinary medicinal product’ means a veterinary medicinal product as defined in point (2) of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council<sup>(8)</sup>;
- (44) ‘preparation’ means the operations of preserving or processing of organic or in-conversion products, or any other operation that is carried out on an unprocessed product without altering the initial product, such as slaughtering, cutting, cleaning or milling, as well as packaging, labelling or alterations made to the labelling relating to organic production;
- (45) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>(9)</sup>;
- (46) ‘feed’ means feed as defined in point (4) of Article 3 of Regulation (EC) No 178/2002;
- (47) ‘feed materials’ mean feed materials as defined in point (g) of Article 3(2) of Regulation (EC) No 767/2009 of the European Parliament and of the Council<sup>(10)</sup>;
- (48) ‘placing on the market’ means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
- (49) ‘traceability’ means the ability to trace and follow food, feed or any product referred to in Article 2(1), and any substance intended or expected to be incorporated into food, feed or any product referred to in Article 2(1), through all stages of production, preparation and distribution;
- (50) ‘stage of production, preparation and distribution’ means any stage from the primary production of an organic product through its storage, processing, transport, and sale or supply to the final consumer, including, where relevant, labelling, advertising, import, export and subcontracting activities;
- (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;

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- (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<sup>(11)</sup> 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<sup>(12)</sup>;
- (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<sup>(13)</sup>;
- (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<sup>(14)</sup>;
- (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<sup>(15)</sup>;
- (67) ‘ionising radiation’ means ionising radiation as defined in point (46) of Article 4 of Council Directive 2013/59/Euratom<sup>(16)</sup>;

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- (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<sup>(17)</sup>, 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;

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- (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;
- (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) [<sup>X1</sup>ensuring the integrity of organic production at all stages of the production, preparation 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:



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- (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.

#### **Editorial Information**

- XI** Substituted by [Corrigendum to Regulation \(EU\) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation \(EC\) No 834/2007 \(Official Journal of the European Union L 150 of 14 June 2018\)](#).

### *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;

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- (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;

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- (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.

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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).

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## 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<sup>(18)</sup> or Regulation (EC) No 1830/2003 of the European Parliament and of the Council<sup>(19)</sup> or any accompanying document provided pursuant thereto.

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

4 For the purposes of the prohibition laid down in paragraph 1, with regard to products not covered by paragraphs 2 and 3, operators using non-organic products purchased from third parties shall require the vendor to confirm that those products are not produced from GMOs or produced by GMOs.

## Article 12

### Plant production rules

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

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

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

### Article 13

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

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

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

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

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

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

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

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

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

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

- a the description of the organic heterogeneous material, including the relevant breeding and production methods and parental material used;

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- 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;



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- 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;

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- 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<sup>(20)</sup>, nor organic.

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

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

#### *Article 17*

### **Production rules for processed feed**

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

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

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

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

#### *Article 18*

### **Production rules for wine**

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

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

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

#### *Article 19*

### **Production rules for yeast used as food or feed**

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

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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.

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## 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;

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- 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;

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- (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:

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- 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<sup>(21)</sup> 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;



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

### *Article 28*

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

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

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

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

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

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

- a the procedural steps to be followed by operators in accordance with points (a) to (e) of paragraph 2 and the relevant documents to be provided by them;

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- 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

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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

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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;

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- (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.

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## 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;

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- 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

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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<sup>(22)</sup>.

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



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- 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.

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

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

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

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

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

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

8 Member States may exempt from the obligation to be in the possession of a certificate, provided for in paragraph 2, operators that sell unpacked organic products other than feed

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directly to the final consumer, provided that those operators do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to a third party, and provided that:

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

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

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

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

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

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

### *Article 36*

#### **Group of operators**

- 1 Each group of operators shall:
- a only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed;
  - b only be composed of members:
    - (i) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000 or whose standard output of organic production is not more than EUR 15 000 per year; or
    - (ii) who have each holdings of maximum:
      - five hectares,
      - 0,5 hectares, in the case of greenhouses, or
      - 15 hectares, exclusively in the case of permanent grassland;
  - c be established in a Member State or a third country;
  - d have legal personality;
  - e only be composed of members whose production activities take place in geographical proximity to each other;
  - f set up a joint marketing system for the products produced by the group; and

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- g establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group.

2 Competent authorities, or, where appropriate, control authorities or control bodies, shall withdraw the certificate referred to in Article 35 for the whole group where deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators, affect the integrity of organic and in-conversion products.

3 The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 1 and 2 of this Article by adding provisions, or by amending those added provisions, in particular as regards:

- a the responsibilities of the individual members of a group of operators;
- b the criteria to determine the geographical proximity of the members of the group, such as the sharing of facilities or sites;
- c the set-up and functioning of the system for internal controls, including the scope, content and frequency of the controls to be carried out and the criteria to identify deficiencies in the set-up or functioning of the system for internal controls.

4 The Commission may adopt implementing acts laying down specific rules concerning:

- a the composition and dimension of a group of operators;
- b the documents and record-keeping systems, the system for internal traceability and the list of operators;
- c the exchange of information between a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission.

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

## CHAPTER VI

### OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES

#### *Article 37*

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

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

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### Article 38

#### **Additional rules on official controls and on action to be taken by the competent authorities**

1 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall include, in particular:

- a the verification of the application by operators of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of this Regulation, at every stage of production, preparation and distribution;
- b where the holding includes non-organic or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units as well as between the respective products produced by those units, and of the substances and products used for organic, in-conversion and non-organic production units; such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period, and checks on the non-organic production units;
- c where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and, where appropriate, measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times and that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other;
- d the verification of the set-up and functioning of the internal control system of groups of operators;
- e where operators are exempted from the notification obligation in accordance with Article 34(2) of this Regulation or from the obligation to be in the possession of a certificate in accordance with Article 35(8) of this Regulation, the verification that the requirements for that exemption have been fulfilled and the verification of the products sold by those operators.

2 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall be performed throughout the entire process at all stages of production, preparation and distribution on the basis of the likelihood of non-compliance as defined in point (57) of Article 3 of this Regulation, which shall be determined taking into account, in addition to the elements referred to in Article 9 of Regulation (EU) 2017/625, in particular the following elements:

- a the type, size and structure of the operators and groups of operators;
- b the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution;
- c the results of the controls performed in accordance with this Article;
- d the point in time relevant for the activities carried out;
- e the product categories;
- f the type, quantity and value of products and their development over time;
- g the possibility of commingling of products or contamination with non-authorised products or substances;

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- h the application of derogations or exceptions to the rules by operators and groups of operators;
- i the critical points for non-compliance and the likelihood of non-compliance at every stage of production, preparation and distribution;
- j subcontracting activities.

3 In any case, all operators and groups of operators, with the exception of those referred to in Articles 34(2) and 35(8), shall be subject to a verification of compliance at least once a year.

The verification of compliance shall include a physical on-the-spot inspection, except where the following conditions have been satisfied:

- a the previous controls of the operator or group of operators concerned have not revealed any non-compliance affecting the integrity of organic or in-conversion products during at least three consecutive years; and
- b the operator or group of operators concerned has been assessed on the basis of the elements referred to in paragraph 2 of this Article and in Article 9 of Regulation (EU) 2017/625 as presenting a low likelihood of non-compliance.

In this case, the period between two physical on-the-spot inspections shall not exceed 24 months.

4 Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall:

- a be performed in accordance with Article 9(4) of Regulation (EU) 2017/625 while ensuring that a minimum percentage of all official controls of operators or groups of operators are carried out without prior notice;
- b ensure that a minimum percentage of additional controls to those referred in paragraph 3 of this Article are carried out;
- c be carried out by taking a minimum number of the samples that have been taken in accordance with point (h) of Article 14 of Regulation (EU) 2017/625;
- d ensure that a minimum number of operators that are members of a group of operators are controlled in connection with the verification of compliance referred to in paragraph 3 of this Article.

5 The delivery or renewal of the certificate referred to in Article 35(1) shall be based on the results of the verification of compliance referred to in paragraphs 1 to 4 of this Article.

6 The written record to be drawn up regarding each official control that has been performed to verify compliance with this Regulation in accordance with Article 13(1) of Regulation (EU) 2017/625 shall be countersigned by the operator or groups of operators as confirmation of their receipt of that written record.

7 Article 13(1) of Regulation (EU) 2017/625 shall not apply to audits and inspections carried out by competent authorities in the context of their supervisory activities over control bodies to which certain official control tasks or certain tasks related to other official activities have been delegated.

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

- a supplementing this Regulation by laying down specific criteria and conditions for the performance of official controls conducted to ensure the traceability at all stages of production, preparation and distribution, and compliance with this Regulation, concerning:
  - (i) checks of documentary accounts;

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- (ii) controls performed on specific categories of operators;
  - (iii) where appropriate, the period within which the controls provided for in this Regulation, including the physical on-the-spot inspections referred to in paragraph 3 of this Article, are to be performed and the particular premises in or area on which they are to be performed;
  - b amending paragraph 2 of this Article by adding further elements based on practical experience, or by amending those added elements.
- 9 The Commission may adopt implementing acts to specify:
- a the minimum percentage of all official controls of operators or groups of operators that are to be carried out without prior notice as referred to in point (a) of paragraph 4;
  - b the minimum percentage of additional controls referred to in point (b) of paragraph 4;
  - c the minimum number of samples referred to in point (c) of paragraph 4;
  - d the minimum number of operators that are members of a group of operators referred to in point (d) of paragraph 4.

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

#### *Article 39*

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

- 1 In addition to the obligations laid down in Article 15 of Regulation (EU) 2017/625, operators and groups of operators shall:
- a keep records to demonstrate their compliance with this Regulation;
  - b make all declarations and other communications that are necessary for official controls;
  - c take relevant practical measures to ensure compliance with this Regulation;
  - d provide, in form of a declaration to be signed and updated as necessary:
    - (i) the full description of the organic or in-conversion production unit and of the activities to be performed in accordance with this Regulation;
    - (ii) the relevant practical measures to be taken to ensure compliance with this Regulation;
    - (iii) an undertaking:
      - to inform in writing and without undue delay buyers of the products and to exchange relevant information with the competent authority, or, where appropriate, with the control authority or control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established,
      - to accept the transfer of the control file in the case of change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for at least five years by the last control authority or control body,
      - to immediately inform the competent authority or the authority or body designated in accordance with Article 34(4) in the event of withdrawal from organic production, and

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- to accept the exchange of information among those authorities or bodies in the event that subcontractors are subject to controls by different control authorities or control bodies.

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

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

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

#### *Article 40*

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

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

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

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

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

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

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

3 For the purpose of point (b)(iv) of Article 29 of Regulation (EU) 2017/625, the standard for the delegation of certain official control tasks and certain tasks related to other official activities to verify compliance with this Regulation which is relevant in relation to the scope of this Regulation is the most recently notified version of the international harmonised standard for ‘Conformity assessment – Requirements for bodies certifying products, processes and services’, the reference of which has been published in the *Official Journal of the European Union*.

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

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

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

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

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

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

- a for a period that shall not exceed 12 months, during which the control body is to remedy the shortcomings identified during audits and inspections or to address the non-compliance about which information was shared with other control authorities and control bodies, with competent authorities as well as with the Commission in accordance with Article 43 of this Regulation; or



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- b for the period during which the accreditation referred to in point (b)(iv) of Article 29 of Regulation (EU) 2017/625, in connection with Article 40(3) of this Regulation, is suspended.

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

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

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

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

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

#### *Article 41*

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

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

- a it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 with a view to verifying compliance with this Regulation; such

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investigation shall be completed as soon as possible, within a reasonable period, and shall take into account the durability of the product and the complexity of the case;

- b) it shall provisionally prohibit both the placing on the market of the products concerned as organic or in-conversion products and their use in organic production pending the results of the investigation referred to in point (a). Before taking such a decision, the competent authority, or, where appropriate, the control authority or control body, shall give the operator an opportunity to comment.

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

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

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

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

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

#### *Article 42*

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

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

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

#### *Article 43*

### **Additional rules on the exchange of information**

1 In addition to the obligations laid down in Article 105(1) and Article 106(1) of Regulation (EU) 2017/625, competent authorities shall immediately share information with

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other competent authorities, as well as with the Commission, on any suspicion of non-compliance that affects the integrity of organic or in-conversion products.

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

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

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

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

5 Competent authorities shall exchange information on the supervision of the control bodies with national accreditation bodies as defined in point (11) of Article 2 of Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>(23)</sup>.

6 Competent authorities shall take appropriate measures and establish documented procedures in order to ensure that information about the results of controls is communicated to the paying agency in accordance with its needs for the purpose of Article 58 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council<sup>(24)</sup> and the acts adopted on the basis of that Article.

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

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

## CHAPTER VII

### TRADE WITH THIRD COUNTRIES

#### *Article 44*

#### **Export of organic products**

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

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards documents intended for customs authorities in third countries, in particular as regards the issuing of organic export certificates in electronic form

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wherever possible and the provision of assurances that exported organic products comply with this Regulation.

#### Article 45

### Import of organic and in-conversion products

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

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

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

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

4 The Commission shall adopt implementing acts to lay down specific rules concerning the content of the certificates referred to in point (b) of paragraph 1, the procedure to be followed for their issuance, their verification and the technical means by which the certificate is issued,

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in particular as regards the role of competent authorities, control authorities and control bodies, ensuring the traceability and compliance of imported products intended to be placed on the Union market as organic products or as in-conversion products as referred to in paragraph 1.

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

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

#### Article 46

### Recognition of control authorities and control bodies

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

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

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

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

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

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

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

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

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

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

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

- 7 The Commission is empowered to adopt delegated acts in accordance with Article 54:
- a amending paragraph 2 of this Article by adding further criteria to those laid down therein for the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article and for the withdrawal of such recognition, or by amending those added criteria;
  - b supplementing this Regulation as regards:
    - (i) the exercise of the supervision of the control authorities and control bodies recognised by the Commission in accordance with paragraph 1, including on-the-spot examinations; and
    - (ii) the controls and other actions to be performed by those control authorities and control bodies.

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

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

9 On duly justified imperative grounds of urgency relating to unfair practices or practices which are incompatible with the principles and rules on organic production, the

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protection of consumers' confidence or the protection of fair competition between operators, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 55(3) to take the measures referred to in paragraph 8 of this Article or to decide on the withdrawal of the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article.

#### *Article 47*

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

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

#### *Article 48*

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

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

That recognition shall expire on 31 December 2025.

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

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

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

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

5 The Commission may adopt implementing acts to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those affecting the integrity of organic or in-conversion products imported from third countries referred to in this Article. Such measures may consist in particular in the verification of the integrity of organic or

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in-conversion products before placing the products on the market within the Union and, where appropriate, in the suspension of the authorisation for the placing on the market of such products within the Union as organic products or in-conversion products.

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

#### *Article 49*

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

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

## CHAPTER VIII

### GENERAL PROVISIONS

#### *SECTION 1*

#### ***Free movement of organic and in-conversion products***

#### *Article 50*

### **Non-prohibition and non-restriction of the marketing of organic and in-conversion products**

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

#### *SECTION 2*

#### ***Information, reporting and related derogations***

#### *Article 51*

### **Information relating to the organic sector and trade**

1 Each year Member States shall transmit to the Commission the information necessary for the implementation and monitoring of the application of this Regulation. As far as possible, such information shall be based on established sources of data. The Commission shall take into



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account the data needs and synergies between potential data sources, in particular their use for statistical purposes where appropriate.

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

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

#### *Article 52*

### **Information relating to the competent authorities, control authorities and control bodies**

- 1 Member States shall keep a regularly updated list of:
  - a the names and addresses of the competent authorities; and
  - b the names, addresses and code numbers of the control authorities and control bodies.

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

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

#### *Article 53*

### **Derogations, authorisations and report**

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

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

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

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

4 From 1 January 2025, the Commission shall be empowered to adopt delegated acts in accordance with Article 54, based on the information as regards availability of organic protein feed for poultry and porcine animals made available by Member States in accordance with

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paragraph 6 of this Article or presented in the report referred to in paragraph 7 of this Article, ending the authorisations to use non-organic protein feed in the nutrition of poultry and porcine animals referred to in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II at an earlier date than 31 December 2025 or extending them beyond that date.

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

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

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

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

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

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

## CHAPTER IX

### PROCEDURAL, TRANSITIONAL AND FINAL PROVISIONS

#### SECTION 1

##### *Procedural provisions*

##### *Article 54*

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

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

2 <sup>[X2]</sup>The power to adopt delegated acts referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2),

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Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) shall be conferred on the Commission for a period of five years from 17 June 2018.] The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

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

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

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

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

#### **Editorial Information**

**X2** Substituted by [Corrigendum to Regulation \(EU\) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation \(EC\) No 834/2007 \(Official Journal of the European Union L 150 of 14 June 2018\)](#).

### *Article 55*

#### **Committee procedure**

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

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

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

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

## SECTION 2

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

#### *Article 56*

#### **Repeal**

Regulation (EC) No 834/2007 is repealed.

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

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

#### *Article 57*

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

1 The recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007 shall expire by 31 December 2023 at the latest.

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

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

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

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#### *Article 58*

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

1 The Commission shall complete the examination of applications from third countries which have been submitted under Article 33(2) of Regulation (EC) No 834/2007 and which are pending on 17 June 2018. That Regulation shall apply to the examination of such applications.

2 The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by laying down the procedural rules necessary for the examination of the applications referred to in paragraph 1 of this Article, including on the information to be submitted by third countries.

#### *Article 59*

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

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

#### *Article 60*

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

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

#### *Article 61*

### **Entry into force and application**

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2021.

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

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- (1) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([OJ L 347, 20.12.2013, p. 671](#)).
- (2) Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ([OJ L 227, 1.9.1994, p. 1](#)).
- (3) Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ([OJ L 317, 23.11.2016, p. 4](#)).
- (4) Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens ([OJ L 203, 3.8.1999, p. 53](#)).
- (5) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC ([OJ L 354, 28.12.2013, p. 22](#)).
- (6) Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) ([OJ L 164, 25.6.2008, p. 19](#)).
- (7) Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture ([OJ L 168, 28.6.2007, p. 1](#)).
- (8) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ([OJ L 311, 28.11.2001, p. 1](#)).
- (9) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([OJ L 31, 1.2.2002, p. 1](#)).
- (10) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC ([OJ L 229, 1.9.2009, p. 1](#)).
- (11) 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](#)).
- (12) 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](#)).
- (13) 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](#)).
- (14) 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](#)).
- (15) 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](#)).
- (16) 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](#)).
- (17) 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](#)).

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- (18) 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](#)).
- (19) 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](#)).
- (20) 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](#)).
- (21) 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](#)).
- (22) 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](#)).
- (23) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30](#)).
- (24) Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([OJ L 347, 20.12.2013, p. 549](#)).

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