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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Status: Point in time view as at 31/12/2020.	
Changes to legislation: There are currently no known outstanding effects for the Regulation (EU)	
2018/848 of the European Parliament and of the Council, CHAPTER I. (See end of Document for details)	

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⁽¹⁾ 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);

- (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⁽²⁾;
 - (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;

- (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⁽³⁾;
- (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⁽⁴⁾;
- (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⁽⁵⁾;
- (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;

- (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⁽⁶⁾, 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⁽⁷⁾, 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⁽⁸⁾;
- (44) 'preparation' means the operations of preserving or processing of organic or inconversion 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⁽⁹⁾;
- (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⁽¹⁰⁾;
- (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;

Status: Point in time view as at 31/12/2020.
Changes to legislation: There are currently no known outstanding effects for the Regulation (EU)
2018/848 of the European Parliament and of the Council, CHAPTER I. (See end of Document for details)

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

Status: Point in time view as at 31/12/2020. **Changes to legislation:** There are currently no known outstanding effects for the Regulation (EU) 2018/848 of the European Parliament and of the Council, CHAPTER I. (See end of Document for details)

- (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⁽¹⁷⁾, 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.

Status: Point in time view as at 31/12/2020.

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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 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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Point in time view as at 31/12/2020.

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