

## I

*(Legislative acts)*

## REGULATIONS

**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**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) Organic production is an overall system of farm management and food production that combines best environmental and climate action practices, a high level of biodiversity, the preservation of natural resources and the application of high animal welfare standards and high production standards in line with the demand of a growing number of consumers for products produced using natural substances and processes. Organic production thus plays a dual societal role, where, on the one hand, it provides for a specific market responding to consumer demand for organic products and, on the other hand, it delivers publicly available goods that contribute to the protection of the environment and animal welfare, as well as to rural development.
- (2) The observance of high standards for health, the environment and animal welfare in the production of organic products is intrinsic to the high quality of those products. As underlined in the communication of the Commission of 28 May 2009 on agricultural product quality policy, organic production forms part of the Union's agricultural product quality schemes, together with geographical indications and traditional specialities guaranteed in accordance with Regulation (EU) No 1151/2012 of the European Parliament and of the Council <sup>(4)</sup> and products of the outermost regions of the Union in accordance with Regulation (EU) No 228/2013 of the European Parliament and of the Council <sup>(5)</sup>. In this sense, organic production pursues the same objectives within the common agricultural policy ("CAP"), which are inherent to all the agricultural product quality schemes of the Union.
- (3) In particular, the objectives of the organic production policy are embedded in the objectives of the CAP by ensuring that farmers receive a fair return for complying with the organic production rules. In addition, the growing consumer demand for organic products creates conditions for further development and expansion of the market in those products and thus for an increase in the return of farmers engaged in organic production.

<sup>(1)</sup> OJ C 12, 15.1.2015, p. 75.

<sup>(2)</sup> OJ C 19, 21.1.2015, p. 84.

<sup>(3)</sup> Position of the European Parliament of 19 April 2018 (not yet published in the Official Journal) and decision of the Council of 22 May 2018.

<sup>(4)</sup> Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

<sup>(5)</sup> Regulation (EU) No 228/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 (OJ L 78, 20.3.2013, p. 23).

- (4) Furthermore, organic production is a system that contributes to the integration of environmental protection requirements into the CAP and that promotes sustainable agricultural production. This is why measures that support organic production financially have been introduced under the CAP, notably under Regulation (EU) No 1307/2013 of the European Parliament and of the Council <sup>(1)</sup>, and strengthened, in particular, in the reform of the legal framework for rural development policy established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council <sup>(2)</sup>.
- (5) Organic production also contributes to the achievement of the objectives of the Union's environmental policy, in particular those set out in the communications of the Commission of 22 September 2006 entitled 'Thematic Strategy for Soil Protection', of 3 May 2011 entitled 'Our life insurance, our natural capital: an EU biodiversity strategy to 2020' and of 6 May 2013 entitled 'Green Infrastructure (GI) — Enhancing Europe's Natural Capital', and in environmental legislation such as Directives 2000/60/EC <sup>(3)</sup>, 2001/81/EC <sup>(4)</sup>, 2009/128/EC <sup>(5)</sup> and 2009/147/EC <sup>(6)</sup> of the European Parliament and of the Council and Council Directives 91/676/EEC <sup>(7)</sup> and 92/43/EEC <sup>(8)</sup>.
- (6) In view of the objectives of the Union's organic production policy, the legal framework established for implementing that policy should aim at ensuring fair competition and the proper functioning of the internal market in organic products, at maintaining and justifying consumer confidence in products labelled as organic, and at providing conditions under which the policy can progress in line with production and market developments.
- (7) The policy priorities of the Europe 2020 strategy, set out in the communication of the Commission of 3 March 2010 entitled 'Europe 2020: A strategy for smart, sustainable and inclusive growth', include achieving a competitive economy based on knowledge and innovation, fostering a high-employment economy delivering social and territorial cohesion, and supporting the shift towards a resource-efficient and low-carbon economy. The organic production policy should therefore provide operators with the right tools to better identify and promote their products while protecting them against unfair practices.
- (8) The organic farming sector in the Union has developed rapidly in the past years, in terms not only of the area used for organic farming but also of the number of holdings and the overall number of organic operators registered in the Union.
- (9) Given the dynamic evolution of the organic sector, Council Regulation (EC) No 834/2007 <sup>(9)</sup> identified the need for a future review of the Union rules on organic production, taking into account the experience gained from the application of those rules. The results of that review carried out by the Commission show that the Union legal framework governing organic production should be improved to provide for rules that correspond to the high expectations of consumers and that guarantee sufficient clarity for those to whom they are addressed. Regulation (EC) No 834/2007 should be therefore repealed and replaced by a new Regulation.
- (10) Experience gained so far with the application of Regulation (EC) No 834/2007 shows the need to make clear to which products this Regulation applies. Primarily, it should cover products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the Treaty on the Functioning of the European Union (TFEU). Moreover, it should cover processed agricultural products for use as food or feed because the placing of such products on the market as organic products provides a major outlet for agricultural products and ensures that the organic nature of the agricultural products from which they are processed is visible to the consumer. Likewise, this

<sup>(1)</sup> Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

<sup>(2)</sup> Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

<sup>(3)</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

<sup>(4)</sup> Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants (OJ L 309, 27.11.2001, p. 22).

<sup>(5)</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

<sup>(6)</sup> Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

<sup>(7)</sup> Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1).

<sup>(8)</sup> Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

<sup>(9)</sup> Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

Regulation should cover certain other products which are linked to agricultural products in a similarly close way as processed agricultural products for use as food and feed because those other products either constitute a major outlet for agricultural products or form an integral part of the production process. Finally, sea salt and other salts used for food and feed should be included in the scope of this Regulation because they may be produced by applying natural production techniques, and because their production contributes to the development of rural areas, and thus falls within the objectives of this Regulation. For reasons of clarity, such other products not listed in Annex I to the TFEU should be listed in an Annex to this Regulation.

- (11) In order to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>(1)</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (12) In order to take into account new production methods, new materials or international commitments, the power to adopt certain acts should be delegated to the Commission in respect of enlarging the list of other products closely linked to agriculture falling within the scope of this Regulation.
- (13) Products covered by this Regulation but originating from hunting or fishing of wild animals should not be considered organic since their production process cannot be fully controlled.
- (14) Because of the local nature of mass catering operations, measures taken by Member States and private schemes in this area are considered adequate to ensure the functioning of the single market. Therefore, food prepared by mass caterers on their premises should not be subject to this Regulation and should therefore not be labelled or advertised with the organic production logo of the European Union.
- (15) Research projects have demonstrated that consumer confidence is crucial in the market for organic food. In the long run, rules that are not trustworthy can jeopardise public confidence and lead to market failure. Therefore, the sustainable development of organic production in the Union should be based on sound production rules which are harmonised at Union level and which meet operators' and consumers' expectations regarding the quality of organic products and compliance with the principles and rules laid down in this Regulation.
- (16) This Regulation should apply without prejudice to related legislation, in particular in the fields of safety of the food chain, animal health and welfare, plant health, plant reproductive material, labelling and the environment.
- (17) This Regulation should provide the basis for the sustainable development of organic production and its positive effects on the environment, while ensuring the effective functioning of the internal market in organic products and fair competition, thereby helping farmers to achieve a fair income, ensuring consumer confidence, protecting consumer interest and encouraging short distribution channels and local production. Those objectives should be achieved through compliance with general and specific principles and general and detailed production rules applicable to organic production.
- (18) Having regard to the particularities of the organic production systems, the choice of plant varieties should focus on agronomic performance, genetic diversity, disease resistance, longevity, and adaptation to diverse local soil and climate conditions, and should respect the natural crossing barriers.
- (19) The risk of non-compliance with organic production rules is considered higher in agricultural holdings which include units that are not managed under those rules. Therefore, after an appropriate conversion period, all

<sup>(1)</sup> OJ L 123, 12.5.2016, p. 1.

agricultural holdings in the Union which aim to become organic should be entirely managed in compliance with the requirements applicable to organic production. However, holdings including both units managed under organic production rules and units managed under non-organic production rules should be allowed under certain conditions, including in particular the condition of clear and effective separation between organic, in-conversion and non-organic production units and between the products produced by those units.

- (20) Since the use of external inputs should be restricted in organic production, certain objectives should be identified for which products and substances are often used in the production of agricultural products or processed agricultural products. When normally used for those objectives, the use of products or substances should only be allowed when they have been authorised in accordance with this Regulation. However, such authorisation should only be valid as long as the use of such external inputs in non-organic production is not prohibited by Union law or by national law that is based on Union law. The use of products or substances which plant protection products contain or consist of, other than active substances, should be allowed in organic production as long as their use is authorised in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(1)</sup> and as long as neither the placing of those plant protection products on the market nor use of those plant protection products is prohibited by Member States in accordance with that Regulation.
- (21) When the entire holding or parts of the holding are intended to produce organic products, they should be subject to a conversion period during which they are managed under organic production rules, but cannot produce organic products. Products should only be allowed to be placed on the market as organic products once the conversion period has elapsed. That period should not start before the farmer or operator producing algae or aquaculture animals has notified that conversion to organic production to the competent authorities of the Member State where the holding is situated, and is therefore subject to the control system that is to be set up by Member States in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council <sup>(2)</sup> and this Regulation. Competent authorities should only be able retroactively to recognise periods before the date of notification as conversion periods where the holding or the relevant parts thereof have been subject to agri-environmental measures supported by Union funds or are natural or agricultural areas which for a period of at least three years have not been treated with products or substances not authorised for use in organic production.
- (22) In order to ensure quality, traceability, compliance with this Regulation as regards organic production and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of further rules on the splitting of holdings into organic, in-conversion and non-organic production units.
- (23) The use of ionising radiation, animal cloning and artificially induced polyploid animals or genetically modified organisms ('GMOs'), as well as products produced from or by GMOs, is incompatible with the concept of organic production and consumers' perception of organic products. Such use should therefore be prohibited in organic production.
- (24) In order to support and facilitate compliance with this Regulation, operators should take preventive measures at every stage of production, preparation and distribution, where appropriate, to ensure the preservation of biodiversity and soil quality, to prevent and control pests and diseases and to avoid negative effects on the environment, animal health and plant health. They should also take, where appropriate, proportionate precautionary measures

<sup>(1)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(2)</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

which are under their control to avoid contamination with products or substances that are not authorised for use in organic production in accordance with this Regulation and to avoid commingling organic, in-conversion and non-organic products.

- (25) Products produced during the conversion period should not be placed on the market as organic products. To avoid the risk of confusing and misleading consumers, those products also should not be marketed as in-conversion products, except in the cases of plant reproductive material, food products of plant origin and feed products of plant origin that have only one agricultural crop ingredient, in all cases subject to the condition that a conversion period of at least 12 months before the harvest has been complied with.
- (26) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of conversion rules for further animal species.
- (27) Detailed production rules should be established with regard to plant, livestock and aquaculture production, including rules for the collection of wild plants and algae, and with regard to the production of processed food and feed, as well as of wine and yeast used as food or feed, to ensure harmonisation of and compliance with the objectives and principles of organic production.
- (28) As organic plant production is based on nourishing the plants primarily through the soil ecosystem, plants should be produced on and in living soil in connection with the subsoil and bedrock. Consequently, hydroponic production should not be allowed, nor growing plants in containers, bags or beds where the roots are not in contact with the living soil.
- (29) However, certain cultivation practices which are not soil-related, such as the production of sprouted seeds or chicory heads and the production of ornamentals and herbs in pots that are sold in pots to the consumers, for which the principle of soil-related crop cultivation is not adapted or for which no risk exists that the consumer is misled regarding the production method, should be allowed. In order to facilitate organic production at an earlier growing stage of plants, growing seedlings or transplants in containers for further transplanting should also be permitted.
- (30) The principle of land-related crop cultivation and the nourishing of plants primarily through the soil ecosystem was established by Regulation (EC) No 834/2007. Some operators have, however, developed an economic activity by growing plants in 'demarcated beds' and have been certified as organic under Regulation (EC) No 834/2007 by their national authorities. An agreement has been reached within the ordinary legislative procedure on 28 June 2017 that the organic production should be based on nourishing the plants primarily through the soil ecosystem and be soil-related, and that growing plants in demarcated beds should not be allowed anymore from that date. In order to give the operators who have developed such economic activity until that date the possibility to adapt, they should be allowed to maintain their production surfaces, if they were certified as organic under Regulation (EC) No 834/2007 before that date by their national authorities, for further 10 years after the date of application of this Regulation. On the basis of the information provided by Member States to the Commission, such activity had only been authorised in the Union before 28 June 2017 in Finland, Sweden and Denmark. The use of demarcated beds in organic agriculture should be subject to a report of the Commission which is to be published five years after the date of application of this Regulation.
- (31) Organic plant production should involve the use of production techniques that prevent or minimise any contribution to the contamination of the environment.
- (32) While non-organic agriculture has more external means to adapt to the environment to achieve optimal crop growth, organic plant production systems need plant reproductive material which is able to adapt to disease resistance, diverse local soil and climate conditions and to the specific cultivation practices of organic agriculture contributing to the development of the organic sector. Therefore, it is important to develop organic plant reproductive material suitable for organic agriculture.
- (33) Concerning soil management and fertilisation, cultivation practices allowed in organic plant production should be specified and conditions should be laid down for the use of fertilisers and conditioners.



- (34) The use of plant protection products should be significantly restricted. Preference should be given to measures to prevent damage by pests and weeds through techniques which do not involve the use of plant protection products, such as crop rotation. Presence of pests and weeds should be monitored to decide whether any intervention is economically and ecologically justified. However, the use of certain plant protection products should be allowed if such techniques do not provide adequate protection and only if those plant protection products have been authorised in accordance with Regulation (EC) No 1107/2009, after having been assessed and found to be compatible with the objectives and principles of organic production, including where those products have been authorised subject to restrictive conditions of use, and consequently have been authorised in accordance with this Regulation.
- (35) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of certain derogations, the use of in-conversion or non-organic plant reproductive material, agreements between operators of agricultural holdings, further pest and weed management measures, and further detailed rules and cultivation practices for specific plants and plant production.
- (36) Research in the Union on plant reproductive material that does not fulfil the variety definition as regards uniformity shows that there could be benefits of using such diverse material, in particular with regard to organic production, for example to reduce the spread of diseases, to improve resilience and to increase biodiversity.
- (37) Therefore, plant reproductive material that does not belong to a variety, but rather belongs to a plant grouping within a single botanical taxon with a high level of genetic and phenotypic diversity between individual reproductive units, should be available for use in organic production.

For that reason, operators should be allowed to market plant reproductive material of organic heterogeneous material without having to comply with the requirements for registration and without having to comply with the certification categories of pre-basic, basic and certified material or with the requirements for other categories set out in Council Directives 66/401/EEC <sup>(1)</sup>, 66/402/EEC <sup>(2)</sup>, 68/193/EEC <sup>(3)</sup>, 98/56/EC <sup>(4)</sup>, 2002/53/EC <sup>(5)</sup>, 2002/54/EC <sup>(6)</sup>, 2002/55/EC <sup>(7)</sup>, 2002/56/EC <sup>(8)</sup>, 2002/57/EC <sup>(9)</sup>, 2008/72/EC <sup>(10)</sup> and 2008/90/EC <sup>(11)</sup>, or in acts adopted pursuant to those Directives.

That marketing should take place following a notification to the responsible bodies referred to in those Directives and, after the Commission has adopted harmonised requirements for such material, provided that it complies with those requirements.

- (38) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of setting out certain rules for the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species.
- (39) In order to meet the needs of organic producers, to foster research and to develop organic varieties suitable for organic production, taking into account the specific needs and objectives of organic agriculture such as enhanced genetic diversity, disease resistance or tolerance and adaptation to diverse local soil and climate conditions, a

<sup>(1)</sup> Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ L 125, 11.7.1966, p. 2298).

<sup>(2)</sup> Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ L 125, 11.7.1966, p. 2309).

<sup>(3)</sup> Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

<sup>(4)</sup> Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

<sup>(5)</sup> Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

<sup>(6)</sup> Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

<sup>(7)</sup> Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

<sup>(8)</sup> Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

<sup>(9)</sup> Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

<sup>(10)</sup> Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

<sup>(11)</sup> Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

temporary experiment should be organised in accordance with Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC. That temporary experiment should be for a term of seven years, should involve sufficient quantities of plant reproductive material and should be subject to yearly reporting. It should help to establish the criteria for the description of the characteristics of that material and to determine the production and marketing conditions for that material.

- (40) As livestock production naturally involves the management of agricultural land, where manure is used to nourish crop production, landless livestock production should be prohibited, except in the case of beekeeping. In the choice of breeds, the choice of characteristics that are important for organic agriculture, such as a high degree of genetic diversity, the capacity to adapt to local conditions and disease resistance, should be encouraged.
- (41) Organic animals are not always available in sufficient quantity and quality to meet the needs of farmers who wish to constitute a herd or a flock for the first time or to increase or renew their livestock. Under certain conditions, it should therefore be possible to bring non-organically raised animals to an organic production unit.
- (42) Livestock should be fed on feed materials produced in accordance with the rules of organic production, and preferably coming from the farmer's own holding, taking into account the physiological needs of the livestock. However, farmers should be given the possibility to use also in-conversion feed coming from their own holdings, under certain conditions. In addition, in order to provide for the basic nutritional requirements of livestock, farmers should be allowed to use certain feed material of microbial or of mineral origin or certain feed additives and processing aids under well-defined conditions.
- (43) Animal health management should mainly be based on the prevention of disease. In addition, specific cleaning and disinfection measures should be applied. The preventive use of chemically synthesised allopathic medicinal products, including antibiotics, should not be permitted in organic production. In the event of sickness or injury of an animal requiring immediate treatment, the use of such products should be limited to the minimum necessary to re-establish the well-being of the animal. In such cases, in order to guarantee the integrity of organic production for consumers, the official withdrawal period after use of such medicinal products as specified in the relevant Union legislation should be double the normal withdrawal period and have a minimum duration of 48 hours.
- (44) Organic livestock housing conditions and husbandry practices should satisfy the behavioural needs of the animals and should ensure a high level of animal welfare, certain aspects of which should go beyond the Union animal welfare standards applicable to livestock production in general. In most cases, livestock should have permanent access to open-air areas for exercise. Any suffering, pain or distress should be avoided, or should be kept to a minimum at all stages of the animals' lives. Tethering and mutilation, such as tail-docking for sheep, beak trimming in the first three days of life and disbudding, should only be possible if allowed by competent authorities, and only under certain conditions.
- (45) Since organic production is the most developed for bovine animals, ovine animals, caprine animals, equine animals, cervine animals and porcine animals, as well as for poultry, rabbits and bees, additional detailed production rules should apply to those species. For those species it is necessary for the Commission to lay down certain requirements that are important for the production of those animals, such as requirements for stocking density, minimum surfaces and characteristics, as well as technical requirements for housing. For other species, such requirements should be laid down once additional detailed production rules apply to those species.
- (46) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of the reduction of the derogations concerning the origin of animals, limits on organic nitrogen linked to the total stocking density, the feeding of bee colonies, acceptable treatments for the disinfection of apiaries, methods and treatments to fight against *Varroa destructor*, and detailed livestock production rules for further species.
- (47) This Regulation reflects the objectives of the new Common Fisheries Policy as regards aquaculture, which plays a key role in ensuring sustainable, long-term food security as well as growth and employment, while reducing pressure on wild fish stocks, in the context of growing global aquatic food demand. The communication of the Commission of 29 April 2013 on Strategic Guidelines for the sustainable development of EU aquaculture highlights the main challenges faced by aquaculture in the Union and its potential for growth. That communication identifies organic aquaculture as a particularly promising sector, and highlights the competitive advantages that derive from organic certification.

- (48) Organic aquaculture is a relatively new field of organic production as compared to organic agriculture, where long experience exists at the farm level. Given consumers' growing interest in organic aquaculture products, further growth in the rate of conversions of aquaculture units to organic production is likely. This will lead to increased experience, technical knowledge and development, with improvements in organic aquaculture that should be reflected in the production rules.
- (49) Organic aquaculture should be based on the rearing of young stock originating from organic production units. Organic aquaculture animals for breeding or on-growing purposes are not always available in sufficient quantity and quality to meet the needs of operators that produce aquaculture animals. Under certain conditions, it should be possible to bring wild caught or non-organic aquaculture animals to an organic production unit.
- (50) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of feed for aquaculture animals and the veterinary treatment of those animals, and in respect of detailed conditions for broodstock management, breeding and juvenile production.
- (51) Operators producing organic food or feed should follow appropriate procedures based on the systematic identification of critical processing steps, in order to ensure that processed products comply with the organic production rules. Processed organic products should be produced using processing methods which guarantee that the organic characteristics and qualities of the products are maintained through all stages of organic production.
- (52) Provisions concerning the composition of processed organic food and feed should be laid down. In particular, such food should be produced mainly from organic agricultural ingredients or from other ingredients falling within the scope of this Regulation that are organic, with the limited possibility of using certain non-organic agricultural ingredients specified in this Regulation. In addition, only certain products and substances authorised in accordance with this Regulation should be allowed for use in the production of processed organic food and feed.
- (53) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of precautionary and preventive measures to be taken by operators producing processed food or feed, in respect of the type and composition of products and substances that are allowed for use in processed food, as well as conditions under which they may be used, and in respect of the calculation of the percentage of agricultural ingredients, including the specification of the additives allowed for use in organic production that are considered as agricultural ingredients for the purpose of calculating the percentage that needs to be achieved in order to describe the product as organic in the sales description.
- (54) Organic wine should be subject to the relevant rules on processed organic food. However, since wine is a specific and important category of organic products, additional detailed production rules should be laid down specifically for organic wine. Organic wine should be produced entirely from organic raw material, and only certain products and substances authorised in accordance with this Regulation should be allowed to be added. The use of certain oenological practices, processes and treatments in the production of organic wine should be prohibited. Other practices, processes and treatments should be permitted under well-defined conditions.
- (55) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of specifying additional prohibited oenological practices, processes and treatments and in respect of amending the list of permitted oenological practices, processes and treatments.
- (56) Initially, yeast was not considered an agricultural ingredient under Regulation (EC) No 834/2007 and therefore it did not count for the agricultural composition of organic products. However, Commission Regulation (EC) No 889/2008 <sup>(1)</sup> introduced the obligation to consider yeast and yeast products as agricultural ingredients for

<sup>(1)</sup> Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).



the purposes of organic production from 31 December 2013. Accordingly, from 1 January 2021, only organically produced substrates should be used in the production of organic yeast for use as food and feed. In addition, only certain products and substances should be allowed for use in its production, confection and formulation.

- (57) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of additional detailed yeast production rules.
- (58) While this Regulation should harmonise the organic production rules in the Union for all products falling within its scope, and should lay down detailed production rules for different categories of products, it will only be possible at a later stage to adopt certain production rules, such as additional detailed production rules for further animal species or for products that do not fall within the categories for which detailed production rules have been laid down in this Regulation. In the absence of such production rules at Union level, Member States should still have the possibility to lay down national rules for their own national production, provided that those rules are not contrary to this Regulation. However, Member States should not apply those national rules to products produced or marketed in other Member States where those products comply with this Regulation. In the absence of such national detailed production rules, operators should at least comply with the general production rules and with the principles for organic production, insofar as those rules and principles could apply to the products concerned, when placing such products on the market with terms referring to organic production.
- (59) In order to take account of any future need to have specific production rules for products whose production does not fall within any of the categories of specific production rules laid down in this Regulation, as well as in order to ensure quality, traceability, compliance with this Regulation and, subsequently, adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of laying down detailed production rules, as well as rules on the obligation to convert, for such products.
- (60) Exceptions from organic production rules should be provided for only in the event of catastrophic circumstances. In order to allow organic production to continue or recommence in such cases, the power to adopt certain acts should be delegated to the Commission in respect of laying down the criteria to determine whether a situation qualifies as catastrophic circumstances as well as specific rules, including possible derogation from this Regulation, on how Member States are to deal with such catastrophic circumstances and on the necessary monitoring and reporting requirements in such cases.
- (61) Under certain conditions organic products, in-conversion products and non-organic products can be collected and transported simultaneously. In order to duly separate organic, in-conversion and non-organic products during their handling and to avoid any commingling, specific provisions should be laid down.
- (62) In order to ensure the integrity of organic production and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of rules on packaging and transport of organic products.
- (63) The use in organic production of certain products or substances as active substances to be used in plant protection products falling within the scope of Regulation (EC) No 1107/2009, fertilisers, soil conditioners, nutrients, non-organic components of animal nutrition of various origin, feed additives, processing aids and products for cleaning and disinfection should be limited to the minimum and made subject to the specific conditions laid down in this Regulation. The same approach should be followed regarding the use of products and substances as food additives and processing aids and regarding the use of non-organic agricultural ingredients in the production of processed organic food. Therefore, any possible use of such products and substances in organic production in general, and in the production of processed organic food in particular, should be defined, subject to the principles laid down in this Regulation and to certain criteria.
- (64) In order to ensure quality, traceability, and compliance with this Regulation as regards organic production in general and the production of processed organic food in particular, as well as to ensure adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of additional criteria for the authorisation of products and substances for use in organic production in general, and in the production of processed organic food in particular, as well as criteria for the withdrawal of such authorisations.

- (65) In order to ensure access to agricultural ingredients, where such ingredients are not available in organic form in sufficient quantity for the production of processed organic food, Member States should also have the possibility to allow the use of non-organic agricultural ingredients under certain conditions and for a limited period.
- (66) In order to foster organic production and address the need for reliable data, information and data on the availability on the market for organic and in-conversion plant reproductive material, for organic animals and for organic aquaculture juveniles needs to be collected and disseminated to farmers and operators. For that purpose, Member States should ensure that regularly updated databases and systems with such information are established on their territories, and the Commission should make such information public.
- (67) In order to ensure compliance with the requirements for organic production and to ensure consumer trust in this production method, it is necessary that operators inform competent authorities, or, where appropriate, control authorities or control bodies, of cases of suspicion of non-compliance with this Regulation, which is substantiated or cannot be eliminated, concerning products they produce, prepare, import or receive from other operators. Such suspicion may, *inter alia*, arise due to the presence of a product or substance that is not authorised for use in the production of a product that is intended to be used or marketed as an organic or in-conversion product. Operators should inform competent authorities where they are in position to substantiate a suspicion of non-compliance or where they cannot eliminate such a suspicion. In such cases, the products concerned should not be placed on the market as organic or in-conversion products for as long as the suspicion cannot be eliminated. Operators should cooperate with the competent authorities, and, where appropriate, with the control authorities or control bodies, in identifying and verifying the reasons for such non-compliance.
- (68) In order to avoid the contamination of organic production with products or substances that have not been authorised by the Commission for use in organic production for certain purposes, operators should take proportionate and appropriate measures which are under their control to identify and avoid risks of such contamination. Such measures should be regularly reviewed and adjusted if necessary.
- (69) In order to ensure a harmonised approach across the Union as regards the measures to be taken in the case of suspicion of non-compliance, especially where such suspicion arises due to the presence of non-authorised products and substances in organic or in-conversion products, and to avoid uncertainties for operators, competent authorities, or, where appropriate, control authorities or control bodies, should carry out an official investigation in accordance with Regulation (EU) 2017/625 in order to verify compliance with the requirements for organic production. In the specific case of suspicion of non-compliance due to the presence of non-authorised products or substances, the investigation should determine the source and the cause of the presence of such products or substances, in order to ensure that operators comply with the requirements for organic production and, in particular, have not used products or substances that are not authorised for use in organic production, and to ensure that those operators have taken proportionate and appropriate precautionary measures to avoid the contamination of organic production with such products and substances. Such investigations should be proportionate to the suspected non-compliance, and therefore should be completed as soon as possible within a reasonable period, taking into account the durability of the product and the complexity of the case. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, including the use of any relevant information that would permit the elimination or confirmation of any suspicion of non-compliance without an on-the spot inspection.
- (70) The occurrence of the presence of products or substances that are not authorised for use in organic production in products that are marketed as organic or in-conversion products, as well as the measures taken in that respect, should be subject to further observation by Member States and the Commission. The Commission should therefore present a report to the European Parliament and the Council four years after the date of application of this Regulation, based on the information collected by Member States about the cases where non-authorised products and substances in organic production have been investigated. Such report could be accompanied, if appropriate, by a legislative proposal for further harmonisation.

- (71) In the absence of such further harmonisation, Member States that have developed approaches to avoid products that contain a certain level of products or substances not authorised for use in organic production for certain purposes being marketed as organic or in-conversion products should have the possibility to keep applying those approaches. However, in order to ensure the free movement of organic and in-conversion products in the internal market of the Union, such approaches should not prohibit, restrict or impede the placing of products produced in other Member States in compliance with this Regulation on the market. Such approaches should therefore only be applied to products produced on the territory of the Member State that has chosen to continue to apply that approach. Member States that decide to use this possibility should inform the Commission without delay.
- (72) In addition to the obligations concerning measures to be taken by operators producing, preparing, importing or using organic and in-conversion products and by competent authorities, or, where appropriate, by control authorities or control bodies, laid down in this Regulation in order to avoid the contamination of organic or in-conversion products with products or substances not authorised for use in organic production, Member States should also have the possibility of taking other appropriate measures on their territory to avoid the unintended presence of non-authorised products and substances in organic agriculture. Member States that decide to use this possibility should inform the Commission and other Member States without delay.
- (73) The labelling of agricultural products and foodstuffs should be subject to the general rules laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council <sup>(1)</sup>, and in particular to the provisions aimed at preventing labelling that might confuse or mislead consumers. In addition, specific provisions relating to the labelling of organic and in-conversion products should be laid down in this Regulation. They should protect both the interests of operators in having their products correctly identified on the market and in enjoying conditions of fair competition, and the interests of consumers in being able to make informed choices.
- (74) Accordingly, the terms used to indicate organic products should be protected throughout the Union against their use in the labelling of non-organic products, independently of the language used. That protection should also apply to the usual derivatives or diminutives of those terms, whether they are used alone or combined.
- (75) Processed food should be labelled as organic only where all or almost all of the ingredients of agricultural origin are organic. To encourage the use of organic ingredients, it should also be possible to refer to organic production only in the list of ingredients of processed food where certain conditions are satisfied, in particular that the food in question complies with certain organic production rules. Special labelling provisions should also be laid down to allow operators to identify the organic ingredients that are used in products which consist mainly of an ingredient that stems from hunting or fishing.
- (76) Processed feed should be labelled as organic only where all or almost all the ingredients of agricultural origin are organic.
- (77) In order to create clarity for consumers throughout the Union market, the use of the organic production logo of the European Union should be obligatory for all organic prepacked food produced within the Union. In addition, it should be possible to use that logo on a voluntary basis in the case of non-prepacked organic products that are produced within the Union and in the case of any organic products imported from third countries, as well as for information and educational purposes. The model of the organic production logo of the European Union should be set out.
- (78) However, in order not to mislead consumers as to the organic nature of the entire product, it is appropriate to limit the use of that logo to products which contain only, or almost only, organic ingredients. It should therefore not be allowed to use it in the labelling of in-conversion products or processed products of which less than 95 % by weight of their ingredients of agricultural origin are organic.

<sup>(1)</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (79) To avoid any possible confusion among consumers about the Union or non-Union origin of a product, whenever the organic production logo of the European Union is used, consumers should be informed about the place where the agricultural raw materials of which the product is composed have been farmed. In that context, it should be allowed to refer to aquaculture in the label of products from organic aquaculture instead of referring to agriculture.
- (80) In order to provide clarity for consumers, and to ensure that the appropriate information is communicated to them, the power to adopt certain acts should be delegated to the Commission in respect of laying down additional rules on the labelling of organic products and amending the list of terms referring to organic production set out in this Regulation, the organic production logo of the European Union, and the rules relating thereto.
- (81) Certain products or substances used in plant protection products or as fertilisers should not fall within the scope of this Regulation and should therefore, in principle, not be subject to the rules of this Regulation, including the rules on labelling. However, since those products and substances play an important role in organic agriculture and their use in organic production is subject to authorisation under this Regulation, and since certain uncertainties as regards their labelling appeared in practice, in particular as regards the use of terms referring to organic production, it should be made clear that where such products or substances are authorised for use in organic production in accordance with this Regulation, they may be labelled accordingly.
- (82) Organic production is only credible if accompanied by effective verification and controls at all stages of production, processing and distribution.
- (83) Specific requirements for operators should be laid down to ensure compliance with this Regulation. In particular, provisions should be made for the notification of operator's activities to the competent authorities and for a certification system to identify the operators that comply with the rules governing organic production and the labelling of organic products. Those provisions should in principle also apply to any subcontractors of the operators concerned, unless the subcontracting activity is entirely integrated within the main activity of the subcontracting operator, and is controlled in that context. The transparency of the certification system should be ensured by requiring Member States to make public the lists of operators that have notified their activities, and any fees that may be collected in relation to the controls performed for the verification of compliance with the rules governing organic production.
- (84) Small retail shops not selling organic products other than prepacked organic products present a relatively low risk of non-compliance with organic production rules, and they should not face disproportionate burdens for selling organic products. They should therefore not be subject to the notification and certification obligations, but should remain subject to official controls performed for the verification of compliance with the rules governing organic production and the labelling of organic products. Equally, small retail shops selling unpacked organic products should be subject to official controls, but in order to facilitate the marketing of organic products, Member States should have the possibility of exempting such shops from the obligation to certify their activities.
- (85) Small farmers and operators that produce algae or aquaculture animals in the Union individually face relatively high inspection costs and administrative burdens linked to organic certification. A system of group certification should be allowed in order to reduce the inspection and certification costs and the associated administrative burdens, strengthen local networks, contribute to better market outlets and ensure a level playing field with operators in third countries. For that reason, the concept of 'group of operators' should be introduced and defined, and rules should be established that reflect the needs and resource capacity of small farmers and operators.
- (86) In order to ensure the effectiveness, efficiency and transparency of the organic production and of the labelling of organic products, the power to adopt certain acts should be delegated to the Commission in respect of the requirements for keeping records by operators or groups of operators and the model of the certificate of compliance.
- (87) In order to ensure that the certification of groups of operators is done effectively and efficiently, the power to adopt certain acts should be delegated to the Commission in respect of the responsibilities of the individual members of groups of operators, the criteria to determine the geographical proximity of their members, and the set-up and functioning of their systems for internal controls.

- (88) Organic production is subject to official controls and to other official activities carried out in accordance with Regulation (EU) 2017/625 to verify compliance with the rules on organic production and the labelling of organic products. However, except as otherwise provided for in this Regulation, rules should apply to organic production in addition to those which are laid down in that Regulation as regards official controls and actions by competent authorities, and, where appropriate, by control authorities and control bodies, as regards actions to be taken by operators and groups of operators, as regards the delegation of certain official control tasks or certain tasks related to other official activities and their supervision, and as regards actions in cases of suspected or established non-compliance, including the prohibition against marketing products as organic or in-conversion products where the established non-compliance affects the integrity of those products.
- (89) In order to ensure a uniform approach on their territories, it should be solely up to the competent authorities to provide for a catalogue of measures to be taken in cases of suspected or established non-compliance.
- (90) Provisions on the exchange of certain relevant information among competent authorities, control authorities, control bodies and certain other bodies and on the action of such authorities and bodies, additional to the provisions of Regulation (EU) 2017/625, should be laid down in this Regulation.
- (91) In order to support the performance of official controls and other official activities to verify compliance with this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of 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 and in respect of additional elements to be taken into account in the determination, based on practical experience, of the likelihood of non-compliance.
- (92) In order to support the performance of official controls and other official activities to verify compliance with this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of the conditions for the delegation of official control tasks and tasks related to other official activities to control bodies, in addition to the conditions laid down in this Regulation.
- (93) The experience with the arrangements for the import of organic products into the Union under Regulation (EC) No 834/2007 has shown that there is a need to revise those arrangements in order to respond to consumer expectations that imported organic products meet standards as high as those of the Union, as well as in order to better ensure the access of Union organic products to the international market. In addition, it is necessary to provide clarity regarding the rules applicable to export of organic products, in particular by establishing organic export certificates.
- (94) The provisions governing the import of products that comply with the Union production and labelling rules, in respect of which operators have been subject to the control of control authorities and control bodies recognised by the Commission to carry out in third countries controls and certification in the field of organic production, should be further reinforced. In particular, requirements concerning the accreditation bodies which accredit control bodies for the purposes of import of compliant organic products into the Union should be laid down in order to ensure a level playing field for the supervision of the control bodies by the Commission. Furthermore, it is necessary to provide for the possibility for the Commission to contact directly the accreditation bodies and competent authorities in third countries to render the supervision of control authorities and control bodies respectively more efficient. In the case of products imported from third countries or the outermost regions of the Union with specific climatic and local conditions, it is appropriate to provide for the possibility for the Commission to grant specific authorisations for the use of products and substances in organic production.
- (95) It should remain possible for organic products to have access to the Union market where such products do not comply with the Union rules on organic production but come from third countries whose organic production and control systems have been recognised as equivalent to those of the Union. However, the recognition of equivalence of third countries, as laid down in Regulation (EC) No 834/2007, should only be granted through international agreements between the Union and those third countries, where a reciprocal recognition of equivalence would be also pursued for the Union.
- (96) Third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 should continue to be recognised as such under this Regulation, for a limited period necessary to ensure a smooth transition to the scheme of recognition through an international agreement, provided that they continue to ensure that their organic



production and control rules are equivalent to the relevant Union rules in force and that they fulfil all requirements relating to the supervision of their recognition by the Commission. That supervision should be based in particular on the annual reports those recognised third countries send to the Commission.

- (97) The experience with the scheme of control authorities and control bodies recognised by the Commission to carry out controls and to issue certificates in third countries for the purpose of importing products, which provides equivalent guarantees, shows that the rules applied by those authorities and bodies differ, and it could be difficult to consider such rules as equivalent to the respective Union rules. Furthermore, the multiplication of standards for control authorities and control bodies hampers adequate supervision by the Commission. Therefore, that scheme of recognition of equivalence should be abolished. However, those control authorities and control bodies should be given sufficient time so that they can prepare themselves to obtain recognition for the purposes of import of products that comply with Union rules. Furthermore, the new rules for the recognition of control authorities and control bodies for the purpose of importing compliant products should already apply from the date of entry into force of this Regulation, in order to allow the Commission to prepare for the recognition of such control authorities and control bodies from the date of application of this Regulation.
- (98) The placing of any product on the market as an organic product, where that product has been imported into the Union under any of the import arrangements provided for in this Regulation, should be subject to the availability of the information necessary to ensure the traceability of the product on the food chain.
- (99) In order to ensure fair competition among operators, the power to adopt certain acts should be delegated to the Commission in respect of the documents intended for customs authorities in third countries, in particular organic export certificates.
- (100) In order to ensure the transparency of the recognition and supervision procedure for control authorities and control bodies within the context of import of compliant organic products and the effectiveness, efficiency and transparency of the controls of imported products, the power to adopt certain acts should be delegated to the Commission in respect of further criteria for recognition of control authorities and control bodies in the context of import of organic products that comply with this Regulation, as well as further criteria for the withdrawal of such recognition, in respect of the exercise of the supervision of the control authorities and control bodies recognised by the Commission and in respect of the controls and other actions to be performed by control authorities and control bodies for that purpose.
- (101) Where serious or repetitive infringements as regards the certification or the controls and actions under this Regulation have been detected, and where the control authority or control body concerned fails to take appropriate and timely remedial action in reaction to a request by the Commission, the recognition of that control authority or control body should be withdrawn without delay.
- (102) In order to ensure the management of the list of third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007, the power to adopt certain acts should be delegated to the Commission in respect of the information to be sent by those recognised third countries which is necessary for the supervision of their recognition and the exercise of that supervision by the Commission.
- (103) Provision should be made for ensuring that the movement of organic products that comply with this Regulation and have been subject to a control in one Member State cannot be restricted in another Member State.
- (104) For the purpose of obtaining reliable information for the implementation of this Regulation, Member States should regularly provide the Commission with the necessary information. For reasons of clarity and transparency, Member States should keep updated lists of competent authorities, control authorities and control bodies. The lists of control authorities and control bodies should be made public by the Member States and published by the Commission.
- (105) In view of the phasing out of the derogations concerning the use of non-organic plant reproductive material, non-organically reared poultry, and non-organic livestock for breeding purposes, the Commission should consider the availability of such material in organic form on the market in the Union. To that end, and on the basis of the data on the availability of organic material collected through the database and systems set up by Member States, five years after the date of application of this Regulation, the Commission should present a report to the European Parliament and the Council on the availability and reasons of a possible limited access of organic operators to such material.

- (106) In view of the phasing out of the derogations concerning the use of non-organic protein feed for poultry and porcine animals, and on the basis of the data provided every year by Member States on the availability of such protein feed in organic form on the market in the Union, five years after the date of application of this Regulation, the Commission should present a report to the European Parliament and to the Council on the availability of and reasons for a possible limited access of organic operators to such organic protein feed.
- (107) In order to take into account the evolution of availability on the market of organic plant reproductive material, organic animals and organic protein feed for poultry and porcine animals, the power to adopt certain acts should be delegated to the Commission in respect of ending or extending derogations and authorisations concerning the use of non-organic plant reproduction material, non-organic animals and non-organic protein feed for poultry and porcine animals.
- (108) It is necessary to lay down measures to ensure a smooth transition to the legal framework governing the import of organic and in-conversion products into the Union as modified by this Regulation.
- (109) Furthermore, a time limit for the expiry of the recognition of control authorities and control bodies for the purpose of equivalence granted under Regulation (EC) No 834/2007 should be set, and provisions to address the situation up to the expiry of their recognition should be laid down. Provisions should also be laid down regarding applications from third countries for recognition for the purpose of equivalence which have been submitted under Regulation (EC) No 834/2007 and which are pending on the date of entry into force of this Regulation.
- (110) In order to ensure the management of the list of control authorities and control bodies recognised for the purpose of equivalence under Regulation (EC) No 834/2007, the power to adopt certain acts should be delegated to the Commission in respect of the information that those control authorities and control bodies should send for the purpose of the supervision of their recognition and in respect of the exercise of that supervision by the Commission.
- (111) In order to facilitate the completion of the examination of applications from third countries for recognition for the purpose of equivalence that are pending on the date of entry into force of this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of the procedural rules necessary for the examination of the pending applications from third countries.
- (112) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the documents that are to be supplied for the purpose of recognising a previous period as being part of the conversion period, as regards the minimum period for feeding of suckling animals with maternal milk and certain technical rules for livestock housing and husbandry practices, as regards detailed rules per species or per group of species of aquaculture animal on the stocking density and on the specific characteristics for production systems and containment systems, as regards techniques authorised in the processing of food and feed products, as regards the authorisation of the products and substances that may be used in organic production in general, and in the production of processed organic food in particular, as well as the withdrawal of such authorisations, and as regards the procedures for the authorisation and the lists of such products and substances and, where appropriate, the description, compositional requirement and conditions for the use of such products.
- (113) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the technical details for establishing and maintaining the databases that list the available organic or in-conversion plant reproductive material obtained by the organic production method, as regards the technical details for establishing and maintaining the systems for making available data on organic or in-conversion plant reproductive material or organic animals or organic aquaculture juveniles and the specifications for the collection of data for that purpose, as regards the arrangements for operators' participation in those systems, and as regards details concerning the information to be provided by Member State as regards derogations from the use of organic plant reproductive material, organic animals and organic feed and as regards the availability on the market of certain organic products.
- (114) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the measures to be adopted and reviewed by operators to identify and avoid risk of contamination of organic production and products with non-authorised products and substances, as regards the procedural steps to be taken in the case of a suspicion of non-compliance and the relevant documents, as regards the methodology on detection and evaluation of the presence of non-authorised products and substances, and as regards the details and format of the information to be transmitted by Member States to the Commission and other Member States concerning results of investigations on the presence of non-authorised products or substances.

- (115) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards detailed requirements for the labelling and advertising of certain in-conversion products, as regards the practical arrangements for the use, presentation, composition and size of the indications referring to the code numbers of control authorities and control bodies and the use, presentation, composition and size of the indication of the place where the agricultural raw materials have been farmed, as regards the assignment of code numbers to control authorities and control bodies and as regards the indication of the place where the agricultural raw materials have been farmed.
- (116) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the details and specifications regarding the format and technical means by which operators and groups of operators are to notify their activities to the competent authorities, as regards the arrangements for the publication of the lists of such operators and groups of operators, as regards the procedures and the arrangements for the publication of the fees that may be collected in relation to the controls, as regards details and specifications regarding the form of the certificate for operators and groups of operators and the technical means by which it is issued, as regards the composition and dimensions of groups of operators, as regards the relevant documents and record-keeping systems, as regards the system for internal traceability and the list of operators, and as regards the exchange of information between groups of operators and competent authorities, control authorities or control bodies and the exchange of information between the Member States and the Commission.
- (117) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the minimum percentage of all official controls to be carried out without prior notice and the minimum percentage of additional controls, as well as the minimum number of samples to be taken and of operators to be controlled within a group of operators, as regards the records for demonstrating compliance, as regards the declarations and other communications that are necessary for official controls, as regards the relevant practical measures for ensuring compliance, as regards uniform arrangements for the cases where competent authorities are to take measures in relation to suspected or established non-compliance, as regards the information to be provided in the case of suspected or established non-compliance, as regards the recipients of such information, and as regards the procedures for the provision of such information, including the functionalities of the computer system used.
- (118) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the content of certificates of inspection issued by third countries, as regards the procedure to be followed for the issuance and verification of such certificates, as regards the technical means by which such certificates are issued, as regards the recognition of control authorities and control bodies competent to carry out controls and to issue organic certificate in third countries, as well as the withdrawal of such recognition, as regards the establishment of the list of those control authorities and control bodies, as regards rules to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those cases that affect the integrity of imported organic or in-conversion products, as regards the establishment of a list of third countries recognised under Article 33(2) of Regulation (EC) No 834/2007 and the amendment of that list, and as regards rules to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those cases that affect the integrity of organic or in-conversion products imported from those countries.
- (119) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the system to be used for transmitting the information necessary for the implementation and monitoring of this Regulation, as regards the details of the information to be transmitted and the date by which that information is to be transmitted, and as regards the establishment of the list of control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and the amendment of that list.
- (120) The implementing powers conferred on the Commission should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(1)</sup>.
- (121) The Commission should be empowered to adopt immediately applicable implementing acts, where, in duly justified cases relating to unfair practices or practices which are incompatible with the principles and rules on organic production, the protection of consumers' confidence or the protection of fair competition between operators, imperative grounds of urgency so require, to ensure the application of measures in relation to cases of suspected or established non-compliance under the control of recognised control authorities or control bodies.

<sup>(1)</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (122) Provision should be made to allow the exhaustion after the date of application of this Regulation of stocks of products which have been produced in accordance with Regulation (EC) No 834/2007 before that date.
- (123) Since the objectives of this Regulation, in particular fair competition and the proper functioning of the internal market in organic products, as well as ensuring consumer confidence in those products and in the organic production logo of the European Union, cannot be sufficiently achieved by the Member States themselves but can rather, by reason of the required harmonisation of the rules on organic production, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (124) It is appropriate to provide for a date of application of this Regulation that would give the possibility to operators to adapt to the new requirements,

HAVE ADOPTED THIS REGULATION:

#### 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.

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.

<sup>(1)</sup> 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).

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 <sup>(1)</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 phenotypic 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 <sup>(2)</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>(3)</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>(4)</sup>;
- (33) 'aquaculture products' means aquaculture products as defined in point (34) of Article 4(1) of Regulation (EU) No 1380/2013;

<sup>(1)</sup> Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1).

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

- (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 <sup>(1)</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>(2)</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>(3)</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>(4)</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>(5)</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;

<sup>(1)</sup> 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).

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).