



21.11.2017

PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS

Subject: Proposal for a regulation of the European Parliament and of the Council on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 (COM(2014)0280 – C7-0109/2014 – 2014/0100(COD))

The interinstitutional negotiations on the aforementioned proposal for a regulation have led to a compromise. In accordance with Rule 69f(4) of the Rules of Procedure, the provisional agreement, reproduced below, is submitted as a whole to the Committee on Agriculture and Rural Development for decision by way of a single vote.

PE-CONS No/YY - 2014/0100(COD)

REGULATION (EU) .../...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C 12, 15.1.2015, p. 75.

² OJ C 19, 21.1.2015, p. 84.

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, the application of high animal welfare standards and 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 it, on the one hand, provides for a specific market responding to consumer demand for organic products and, on the other hand, delivers publicly available goods contributing to the protection of the environment and animal welfare, as well as to rural development.

- (2) The observance of high health, environmental and animal welfare standards in the production of organic products is intrinsic to the high quality of those products. As underlined in the Communication from the Commission to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions on agricultural product quality policy¹, organic production forms part of the Union's agricultural product quality schemes together with geographical indications, traditional specialties guaranteed and products of the outermost regions of the Union, as laid down in Regulation (EU) No 1151/2012 of the European Parliament and of the Council² and Regulation (EU) No 228/2013 of the European Parliament and of the Council³, respectively. 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.

¹ COM (2009) 234 final.

² 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).

³ 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).

- (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.
- (4) Furthermore, organic production is a system that contributes to the integration of environmental protection requirements into the CAP ¹ and promotes sustainable agricultural production. That is why ² measures financially supporting organic production have been introduced under the CAP, *notably* under Regulation (EU) No 1307/2013 of the European Parliament and of the Council¹, and in particular strengthened in the ² reform of the legal framework for rural development policy as established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council².

¹ 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).

² 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).

- (5) Organic production also contributes to the achievements of the Union environmental policy objectives, in particular those of the 2020 Biodiversity Strategy¹, the Green Infrastructure Communication², the Soil Thematic Strategy³ and environmental legislation such as the Birds⁴ and *Habitats*⁵ Directives, the Nitrates Directive⁶, the Water Framework Directive⁷, the National Emissions Ceiling Directive⁸ and the Directive on the sustainable use of pesticides⁹.
- (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 a proper functioning of the internal market in organic products, and at maintaining and justifying consumer confidence in products labelled as organic. It should further aim at providing conditions under which the policy can progress in line with production and market developments.

¹ COM(2011) 244 final, 'Our life insurance, our natural capital: an EU biodiversity strategy to 2020'.

² SWD(2013) 155 final, 'Green Infrastructure (GI) – Enhancing Europe's Natural Capital'.

³ COM(2006) 231 final, 'Thematic Strategy for Soil Protection'.

⁴ 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).

⁵ 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).

⁶ 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).

⁷ 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).

⁸ 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).

⁹ Directive 2009/18/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).

- (7) The policy priorities of the Europe 2020 strategy as set out in the Commission Communication entitled ‘Europe 2020: A strategy for smart, sustainable and inclusive growth’¹ include the aims of 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 834/2007² 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. Therefore, Regulation (EC) No 834/2007 should be repealed and replaced by a new Regulation.

¹ COM(2010)2020 final.

² 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).

(10) Experience gained so far with the application of Regulation (EC) No 834/2007 shows a need to clarify the products to which 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 ('the Treaty'). Moreover, it should cover processed agricultural products for use as food or feed because the placing on the market of such products as organic provides a major outlet for agricultural products and ensures visibility to the consumer of the organic nature of the agricultural products from which they are processed. Likewise, this 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 *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 Treaty, 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 of the Treaty 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.¹ 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 or material 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 the scope of this Regulation but originating from hunting and fishing of wild animals should not be considered organic since the production process cannot be fully controlled.***

¹ ***OJ L 123, 12.5.2016, p. 1.***

- (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. In addition, those production rules should meet operators' and consumers' expectations regarding the quality of organic products and the 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 field 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 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 the respect of 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, adaptation to diverse local soil and climate conditions and should respect the natural crossing barriers.

*(19) The risk of non-compliance with the organic production rules is considered higher in agricultural holdings which include units not managed under organic production rules. Therefore, after an appropriate conversion period, all 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 involving units which are managed under both organic production rules and non-organic production rules should be allowed under certain conditions, including in particular clear and effective separation between organic, in-conversion and non-organic production units and of the products produced by these units.** █*

(20) *Since the use of external inputs should be restricted in organic production, this Regulation should identify certain objectives for which products and substances are often used in the production of agricultural products or processed agricultural products. When normally used for these objectives, the use of products and substances should only be allowed when they have been authorised in accordance with this Regulation. The authorisation under this Regulation should, however, only be valid as long as the use is not prohibited in non-organic production by Union law or national law based on Union law. The use of products and substances which plant protection products contain or consist of, other than active substances, should be allowed in organic farming as long as their use is authorised and the placing on the market or use of the plant protection product is not prohibited by Member States in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹.*

¹ ***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).***

- (21) *When the entire holding or parts of the holding are intended to produce organic products, they should undergo a conversion period during which they are managed under organic production rules, but cannot produce organic products. Products should only be allowed to be sold as organic once the conversion period has elapsed. That period should not start before the farmer or operator producing algae or aquaculture animals has notified the conversion to organic production to the competent authorities of the Member State where the holding is situated and therefore submitted to the control system to be set up by Member States in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council¹ and this Regulation. Competent authorities should only be able to recognise retroactively periods before the date of notification as conversion periods when the holding or the relevant parts of it have been subject to agri-environmental measures supported by Union funds or have been natural or agricultural areas which have not been treated with products and substances not authorised for organic production for a period of at least three years.*
- (22) In order to ensure quality, traceability and 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* **■**.

¹ *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).*

- (23) *The use of ionising radiation, animal cloning and artificially induced polyploid animals or genetically modified organisms (GMOs) and products produced from or by GMOs are incompatible with the concept of organic production and consumers' perception of organic products. They should therefore be prohibited in organic production.*
- (24) *In order to support and facilitate compliance with this Regulation, operators should take, at all stages of production, preparation and distribution, preventive measures, as appropriate, to ensure the preservation of biodiversity, soil quality as well as prevention and control of pests and diseases and to avoid negative effects on the environment and on animal and plant health. They should also take, as appropriate, proportionate precautionary measures which are under their control to avoid contamination with products or substances that are not authorised to be used in organic production in accordance with this Regulation and to avoid commingling of organic, in-conversion and non-organic products.*
- (25) *Products produced during the conversion period should not be placed on the market as organic. To avoid the risk of confusing and misleading consumers, products also should not be marketed as in-conversion products, except in the case of plant reproductive material and of food or feed products of plant origin with only one agricultural crop ingredient, in all cases under the condition that a conversion period of at least 12 months before the harvest has been respected.*

- (26) In order to ensure quality, traceability and 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 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 and respect of 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 soil*.
- (29) *However, certain cultivation practices which are not soil related, such as the production of sprouted seeds or chicory heads, 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 had been 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 as of that date. In order to give those operators, which have developed such economic activity until that date, the possibility to adapt, they should be allowed to maintain their production surfaces certified as organic under Regulation (EC) No 834/2007 before that date by their national authorities for a period of 10 years starting from 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 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 conventional 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 both 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, conditions should be laid down for the use of cultivation practices allowed in organic plant production and for the use of fertilisers and conditioners.
- (34) The use of *plant protection products*, should be significantly restricted. Preference should be given to the application of measures that prevent any 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. 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 to be compatible with objectives and principles of organic production, including with restrictive conditions of use, and consequently authorised in accordance with this Regulation.

- (35) In order to ensure quality, traceability and 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 with other 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 this diverse material, in particular with regards to organic production, for example to reduce the spread of diseases and improve resilience and increasing biodiversity.*

(37) *Therefore, plant reproductive material not belonging to a variety, but belonging 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 to be used for organic production. For this reason, operators should be allowed to market plant reproductive material of organic heterogeneous material without complying with the requirements for registration and the certification categories of pre-basic, basic and certified material, or the requirements for other categories, as set out in Council Directives 66/401/EEC¹, 66/402/EEC², 68/193/EEC³, 98/56/EC⁴, 2002/53/EC⁵, 2002/54/EC⁶, 2002/55/EC⁷, 2002/56/EC⁸, 2002/57/EC⁹, 2008/72/EC¹⁰ and 2008/90/EC¹¹, or acts adopted pursuant to those Directives, following a notification to the responsible bodies referred to in those Directives and, once the Commission has adopted harmonised requirements, provided that such material complies with those requirements.*

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

² Council Directive 66/421/EEC of 14 June 1966 on the marketing of cereal seed (OJ L 125, 11.7.1966, p. 2309).

³ 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).

⁴ 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).

⁵ 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).

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

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

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

⁹ 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).

¹⁰ 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).

¹¹ 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).

- (38) *In order to ensure quality, traceability and 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 soil and climate specific conditions, a 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. This temporary experiment, carried out for a term of seven years, with sufficient quantities of the material concerned and being subject to yearly reporting, should serve to establish the criteria for the description of the characteristics, as well as the definition of the production and marketing conditions for that material.*

(40) As livestock production naturally involves the management of agricultural land, where the manure is used to nourish crop production, ***except in the case of beekeeping***, landless livestock production should be prohibited. ***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 ***the*** resistance to disease ■ 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 be possible to bring non-organically raised animals onto 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 own holding, taking their physiological needs into account. ***However, farmers should be given the possibility to use in-conversion feed coming from their own holdings, under certain conditions.*** In addition, in order to provide for the basic nutritional requirements of livestock, ***it should be allowed to use certain feed material of microbial or of mineral origin or feed additives and processing aids*** ■ under well-defined conditions.

- (43) Animal health management should mainly be based on prevention of disease. In addition, specific cleaning and disinfection measures should be applied. The preventive use of chemically-synthesised allopathic medicinal products 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 the double of 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. Those conditions and practices should ensure a high level of animal welfare, which in certain aspects 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 and distress should be avoided and kept to a minimum at all stages of life of the animals. Tethering and mutilations, 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 under certain conditions.*

- (45) *Since for bovine, ovine, caprine, equine, cervine, porcine animals, as well as for poultry, rabbits and bees, organic production is the most developed, additional detailed production rules should apply. For these species it is necessary that the Commission lays down certain elements that are important for their production, such as stocking density, minimum surfaces and characteristics and technical requirements of housing. For other species such requirements should be laid down, when additional detailed production rules also apply to these species.*
- (46) In order to ensure quality, traceability and 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, the limit of organic nitrogen linked to the total stocking density, the feeding of bee colonies, the acceptable treatments for disinfection of apiaries and for the fight against Varroa destructor, as well as 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 a context of growing global aquatic food demand. The 2013 Communication from the Commission to **█** the European Parliament, *the Council, the European Economic and Social Committee and the Committee of Regions* on Strategic Guidelines for the sustainable development of *EU* aquaculture¹ highlights the main challenges faced by the Union aquaculture and its potential for growth. It identifies organic aquaculture as a particularly promising sector, and highlights the competitive advantages deriving from organic certification.
- (48) Organic aquaculture is a relatively new field of organic production compared to organic agriculture where long experience exists at the farm level. Given consumers' growing interest in organic aquaculture products, further growth in the conversion of aquaculture units to organic production is likely. This is leading to increased experience, technical knowledge and development, with improvements in organic aquaculture that should be reflected in the production rules.

¹ COM(2013) 229 *final* of 29.4.2013.

(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 producing aquaculture animals. Under certain conditions, it should be possible to bring wild caught or non-organic aquaculture animals onto an organic production unit.

■

(50) In order to ensure quality, traceability and 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, their veterinary treatment and detailed conditions for broodstock management, breeding and juvenile production.* ■

(51) Operators producing organic food or feed should follow appropriate procedures based on systematic identification of critical processing steps in order to ensure that processed products comply with the organic production rules. Organic processed products should be produced by means of 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 organic processed food *and feed* should be laid down. In particular, such food should be produced mainly from agricultural ingredients *or other ingredients falling within the scope of this Regulation* that are organic with a limited possibility to use certain non-organic agricultural ingredients specified in this Regulation. In addition, only certain substances authorised in accordance with this Regulation should be allowed for use in the production of organic processed food *and feed*.

█
(53) In order to ensure quality, traceability and 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*, the *type*, composition *and conditions of use of products and substances allowed for use in* processed food █ *and the calculation of the percentage of agricultural ingredients, including the identification of additives allowed for use in organic production that are calculated as agricultural ingredient in the context of the percentage that needs to be achieved in order to label the product in the sales description as organic.* █ .

- (54) Organic wine *should be subject to the relevant rules on organic processed 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 substances authorised in accordance with this Regulation should be allowed to be added. Certain oenological practices, processes and treatments should be prohibited in the production of organic wine. Other practices, processes and treatments should be permitted under well-defined conditions.
- (55) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of *identifying further prohibited* oenological practices, *processes and treatments* and *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 889/2008¹ introduced the obligatory calculation of yeast and yeast products as agricultural ingredients for the purposes of organic production as of 31 December 2013 ■ . Accordingly, *as of 1 January 2021*, only organically produced substrates should be used in the production of organic yeast *to be used as food and feed. In addition*, only certain substances should be allowed for use in its production, confection and formulation. ■

¹ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for 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).

- (57) In order to ensure quality, traceability and 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 lay down detailed production rules for different categories of products, it will only be possible to adopt certain production rules, such as additional detailed production rules for other animal species or products that do not fall within the categories for which detailed production rules are laid down in this Regulation, at a later stage. In the absence of these production rules laid down at Union level, Member States should still have the possibility to lay down national rules for their own national production provided that these rules are not contrary to the rules laid down in this Regulation. They should, however, not apply those national rules to products produced or marketed in other Member States when these products comply with this Regulation. In the absence of such national detailed production rules, for products that do not fall within the categories for which detailed production rules are laid down, operators should at least comply, as far as they can apply to the products concerned, with the general production rules and with the principles for organic production when placing 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 and 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 cases 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 qualify** catastrophic circumstances **as well as** specific rules, **including possible derogation from this Regulation, on how Member States shall deal with such catastrophic circumstances** and **■ on** the necessary monitoring and reporting requirements **in this respect**.

(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 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 *active* substances *to be used* as plant protection products *as regulated by 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 under 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 non-organic agricultural ingredients* in the production of organic processed food. Therefore, provisions should be laid down to define any possible use of such products and substances in organic production in general and in the production of organic processed food in particular, 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, and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission to provide for additional criteria for the authorisation or withdrawal of the authorisation of products and substances for use in organic production in general and in the production of **■** processed *organic* food in particular **■** .
- (65) *In order to ensure access to agricultural ingredients which are not available in sufficient quantity in organic form for the production of organic processed 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 of time.*
- (66) *In order to foster organic production, and to address the need for reliable data, information and data on the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles needs to be collected and disseminated to farmers or operators. For this purpose, Member States should ensure that regularly updated databases and systems with such information are established on their territories and the Commission should make this information public.*

(67) **█** *In order to ensure compliance with the requirements for organic production and consumer trust in this production method, it is necessary that operators inform competent authorities, or where appropriate control authorities and control bodies, of cases of suspicion of non-compliance with the requirements of this Regulation, which is substantiated or cannot be eliminated, concerning products they produce, prepare, import or receive from other operators. Such suspicion may, among others, arise due to the presence of a product or substance that is not authorised in organic production in a product that is intended to be used or marketed as an organic or in-conversion product. Operators should inform competent authorities in the cases where they are in position to substantiate or when they cannot eliminate a suspicion of non-compliance. In such cases, the products concerned should not be put on the market as organic or in-conversion products as long as the suspicion cannot be eliminated. Operators should cooperate with the competent authorities and where appropriate with the control authorities and control bodies in verifying and identifying the reasons for such non-compliances.*

- (68) *In order to avoid the contamination with products or substances that have not been authorised by the Commission for certain purposes for use in organic production, operators should adopt 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 measures to be taken in case of suspicion of non-compliance, especially 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 and substances, the investigation should serve to determine the source and the cause of the presence of such products and substances in order to ensure that operators comply with the requirements for organic production, and notably have not used products or substances not authorised in organic production and have taken proportionate and appropriate precautionary measures to avoid contamination of organic production with such products and substances. Such investigations should be proportionate in relation to the suspected non-compliance and therefore completed as soon as possible and within a reasonable time, 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, in order to eliminate or confirm, efficiently and without any unnecessary delay, any suspicion of non-compliance with the requirements of this Regulation, including the use of any relevant information that would permit to eliminate or confirm any suspicion of non-compliance without an on-the spot inspection.*

- (70) *The occurrence of the presence of products or substances not authorised for organic production in products that are marketed as an organic or in-conversion products and the measures taken in this respect should be subject to further observation by Member States and the Commission. It is therefore appropriate that the Commission presents 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 on the cases where non-authorised products and substances have been investigated in organic production. Such report could be accompanied, if appropriate, by a legislative proposal to provide for further harmonisation.***
- (71) *In the absence of such further harmonisation, Member States that had developed approaches to avoid that products, that contain a certain level of products and substances that have not been authorised by the Commission for use in organic production for certain purposes, are marketed as organic or in-conversion products should have the possibility to keep applying these approaches. However, in order to ensure the free movement of organic and in-conversion products in the Union's internal market, such approaches should not prohibit, restrict or impede the placing on the market of products produced in other Member States in compliance with the requirement of this Regulation. Such approaches should therefore only be applied to products produced on the territory of the Member State choosing to continue applying such an 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, 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 that have not been authorised by the Commission in accordance with this Regulation, Member States should also have the possibility to take other measures on their territory that are appropriate 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.

I

(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 Council¹, and in particular *to* the provisions aimed at preventing labelling that may 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 those of consumers in enabling them to make informed choices.

¹ 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).

- (74) Accordingly, the terms used to indicate organic products should be protected from being used in the labelling of non-organic products throughout the Union and independently of the language used. The 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 the ingredients of agricultural origin are organic. To encourage the use of organic ingredients, it should also be made possible to refer to organic production only in the list of ingredients of processed food under certain conditions, in particular that the food in question complies with certain production rules of this Regulation. Special labelling provisions should also be laid down to give the possibility to operators to identify organic ingredients used in products which consist mainly of an ingredient that stems from hunting and 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 made obligatory for all organic pre-packed food produced within the Union. It should otherwise be possible to use that logo on a voluntary basis in the case of non pre-packed organic products produced within the Union or any organic products imported from third countries. ***The organic production logo could also be used for information and educational purposes.*** The model of the organic production logo of the European Union should be set out in this Regulation.
- (78) However, in order not to mislead consumers as to the organic nature of the entire product, it is considered 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.
- (79) For the sake of avoiding any possible confusion amongst 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 this 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, amending** the list of terms referring to organic production ■ set out in this Regulation, and amending the organic production logo of the European Union and the rules relating thereto.
- (81) *Certain substances or products used in plant protection products or as fertilisers should not fall within the scope of this Regulation and should therefore not be subject to the rules of this Regulation, including the rules on labelling. However, since these products and substances play an important role in organic agriculture and their use in organic production is subject to authorisation under this Regulation, certain uncertainties appeared in practice as regards their labelling, and in particular as regards the use of terms referring to organic production. Therefore, it should be clarified that when these products and 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 *defined* to ensure compliance with the rules *laid down in this Regulation*. In particular, provisions should be made for notification of the activities of the operators and for a certification system to identify the operators that comply with the rules governing organic production and 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 in the main activity of the subcontracting operator and is controlled in this 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 for verifying compliance with the organic production rules.
- (84) *In order to avoid that small retail shops not selling other organic products than pre-packed organic products, and therefore presenting a relatively low risk as regards non-compliance with organic production rules, face disproportionate burdens for selling organic products, such shops should not be subject to the notification and certification obligations. They should remain, however, subject to official controls performed for the verification of the rules on organic production and labelling of organic products. Equally, small retail shops selling un-packed organic products should be subject to official controls, but in order to facilitate the marketing of organic products, Member States should have the possibility to exempt these shops from the obligation to certify their activity.*

- (85) Small farmers **and operators producing algae or aquaculture animals** in the Union face, individually, relatively high inspection costs and administrative burden linked to organic certification. A system of group certification should be allowed with a view to reducing the inspection and certification costs and the associated administrative burden, strengthening local networks, contributing to better market outlets and ensuring 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 reflecting 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 labelling system, 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 a group 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 a group of operators, the **criteria to determine the geographical proximity of its members,** and the set up and functioning of **its** system for internal controls ■ .

- (88) *Organic production is subject to official controls and other official activities carried out in accordance with Regulation (EU) No 2017/625 to verify compliance with the rules on organic production and labelling of organic products. However, save as otherwise provided for in this Regulation, additional rules to those which are laid down in that Regulation should apply to organic production as regards official controls and actions by competent authorities and, where appropriate control authorities and control bodies, actions to be taken by operators and groups of operators, the delegation of certain tasks related to official controls and other official activities and their supervision and as regards actions in case of suspicion of non-compliance or established non-compliance, including the prohibition to market products as organic or in-conversion products when the established non-compliance affects the integrity of the organic or in-conversion products.***
- (89) *In view of ensuring a uniform approach on their territories, it should be up to the competent authorities only to provide for a catalogue of measures for cases of suspicion or established non-compliances.***

- (90) *Additional provisions on the exchange of certain relevant information and action by competent authorities, control authorities or control bodies and certain other bodies 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 the requirements laid down in 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 aimed at ensuring the traceability at all stages of production, preparation and distribution, and compliance with the requirements laid down in this Regulation and in respect of additional elements to be taken into account in the determination of likelihood of non-compliance based on practical experience.***
- (92) *In order to support the performance of official controls and other official activities to verify compliance with the requirements laid down in this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of conditions for the delegation of official controls tasks and other official activities to control bodies additional to the conditions laid down in this Regulation.***

- (93) The experience with the arrangements for 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 rules as high as those of the Union, as well as to better ensure the access of Union organic products to the international market. In addition, it is necessary to provide for clarity regarding the rules applicable to export of organic products, in particular by establishing *an organic export certificate* .
- (94) The provisions governing the import of products that comply with the Union production and labelling rules and in respect of which operators have been subject to the control of control authorities and control bodies recognised by the Commission as competent to carry out controls and certification in the field of organic production in third countries, 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, aiming at ensuring 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 where specific climatic and local conditions occur, it is appropriate to provide for the possibility for the Commission to grant specific authorisations for the use of products and substances.*

- (95) The possibility for organic products to get 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 should be preserved. However, the recognition of equivalence of third countries, as laid down in Regulation (EC) No 834/2007, should only be granted through an international agreement 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 of time necessary to ensure a smooth transition to the scheme of recognition through an international agreement, provided that they continue to ensure the equivalence of their organic production and control rules 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 the third countries send to the Commission.

- (97) The experience with the scheme of control authorities and control bodies recognised as competent to carry out controls and issue certificates in third countries for the purpose of import of products providing equivalent guarantees shows that the rules applied by those authorities and bodies are different and could be difficult to be considered as equivalent to the respective Union rules. Furthermore, multiplication of control authorities and control bodies standards hampers adequate supervision by the Commission. Therefore that scheme of recognition of equivalence should be abolished. However, sufficient time should be given to those control authorities and control bodies so that they can prepare themselves for obtaining recognition for the purposes of import of products complying with Union rules. ***Furthermore, the new rules for the recognition of control authorities and control bodies for the purpose of import of compliant products should already apply at the date of entry into force of the Regulation in order to provide the Commission with the possibility to prepare the recognition of such control authorities and control bodies as of the date of application.***
- (98) The placing on the market as organic of any organic product 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 an organic export certificate **■** .
- (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, or the withdrawal of the recognition, of control authorities and control bodies in the context of import of compliant organic products, 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) When serious or repetitive infringements as regards the certification or the controls and actions laid down in accordance with this Regulation have been detected and when the control body or control authority concerned have failed to take appropriate and timely remedial action after request of the Commission, the recognition of those control authorities or of control bodies 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 third countries recognised which is necessary for the supervision of their recognition and the exercise of that supervision by the Commission.*
- (103) Provision should be made to ensure that the movement of organic products that have been subject to a control in one Member State and which comply with this Regulation cannot be restricted in another Member State. █
- (104) For the purpose of obtaining reliable information needed for the implementation of this Regulation, Member States should provide the Commission *regularly* 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 derogations to the use of non-organic plant reproductive material, non-organically reared poultry and non-organic livestock for breeding purposes, the Commission should consider the situation of the availability of such material in the Union. To this 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, the Commission should present, five years after the entry into application of this Regulation, 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 derogations to the use of non-organic protein feed for poultry and porcine animals and on the basis of the data on the availability on the market of the Union of such protein feed in organic form, provided every year by Member States, the Commission should present, five years after the entry into application of this Regulation, a report to the European Parliament and the Council on the availability and reasons of a possible limited access of organic operators to such organic protein feed.***

- (107) *In order to take into account the evolution of availability of organic plant reproduction material, organic animals and organic protein feed for poultry and porcine animals on the market, 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 some modifications of the legal framework governing the import of organic products into the Union, as introduced by this Regulation. ■
- (109) Furthermore, a *deadline* for the expiration of the recognition of control authorities and control bodies for the purpose of equivalence should be set and provisions to address the situation until the expiration of their recognition should be laid down. Provisions should also be laid down regarding applications from third countries for the purpose of equivalence which have been submitted under Regulation (EC) No 834/2007 and which are pending at the time 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 to be sent by those control authorities and control bodies that is necessary for 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 to be supplied in view of the recognition of 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 group of species of algae and aquaculture animals 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, and as regards the authorisation or the withdrawal of 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 procedures to be followed for the authorisation and the lists of those products and substances and, where appropriate, their description, compositional requirement and conditions for use.

(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 for the listing of the available organic or in-conversion plant reproductive material obtained by the organic production method and the systems for making available data on organic or in-conversion plant reproductive material or organic animals or organic aquaculture juveniles, as well as specifications for the collection of data for that purpose, as regards the arrangements for operators' participation in these systems, and as regards details concerning the information to be provided by Member State on derogations to the use of organic plant reproductive materials, of organic animals and organic feed as well as on the availability on 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 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 and 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, and as regards the practical modalities regarding the use, presentation, composition and size of the indications referring to the code numbers of control authorities and control bodies and of the indication of the place where the agricultural raw materials have been farmed, the assignment of code numbers to control authorities and control bodies and 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 form and technical means of the notification by operators and groups of operators of their activity to the competent authorities, the modalities of the publication of lists of such operators and groups of operators and the procedures and modalities of publication of the fees that may be collected for 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, and as regards the composition and dimension of a group of operators, the relevant documents and record-keeping systems, the system for internal traceability and the list of operators, as well as the exchange of information between groups of operators and competent authorities, control authorities or control bodies and 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 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 to demonstrate compliance, the necessary declarations and other communications to support official controls as well as the relevant practical measures to ensure compliance, as regards uniform arrangements for the cases where competent authorities are to take measures in relation to suspicion of non-compliance or to established non-compliance, and as regards the information to be provided in the case of suspicion of non-compliance or established non-compliance, the recipients of such information and the procedures, including the functionalities of the computer system used for such provision of information.

(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, the procedure to be followed for their issuance, their verification and the technical means by which the certificate is issued, as regards the recognition or withdrawal of the recognition of control authorities and control bodies competent to carry out controls and to issue organic certificate in third countries and 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 non-compliance, or suspicion thereof, in particular those affecting 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 non-compliance, or suspicion thereof, in particular those affecting 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, 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 Council¹.*

(121) The Commission should be empowered to adopt immediately applicable implementing acts where, in duly justified cases relating to the protection against 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 non-compliance, or the suspicion thereof, under the control of recognised control authorities or control bodies.

█

(122) Provision should be made to allow the exhaustion of stocks of products which have been produced in accordance with Regulation (EC) No 834/2007 █ before this Regulation starts to apply. █

█

¹ ***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 the Member States of Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).***

- (123)* Since the objectives of this Regulation, in particular fair competition and 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 instead, because 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 introduced,

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*, 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 shall apply to *the following* products *originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the Treaty on the Functioning of the European Union ('the Treaty') or originating from these products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, or imported into or exported from the Union:*
 - (a) *live or unprocessed agricultural products, including seed and other plant reproductive material;*
 - (b) *processed agricultural products for use as food;*
 - (c) *feed,**and to certain other products closely linked to agriculture listed in Annex I to this Regulation which are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported or exported* .

2. This Regulation shall apply to any operator involved in activities, at any stage of production, preparation and distribution, 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 **■** shall not be 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, presentation and advertising of these products or to advertise the mass caterer.*
4. *Except where otherwise provided, this* Regulation shall apply without prejudice to related Union legislation, *in particular* in the fields of safety of the food chain, animal health and welfare, plant health, and plant reproductive material **■**.
5. This Regulation shall apply without prejudice to other specific Union provisions relating to the placing of products on the market and, in particular, to Regulation (EU) No 1308/2013 of the European Parliament and of the Council ¹ **■** and to Regulation (EU) No 1169/2011.
6. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 amending the list of products set out in Annex I *by adding further products, or by amending those added entries*. Only products which are closely linked to agricultural products shall be eligible for inclusion in that list.

¹ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

Article 3
Definitions

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

- (1) 'organic production' means the use of production methods compliant with this Regulation, at all stages of production, preparation and distribution, ***including during the conversion period referred to in Article 10;***
- (2) 'organic ***products***' means ***products*** coming from **■** organic production, ***excluding the products produced during the conversion period referred to in Article 10. The products of hunting and fishing of wild animals shall not be 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 to be taken ***by operators at all stages of production, preparation and distribution*** in order to ensure ***the preservation of biodiversity***, soil quality as well as prevention and control of pests and ***diseases and to avoid negative effects on the environment, animal health and plant health;***

- (5) ***‘precautionary measures’ means measures to be taken by operators at all stages of production, preparation, and distribution to avoid contamination with products or substances that are not authorised to be used in organic production in accordance with this Regulation and to avoid commingling of organic products with non-organic products;***
- (6) ***‘conversion’ means the transition from non-organic to organic production within a given period of time during which the provisions of this Regulation concerning organic production are applied;***
- (7) ***‘in-conversion products’ means products that are produced during the conversion period in accordance with Article 10;***
- (8) ***‘holding’ means all the production units operated under a single management for the purpose of producing live or unprocessed agricultural products, including products originating from aquaculture and beekeeping, as referred to in Article 2(1)(a) and/or producing 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 or sites for algae or aquaculture animals, rearing units, shore or seabed concessions, the premises for the storage of crops, crop products, algae products, animal products, raw materials and any other relevant inputs managed according to points (10), (11) or (12);***

- (10) *‘organic production unit’ means a production unit which is managed in compliance with the requirements applicable to organic production, excluding during the conversion period referred to in Article 10;*
- (11) *‘in-conversion production unit’ means a production unit which is managed in compliance with the requirements applicable to organic production during the conversion period referred to in Article 10; 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 all stages of production, preparation and distribution under their control;
-
- (14) ‘farmer’ means a natural or legal person, or a group of natural or legal persons, regardless of the legal status granted to such group and its members by 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 as well as all parts of plants at any growth stage including seeds, capable of, and intended for, producing entire plants;***
- (18) ***'organic heterogeneous material' means plant grouping within a single botanical taxon of the lowest known rank which:***
- (a) presents common phenotypic characteristics;***
 - (b) is, however, characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that this 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 2100/94¹;***
 - (d) is not a mixture of varieties;***
 - (e) has been produced in accordance with the requirements of this Regulation;***

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

- (19) *‘organic variety suitable for organic production’ means a variety within the meaning of Article 5(2) of Regulation (EC) No 2100/94 which:*
- (a) *is characterised by a high level of genetic and phenotypical diversity between individual reproductive units;*
 - (b) *results from organic breeding activities referred to in Annex II, Part I, point 1.8.4;*
- (20) *‘mother plant’ means an identified plant from which plant reproductive material is taken for 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 Council¹;*

¹ *Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).*

- (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 being usually equipped with wire fencing or netting with outdoor climate, natural and/or artificial illumination and a littered floor;
- (29) ***‘pullets’ means young animals of the Gallus gallus species of an age of less than 18 weeks;***
- (30) ***‘laying hens’ means animals of the Gallus gallus species intended for the production of eggs for consumption and 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/EC¹;*
- (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 Council²;*
- (33) *‘aquaculture products’ means aquaculture products as defined in point 34 of Article 4(1) of Regulation (EU) No 1380/2013;*
- (34) *‘closed recirculation aquaculture facility’ means a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the recirculation of water, and depending on permanent external energy input to stabilise the environment for the aquaculture animals;*
- (35) *‘energy from renewable sources’ means renewable non-fossil energy sources such as wind, solar, geothermal wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;*

¹ *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).*

² 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).

- (36) *'hatchery' means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;*
- (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 Directive 2008/56/EC of the European Parliament and of the Council¹, in the waters to which each of those Directives applies, respectively;*
- (39) *'polyculture' means the rearing in aquaculture of two or more species usually from different trophic levels in the same culture unit;*

¹ *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).*

- (40) *‘production cycle’ means the lifespan of an aquaculture animal or algae 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, respectively, points 6 and 7 of Article 3 of Council Regulation (EC) No 708/2007¹, 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 one occurrence of a specific disease;
- (43) ‘veterinary medicinal products’ means veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council²;

¹ *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).*

² 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).

- (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, and/or* 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 Council¹;
- (46) ‘feed’ means feed as defined in point 4 of Article 3 of Regulation (EC) No 178/2002;
- (47) ‘feed material’ means feed material as defined in point (g) of Article 3(2) of Regulation (EC) No 767/2009 of the European Parliament and of the Council²;
-

¹ 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).

² 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).

(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 a food, feed or any product referred to in Article 2(1) or substance intended to be, or expected to be incorporated into a food or feed or in any product referred to in Article 2(1), through all stages of production, preparation and distribution;***

(50) ‘stages of production, preparation and distribution’ means any stage from and including the primary production of an organic product up to and including its storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;

■

(51) ‘ingredient’ means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011 ***or for products other than food, any substance or product used in the manufacture or preparation of products, that is still present in the finished product, even in altered form;***

(52) ‘labelling’ means ***any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such product; ■*** ;

- (53) ‘advertising’ means any presentation of **U** products to the public, by any means other than a label, that is intended or is likely to influence and shape attitude, beliefs and behaviours in order to promote directly or indirectly the sale of **U** products;
- (54) ‘competent authorities’ means competent authorities as defined in point 3 of Article 3 of Regulation (EU) No **2017/625**;
- (55) ‘control authority’ means **an organic** control authority for organic production and labelling of organic products as defined in point 4 of Article 3 of Regulation (EU) No **2017/625 as well as an authority recognised by the Commission or by a third country recognised by the Commission to carry out controls in third countries for the import of organic products into the Union**;
- (56) ‘control body’ means a delegated body as defined in point 5 of Article 3 of Regulation (EU) No **2017/625**, as well as a body recognised by the Commission or by a third country recognised by the Commission to carry out controls in third countries for the import of organic products into the Union;

- (57) ‘non-compliance’ means non-compliance with this Regulation *or, with the delegated or implementing acts adopted in accordance with this Regulation*;
- (58) ‘genetically modified organism’ *or 'GMO'* means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council¹ which is not obtained through the techniques of genetic modifications listed in Annex I.B to that Directive ■ ;
- (59) ‘produced from GMOs’ means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (60) ‘produced by GMOs’ means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;
- (61) ‘food additive’ means ■ food additive as defined in point (a) of Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council²;
- (62) ‘feed additive’ means ■ feed additive as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council³;

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

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

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

- (63) ***‘engineered nanomaterial’ means engineered nanomaterial as defined in point (t) of Article 2(2) of Regulation (EU) No 1169/2011;***
- (64) ‘equivalence’ means meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;
- (65) ‘processing aid’ means processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008 ***for food and in point (h) of Article 2(2) of Regulation (EC) No 1831/2003 for feed;***
- (66) ‘food enzyme’ means ■ food enzyme as defined in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council¹;
- (67) ‘ionising radiation’ means ionising radiation as defined in Article 1 of Council Directive 96/29/Euratom² ■ ;
- (68) ***‘pre-packed food’ means pre-packed food as defined in Article 2(2)(e) of Regulation (EU) No 1169/2011;***

¹ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7)

² Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L 159, 29.6.1996, p. 1).

- (69) *‘poultry house’ means a building for accommodating flocks of poultry, which includes all surfaces covered by fixed or mobile roofs, including a veranda. The house may be subdivided into separate compartments, each accommodating a single flock.*
- (70) *‘soil-related crop cultivation’ means production in living soil or in soil mixed or fertilised with materials and products allowed in organic production in connection with the subsoil and bedrock;*
- (71) *‘unprocessed products’ means unprocessed products as defined in point (n) of Article 2(1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council¹, irrespective of packaging or labelling operations;*
- (72) *‘processed products’ means processed products as defined in point (o) of Article 2(1) of Regulation (EC) No 852/2004, irrespective of packaging or labelling operations;*
- (73) *‘processing’ means processing as defined in point (m) of Article 2(1) of Regulation (EC) No 852/2004, including the use of substances referred to in Articles 24 and 25 of this Regulation. Packaging or labelling operations shall not be considered as processing;*

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

- (74) *‘integrity of organic or in-conversion products’ means that the product does not present non-compliances that:*
- *affect the organic or respectively in-conversion characteristics of the product in any stage of production, preparation and distribution; and/or*
 - *are repetitive or intentional;*
- (75) *‘pen’ means an enclosure that includes a part where animals are provided with protection from the weather.*

Chapter II

Objectives of, and principles for, organic production

Article 4

Objectives

The organic production shall pursue the following general objectives:

- *contribution to protection of the environment and the climate,*
- *maintenance of the long-term fertility of soils,*
- *contribution to a high level of biodiversity,*
- *substantial contribution to a non-toxic environment,*
- *contribution to high animal welfare standards and, in particular, meeting animals' species-specific behavioural needs,*

- *encouragement of short distribution channels and local production in the various areas of the Union,*
- *encouragement of the preservation of rare and/or native breeds in danger of extinction,*
- *contribution to the development of the offer of plant genetic material adapted to the specific needs and objectives of organic agriculture,*
- *contribution to a high level of biodiversity, notably by using diverse plant genetic material, such as organic heterogeneous material and organic varieties suitable for organic production,*
- *foster the development of organic plant breeding activities in order to contribute to favourable economic perspectives of the organic production sector.*

Article 5

General principles

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

- (a) respect for nature's systems and cycles and sustainment and enhancement of the state of soil, water *and* air, of the health of plants and animals and of the balance between them;
- (b) *preservation of natural landscape elements such as natural heritage sites;*
- (c) responsible use of energy and natural resources, such as water, soil, organic matter and air;
- (d) *production of a wide variety of high quality food and other agricultural and aquaculture products that respond to consumers' demand for goods produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare;*
- (e) *ensuring the integrity of organic production at all stages of production, processing and distribution of food and feed;*

- (f) appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:
 - (i) use living organisms and mechanical production methods;
 - (ii) practice *soil*-related crop cultivation and *land-related* livestock production or practice aquaculture which complies with the principle of sustainable exploitation of **■** *aquatic resources*;
 - (iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products;
 - (iv) are based *on risk assessment, and* the use of *precautionary measures and* preventive measures, when appropriate;
- (g) restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, these *external inputs* shall be limited to:

- (i) inputs from organic production, ***in the case of plant reproductive material, priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic farming;***
- (ii) natural or naturally-derived substances;
- (iii) low solubility mineral fertilisers;
- (h) adaptation, where necessary, and within the framework of this Regulation, of the production process, taking account of the sanitary status, regional differences in ecological balance, climate and local conditions, stages of development and specific husbandry practices;
- (i) ***exclusion of animal cloning, rearing artificially induced polyploid animals and ionising radiation from the whole organic food chain;***
- (j) ***observance of a high level of animal welfare respecting species-specific needs.***

Article 6

Specific principles applicable to agricultural activities and aquaculture

In the framework of agricultural activities and aquaculture, organic production shall in particular be based on the following specific principles:

- (a) maintenance and enhancement of soil life and natural soil fertility, soil stability, soil water retention and soil biodiversity preventing and combating loss of soil organic matter, soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem;
- (b) limitation of the use of non-renewable resources and external inputs to a minimum;
- (c) recycling of wastes and by-products of plant and animal origin as input in plant and livestock production;
- (d) maintenance of plant health by preventive measures, in particular the choice of appropriate species, varieties or heterogeneous material ■ resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests;
- (e) *use of seeds and animals with a high degree of genetic diversity, resistance against diseases and longevity;*

- (f) *choice of plant varieties having regard to the particularities of the organic production systems, focussing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect of the natural crossing barriers;***
- (g) *use of organic plant reproductive material such as organic heterogeneous material, and organic varieties suitable for organic production;***
- (h) *production of organic varieties through natural reproductive ability and focussing on containment within natural crossing barriers;***
- (i) *without prejudice to Article 14 of Regulation (EC) No 2100/94 and to the national plant variety rights granted under Member States' national law, possibility for farmers to use plant reproductive material obtained from their own farm in order to foster genetic resources adapted to the special conditions of organic production;***
- (j) *choice of animal breeds having regard to a high degree of genetic diversity, the capacity of animals to adapt to local conditions, their breeding value, their longevity, their vitality and their resistance to disease or health problems;***
- (k) *the practice of site-adapted and land-related livestock production;***

- (l) ***the application of animal husbandry practices, which enhance the immune system and strengthen the natural defence against diseases, in particular including regular exercise and access to open air areas and pastureland;***
- (m) feeding of livestock with organic feed composed of agricultural ingredients from organic production and of natural non-agricultural substances;
- (n) ***production of organic livestock products derived from animals that have been raised on organic holdings since their birth or hatching and throughout their life;***
- (o) continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems;
- (p) feeding of aquatic organisms with feed from sustainable exploitation of fisheries in accordance with Regulation (EU) No 1380/2013 or with organic feed composed of agricultural ingredients from organic production, including organic aquaculture, and of natural non-agricultural substances;
- (q) ***avoiding any endangerment of species of conservation interest that might arise from organic production.***

Article 7

Specific principles applicable to the processing of organic food shall
Production of processed organic food shall, in particular, be based on the following specific principles:

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

Article 8

Specific principles applicable to the processing of organic feed

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

- (a) production of organic feed from organic feed materials;*
- (b) restriction of the use of feed additives and processing aids, so that they are used to a minimum extent and only in cases of essential technological or zootechnical needs or for particular nutritional purposes;*
- (c) exclusion of substances and processing methods that might be misleading as regards the true nature of the product;*
- (d) processing of feed with care, preferably through the use of biological, mechanical and physical methods.*

Chapter III
Production rules
Article 9

General production rules

1. Operators shall comply with the general production rules laid down in this Article.
2. ***The entire holding shall be managed in compliance with the requirements of this Regulation applicable to organic production.***
3. ***For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances authorised pursuant to those provisions may be used in organic production, provided that their use has also been authorised for conventional production in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law. The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production provided that they are authorised pursuant to Regulation (EC) No 1107/2009:***
 - (a) ***safeners, synergists and co-formulants as components of plant protection products;***
 - (b) ***adjuvants to be mixed with plant protection products.******The use in organic production of products and substances for other purposes not regulated in this Regulation shall be allowed provided that their use respects the principles laid down in Chapter II.***

4. *The use of ionising radiation for the treatment of organic food or feed, or of raw materials used in organic food or feed shall be prohibited.*
5. *The use of animal cloning and the rearing of artificially induced polyploid animals shall be prohibited.*
6. *Preventive and precautionary measures shall be taken, as appropriate, at all stages of production, preparation and distribution.*
7. *Notwithstanding paragraph 2, a holding may be split into clearly and effectively separated organic, in-conversion and non-organic production units, provided that for the non-organic production units:*
 - (a) *as regards livestock, different species are involved;*
 - (b) *as regards plants, different varieties that can be easily differentiated are involved.*

As regards algae and aquaculture animals, the same species may be involved, provided that there is a clear and effective separation between the productions sites or units.

8. *By way of derogation from point (b) of paragraph 7, in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated or the same varieties may be involved provided that the production in question forms part of a conversion plan and that the conversion to organic production of the last part of the area related to the production in question begins within the shortest possible period and is completed within a maximum of five years.*

In such cases:

- (a) the competent authority or where appropriate, the control authority or the control body, shall be notified of the harvest of each of the products concerned at least 48 hours in advance;***
- (b) upon completion of the harvest, the producer shall inform the competent authority or where appropriate, the control authority or the control body, of the exact quantities harvested on the units concerned and of the measures applied to separate the products;***
- (c) the conversion plan and the measures to ensure the effective and clear separation shall be confirmed each year by the competent authority or where appropriate, the control authority or the control body, after the start of the conversion plan.***

9. *By way of derogation from points (a) and (b) of paragraph 7, in the case of research and educational centres, plant nurseries, seed multipliers, and breeding operations, the requirements concerning different species and varieties shall not apply.*
10. *Where, in the cases referred to in paragraphs 7, 8 and 9, not all production units of a holding are managed under organic production rules, the operators shall keep the products used for the organic and in-conversion production units separate from those used for the non-organic production units. Operators shall keep separate the products produced by the organic, in-conversion and non-organic production units.
Operators shall keep adequate records to show the effective separation of the production units and of the products.*
11. *The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraph 7 of this Article by adding further rules on the splitting of a holding into organic, in-conversion and non-organic production units, in particular in relation to products listed in Annex I, or by amending those added rules.*

Article 10
Conversion

1. Farmers and operators producing *algae* or aquaculture animals shall respect a conversion period. During the whole conversion period they shall apply *all* rules on organic production laid down in this Regulation **■**, in particular the **■** *applicable* rules on conversion set out in this Article and in Annex II.
2. The conversion period shall start at the earliest when the farmer or the operator producing *algae* or aquaculture animals has notified his activity to the competent authorities *as referred to in Article 34(1) in the Member State in which his activity is carried out and his holding is submitted to the control system.*
3. No previous period may be recognised retroactively as being part of the conversion period *except where:*
 - (a) *the operator's land parcels were subject of measures defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 which ensure that no products or substances not authorised for organic production have been used on those land parcels; or*
 - (b) *proof can be provided by the operator that the land parcels were natural or agricultural areas and were not treated with products or substances not authorised for organic production for a period of at least three years.*

4. Products produced during the conversion period shall not be marketed as organic *or as in-conversion products*.

However, the following products produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products:

- (a) plant reproductive material, provided that a conversion period of at least 12 months has been complied with;*
- (b) food or feed products of plant origin provided that the product contains only one agricultural crop ingredient and that a conversion period of at least 12 months before the harvest has been complied with.*

5. **█** *The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.2.2 of Part II of Annex II by adding conversion rules for species other than those regulated in Part II of Annex II at the date of entry into force of this Regulation, or by amending those added rules.*

6. *The Commission shall, where appropriate, adopt implementing acts specifying the documents to be supplied in view of the recognition of previous retroactive period in accordance with paragraph 3.*

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

Article 11
Prohibition of the use of GMOs

1. GMOs and products produced from or by GMOs shall not be used in food or feed or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms *or* animals in organic production.
2. For the purposes of ***the prohibition laid down in*** paragraph 1, with regard to GMOs or products produced from **■** GMOs for food and feed, operators may rely on the labels of a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council¹ or Regulation (EC) No 1830/2003 of the European Parliament and of the Council².

¹ Regulation (EC) **No** 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

² Regulation (EC) **No** 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

3. Operators may assume that no GMOs or products produced from **■** GMOs have been used in the manufacture of purchased food and feed when such products are not labelled, or accompanied by a document, pursuant to the Regulations referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those Regulations.
4. ***For the purpose of the prohibition laid down in paragraph 1 with regard to products not covered by the paragraphs 2 and 3, operators using non-organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs.***

Article 12

Plant production rules

1. Operators producing plants or plant products shall in particular comply with the **■** detailed rules set out in Part I of Annex II. **■**
2. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 amending **■** :

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

Article 13

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

- 1. Plant reproductive material of organic heterogeneous material may be marketed without complying with the requirements for registration and the certification categories of pre-basic, basic and certified material, or the requirements for other categories, as set out in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, or acts adopted pursuant to those Directives.**
- 2. Plant reproductive material of organic heterogeneous material as referred to in paragraph 1 may be marketed following a notification of the organic heterogeneous material by the supplier to the responsible official bodies referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC of a dossier containing:**
 - (a) the contact details of the applicant;**
 - (b) the species and denomination of the organic heterogeneous material;**
 - (c) the description of the main agronomic and phenotypic characteristics that are common to that plant grouping, including breeding methods, results from tests, if available, the country of production and the parental material used;**

(d) a declaration by the applicant concerning the trueness of the elements in points (a) to (c);

(e) a representative sample.

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

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

After express or implied acknowledgment of the notification, the competent authority may proceed to the listing of the notified organic heterogeneous material. This listing shall be free of charge for the supplier.

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

The organic heterogeneous material shall comply with the delegated acts adopted in accordance with paragraph 3.

3. *The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by setting out rules for the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species, as regards:*
- (a) *the description of the organic heterogeneous material, including the relevant breeding and production methods and parental material used;*
 - (b) *the minimum quality requirements of seeds lots, including identity, specific purity, germination rates and sanitary quality;*
 - (c) *labelling and packaging;*
 - (d) *information and samples of production to be kept by the professional operators;*
 - (e) *where applicable, maintenance of the organic heterogeneous material.*

Article 14

Livestock production rules

1. Livestock operators shall in particular comply with the *detailed* production rules set out in Part II of Annex II *and in any implementing acts referred to in paragraph 3*.
2. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 amending **■** :

- (a) *points 1.3.4.3, 1.3.4.4.2 and 1.3.4.4.3 of Part II of Annex II by reducing the percentages as regards the origin of animals once sufficient availability on the Union market of organic animals has been established;***
- (b) *point 1.6.6 of Part II of Annex II as regards the limit of organic nitrogen linked to the total stocking density;***
- (c) *point 1.9.6.2(b) of Part II of Annex II as regards the feeding of bee colonies;***
- (d) *points 1.9.6.3(b) and (e) of Part II of Annex II as regards the acceptable treatments for disinfection of apiaries and for the fight against Varroa destructor;***
- (e) *Part II of Annex II by adding detailed livestock production rules for species other than those regulated in that Part at the date of entry into force of this Regulation, or by amending those added rules, as regards:***
 - (i) *derogations as regards the origin of animals;***
 - (ii) *nutrition;***
 - (iii) *housing and husbandry practices;***
 - (iv) *health care;***
 - (v) *animal welfare.***

3. *The Commission shall, where appropriate, adopt implementing acts regarding Part II of Annex II providing rules on:*

- (a) the minimum period referred to in point 1.4.1(g) to be respected for feeding of suckling animals with maternal milk;*
- (b) the stocking density and minimum surface for indoor and outdoor areas to be respected for specific livestock species to ensure, in accordance with points 1.6.3, 1.6.4 and 1.7.2, that the developmental, physiological and ethological needs of animals are met,*
- (c) the characteristics and technical requirements of the minimum surface for indoor and outdoor areas;*
- (d) the characteristics and technical requirements of buildings and pens for all livestock species, except for bees, to ensure, in accordance with point 1.7.2, that the developmental, physiological and ethological needs of animals are met;*
- (e) vegetation requirements and characteristics of protected facilities and open air areas.*

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

Article 15

Production rules for *algae* and aquaculture animals

1. Operators producing *algae* and aquaculture animals shall in particular comply with the *detailed* production rules set out in Part III of Annex II **and in any implementing acts referred to in paragraph 4.**
2. **■** The Commission *is* empowered to adopt delegated acts in accordance with Article 54 amending **■** :
 - (a) *point 3.1.3.3 of Part III of Annex II as regards feed for carnivorous aquaculture animals;*
 - (b) *point 3.1.3.4 of Part III of Annex II by adding further specific rules on feed for certain aquaculture animals, or by amending those added rules;*
 - (c) *point 3.1.4.2 of Part III of Annex II as regards veterinary treatments for aquaculture animals;*
 - (d) *Part III of Annex II by adding further detailed conditions per species for broodstock management, breeding and juvenile production, or by amending those added detailed conditions.*

3. *The Commission shall, where appropriate, adopt implementing acts laying down detailed rules per species or group of species on the stocking density and on the specific characteristics for production systems and containment systems to ensure that the species specific needs are met.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*
4. *For the purpose of this Article and Part III of Annex II, 'stocking density' means the live weight of aquaculture animals per cubic metre of water at any time during the grow-out phase and in the case of flatfish and shrimp the weight per square metre of surface.*

Article 16

Production rules for processed food

1. Operators producing processed food shall in particular comply with the *detailed* production rules set out in Part IV of Annex II *and in any implementing acts referred to in paragraph 3 of this Article.*
2. **The Commission is** empowered to adopt delegated acts in accordance with Article 54 amending **:**

- (a) *point 1.4 of Part IV of Annex II as regards precautionary and*¹ preventive measures to be taken *by operators*;
- (b) *point 2.2.2 of Part IV of Annex II as regards the type, composition and conditions of use of* products and substances allowed for use in processed food ;
- (c) *point 2.2.4 of Part IV of Annex II as regards the calculation of the percentage of agricultural ingredients referred to in Article 30(5)(a)(ii) and (b)(i), including the food additives authorised for use in organic production pursuant to Article 24 that are calculated as agricultural ingredients.*

Those delegated acts shall not include the possibility to use flavouring substances or flavouring preparations which are neither natural, within the meaning of Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council¹, nor organic.

3. *The Commission may adopt implementing acts laying down the techniques authorised in the processing of food products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*

¹ *Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).*

Article 17

Production rules for processed feed

- 1. Operators producing processed feed shall in particular comply with the detailed production rules set out in Part V of Annex II and in any implementing acts referred to in paragraph 3 of this Article.*
- 2. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending point 1.4 of Part V of Annex II by adding further precautionary and preventive measures to be taken by operators, or by amending those added measures.*
- 3. The Commission may adopt implementing acts laying down the techniques authorised in the processing of feed products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*

Article 18

Production rules for wine

1. Operators producing products of the wine sector shall in particular comply with the *detailed* production rules set out in Part VI of Annex II.
2. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 amending **■** :
 - (a) *point 3.2 of Part VI of Annex II by adding further oenological practices, processes and treatments that are prohibited, or by amending those added elements;*
 - (b) *point 3.3. of Part VI of Annex II.*

Article 19

Production rules for yeast used as food or feed

1. Operators producing yeast to be used as food or feed shall in particular comply with the *detailed* production rules set out in Part VII of Annex II.
2. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 amending **■** *point 1.3 of Part VII of Annex II by adding further detailed yeast production rules, or by amending those added rules.*

Article 20

***Absence of certain production rules for specific livestock species
and species of aquaculture animals***

Pending the adoption of:

- (a) additional general rules for other livestock species than those regulated in point 1.9 of Part II of Annex II, in accordance with point (e) of Article 14(2);***
- (b) the implementing acts referred to in Article 14(3) for livestock species;***
- or***
- (c) the implementing acts referred to in Article 15(3) for species or group of species of aquaculture animals,***

a Member State may apply detailed national production rules for specific species or groups of species of animals on the elements to be covered by the rules referred to in points (a) to (c), provided that those national rules are in accordance with this Regulation and that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with the requirements of this Regulation.

Article 21

Production rules for products not falling within the categories of products referred to in Articles 12 to 19

- 1. *The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex II by adding detailed production rules, as well as rules on the obligation to convert, for products that do not fall within the categories of products referred to in Articles 12 to 19, or by amending those added rules. Those delegated acts shall be based on the objectives and principles of organic production laid down in Chapter II and shall respect the general production rules laid down in Articles 9, 10 and 11 as well as existing detailed production rules laid down for similar products in Annex II. They shall lay down requirements concerning in particular allowed or prohibited treatments, practices and inputs or conversion periods:***
- 2. *In the absence of the detailed production rules referred to in paragraph 1:***
 - (a) *operators shall, as regards products referred to in paragraph 1, comply with the principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11;***

- (b) a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation and that they do not prohibit, restrict or impede the placing on the market of products produced outside its territory and which comply with the requirements of this Regulation.**

Article 22

Adoption of exceptional production rules

- 1. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by laying down:**
- (a) the criteria to qualify catastrophic circumstances deriving from an 'adverse climatic event', 'animal diseases', 'environmental incident', natural disaster' or a 'catastrophic event' as defined in points (h), (i), (j), (k) and (l), respectively, of Article 2(1) of Regulation (EU) No 1305/2013 as well as any comparable situation;**
 - (b) specific rules, including possible derogation from this Regulation, on how Member States shall deal with such catastrophic circumstances if they decide to apply this Article; and**
 - (c) specific rules on monitoring and reporting in such cases.**
- Those criteria and rules shall be subject to the principles of organic production laid down in Chapter II.**

2. *In cases where a Member State has formally recognised an event as a natural disaster as referred to in Articles 18(3) or 24(3) of Regulation (EU) No 1305/2013 and this event makes it impossible to respect the production rules laid down in this Regulation, that Member State may grant exceptions to the production rules for a limited period of time and until organic production can be re-established, subject to the principles laid down in Chapter II and to any delegated act adopted in accordance with paragraph 1.*
3. *Member States may adopt measures in accordance with the delegated act referred to in paragraph 1 to allow the organic production to continue or recommence in the event of catastrophic circumstances.*

Article 23

Collection, packaging, transport and storage

1. *Operators shall ensure that organic and in-conversion products are collected, packaged, transported and stored in accordance with the rules set out in Annex III.*
2. **■** *The Commission is empowered to adopt delegated acts in accordance with Article 54 ■ :*
 - (a) *amending point 2 of Annex III;*
 - (b) *amending points 3, 4 and 6 of Annex III by adding further special rules for the transport and reception of the products concerned, or by amending those added rules.*

Article 24

Authorisation of products and substances used in organic production

1. The Commission may authorise certain products and substances for use in organic production and **shall** include **any such authorised products and substances** in restricted lists, for the following purposes:
 - (a) as **active substances to be used in** plant protection products;
 - (b) as fertilisers, soil conditioners and nutrients;
 - (c) **as non-organic feed material of plant, algae, animal or yeast origin or as feed material of microbial or mineral origin**;
 - (d) as feed additives and processing aids;
 - (e) as products for cleaning and disinfection of ponds, cages, tanks, raceways, buildings and installations used for animal production;
 - (f) as products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding;
 - (g) **as products for cleaning and disinfection in processing and storage facilities.**

2. In **addition**, the Commission may authorise certain products and substances for use in the production of [] processed **organic** food **and of yeast used as food or feed** and **shall** include **any such authorised products and substances** in restricted lists, for the following purposes:
 - (a) as food additives [] and processing aids;
 - (b) **as non-organic agricultural ingredients to be used for the production of organic processed food;**
 - (c) as processing aids for the production of yeast and yeast products.
3. The authorisation of the products and substances referred to in [] paragraph 1 for use in organic production shall be subject to the principles laid down in Chapter II and to the following criteria which shall be evaluated as a whole:
 - (a) **they are essential** for sustained production and [] for **the** intended use;
 - (b) all products and substances **concerned** are of plant, **algae**, animal, microbial or mineral origin, except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available;
 - (c) in the case of products referred to in point (a) of [] paragraph 1 [] :
 - (i) their use is essential for the control of a pest for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available;

- (ii) if *those* products are not of plant, *algae*, animal, microbial or mineral origin and are not identical to their natural form, ■ their conditions for use preclude any direct contact with the edible parts of the crop;
- (d) in the case of products referred to in point (b) of ■ paragraph 1, their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or for specific soil-conditioning purposes;
- (e) in the case of products referred to in points (c) and (d) of ■ paragraph 1 ■ :
 - (i) their use is necessary to maintain animal health, animal welfare and vitality and *contributes* to an appropriate diet fulfilling the physiological and behavioral needs of the species concerned or their use is necessary to produce or preserve feed because the production or preservation of feed is not possible without having recourse to such substances;
 - (ii) feed of mineral origin, trace elements, vitamins or provitamins *are* of natural origin, except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available;

- (iii) *the use of non-organic feed material of plant or animal origin when feed material of plant or animal origin produced in accordance with organic production rules is not available in sufficient quantity;*
- (iv) *the use of non-organic spices, herbs, and molasses provided that:*
 - *they are not available in organic form;*
 - *they are produced or prepared without chemical solvents;*
 - *their use is limited to 1 % of the feed ration of a given species, calculated annually as a percentage of the dry matter of feed from agricultural origin.*

4. The authorisation of the products and substances referred to in **■** paragraph 2 for use in the production of **■** processed *organic* food *and of yeast used as food or feed* shall be subject to the principles laid down in Chapter II and to the following criteria which shall be evaluated as a whole:

- (a) *alternative products or substances* authorised in accordance with this Article *or techniques compliant with this Regulation* are not available;

- (b) it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of [] Union legislation, without having recourse to those products and substances;
 - (c) they are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where products and substances from such sources are not available in sufficient quantities or qualities;
 - (d) *the organic ingredient is not available in sufficient quantity.*
5. The authorisation of the use of [] *chemically synthesised products and substances in accordance with paragraphs 1 and 2* shall be strictly limited to cases where the use of external inputs referred to in point (g) of Article 5 [] would contribute to unacceptable [] impacts *on the environment*.
6. [] *The Commission is* empowered to adopt delegated acts in accordance with Article 54 [] *amending paragraphs 3 and 4 of this Article by adding further* criteria for the authorisation or withdrawal of the authorisation of products and substances referred to in *paragraphs 1 and 2 of this Article* for use in organic production in general and in the production of [] processed *organic* food in particular, *or by amending those added criteria.*

7. Where a Member State considers that a product or substance should be added to, or withdrawn from the lists of authorised products and substances referred to in **paragraphs 1 and 2**, or that the specifications of use **referred to** in the production rules should be amended, the Member State concerned shall ensure that a dossier giving the reasons for the inclusion, withdrawal or **other** amendments is sent officially to the Commission and to the other Member States **and is publicly available, subject to Union and national legislation on data protection**. Any requests **referred to in this paragraph** shall be published by **the Commission**.
8. **The Commission shall regularly review the lists referred to in this Article. The list of non-organic ingredients, referred to in point (b) of paragraph 2, shall be reviewed at least once a year.**
9. The Commission shall adopt implementing acts authorising or withdrawing the authorisation of products and substances **referred to in paragraphs 1 and 2** that may be used in organic production in general and **■** in the production of processed organic food in particular, and establishing the procedures to be followed for the authorisation and the lists of those products and substances and, where appropriate, their description, compositional requirements and conditions for use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

Article 25

*Authorisation of non-organic agricultural ingredients
for processed organic food by Member States*

- 1. Where it is necessary in order to ensure access to certain agricultural ingredients and where such ingredients are not available in sufficient quantity in organic form a Member State may, upon request of an operator, provisionally authorise on its territory the use of non-organic agricultural ingredients for the production of processed organic food for a period of maximum 6 months. The authorisation granted shall apply to all operators in that Member State.*
- 2. The Member State shall immediately notify to the Commission and the other Member States, via a computer system enabling the exchanges of documents and information made available by the Commission, any authorisation granted for its territory.*
- 3. The Member State may prolong the authorisation provided for in paragraph 1 for a maximum of two times for 6 months each, if no other Member State has objected by indicating, via the system referred to in paragraph 2, that there is sufficient quantity available.*

4. *Control authorities or control bodies recognised in accordance with Article 46(1) may grant for a maximum of 6 months a provisional authorisation as referred to in paragraph 1 to operators in third countries that request such an authorisation and that are subject to their controls when the conditions of that paragraph are fulfilled in the third country concerned. The authorisation may be prolonged for a maximum of two times 6 months each.*
5. *Where, after two prolongations, a Member State considers, on the basis of objective information, that the availability of the said ingredient in organic form remains insufficient to meet the qualitative and quantitative needs of operators, it may make a request in accordance with Article 24(7) to the Commission.*

Article 26

Collection of data concerning the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles

1. *Each Member State shall ensure that a regularly updated database is established for the listing of the organic or in-conversion plant reproductive material, except seedlings but including seed potatoes, which is available on its territory.*
2. *Member States shall have in place systems that allow operators who market organic or in-conversion plant reproductive material or organic animals or organic aquaculture juveniles and who are able to supply them in sufficient quantities and within a reasonable time period, to make public on a voluntary basis, free of charge, together with their names and contact details, the following data:*

- (a) *the organic and in-conversion plant reproductive material, such as organic heterogeneous material, organic varieties suitable for organic production, except seedlings but including seed potatoes, which is available; the quantity in weight of that material and the period of the year of its availability. That material shall be listed using at least the Latin scientific name;*
 - (b) *the organic animals for which derogation may be provided in accordance with point 1.3.4.4 of Annex II, part II; the number of available animals categorised by sex; information, if relevant, relating to the different species of animals as regards the breeds and strains available; the races, the age of the animals and any other relevant information;*
 - (c) *the organic aquaculture juveniles available on their holding and the production capacity for each aquaculture species and their health status in accordance with Council Directive 2006/88/EC¹.*
3. *Member States may also set up systems which allow operators who market breeds and strains adapted to organic production in accordance with point 1.3.3 of Part II of Annex II or organic pullets, and who are able to supply these animals in sufficient quantities and within a reasonable time period to make public the relevant data on a voluntary basis, free of charge, together with name and contact details.*

¹ *Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).*

4. *Operators who opt to include plant reproductive material or animals or aquaculture juveniles in the systems referred to in paragraphs 2 and 3 shall ensure that the information is updated regularly and that the information is withdrawn from the lists once the plant reproductive material or animals or aquaculture juveniles are no longer available.*
5. *For the purpose of paragraphs 1, 2 and 3, Member States may continue to use already existing relevant information systems.*
6. *The Commission shall make public the link to each of the national databases or systems in a Commission dedicated website, thus allowing users to have access to such a data throughout the Union.*
7. *The Commission may adopt implementing acts*
 - (a) *to provide technical details for establishing and maintaining the databases referred to in paragraph 1 and the systems referred to in paragraph 2;*
 - (b) *to provide specifications as regards the collection of data referred to in paragraph 1 and 2;*
 - (c) *to provide specifications as regards the arrangements for participation in the databases referred to in paragraph 1 and in the systems as referred to in paragraph 4; and*

- (d) *to provide details as regards the information to be provided by Member States in accordance with Article 53(5).*

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

Article 27

Obligations and action in the event of suspicion of non-compliance

Where an operator suspects that a product he has produced, prepared, imported or that he has received from another operator is not in compliance with the requirements of this Regulation, that operator shall, subject to Article 28(2):

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

Article 28

Precautionary measures to avoid the presence of non-authorized products and substances

- 1. *In order to avoid contamination with products and substances that are not authorised to be used in organic production in accordance with Article 9(3) first subparagraph, operators shall take the following precautionary measures at all stages of production, preparation and distribution:***
 - (a) put in place and maintain proportionate and appropriate measures to identify risks of contamination of organic production and products with non-authorized products and substances, including systematic identification of critical procedural steps;***
 - (b) put in place and maintain proportionate and appropriate measures to avoid risks of contamination of organic production and products with non-authorized products and substances;***
 - (c) regularly review and adjust such measures; and***
 - (d) comply with other relevant requirements of this Regulation that ensure the separation of organic and non-organic products.***
- 2. *Where an operator suspects due to the presence of a product or substance that is not authorised in organic production pursuant to Article 9(3), first subparagraph in a product that is intended to be used or marketed as an organic or in-conversion product, that the latter product is not in compliance with the requirements of this Regulation, the operator shall:***

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

3. The Commission may adopt implementing acts laying down uniform rules specifying:

- the procedural steps to be followed by operators as referred to in paragraph 2(a) to (e) and the relevant documents to be provided by them;*
- the proportionate and appropriate measures to be adopted and reviewed by operators to identify and avoid risks of contamination as referred to in paragraph 1(a) to (c).*

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

Article 29

Measures to be taken in cases of the presence of non-authorised products and substances

- 1. *When a competent authority or, where appropriate, a control authority or control body receives substantiated information about the presence of products or substances that are not authorised in organic production pursuant to Article 9(3) first subparagraph, or is informed by an operator in accordance with Article 28(2) or detects such products or substances in an organic or an in-conversion product:***
 - (a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case, with a view to determine the source and the cause in view of verifying compliance with Article 9(3) and Article 28(1);***
 - (b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in-conversion products and their use in organic production while expecting the results of the investigation as referred to in point (a).***
- 2. *When the competent authority or, where appropriate, a control authority or control body, has established that the operator concerned:***
 - (a) has used products or substances not authorised in organic production pursuant to Article 9(3) first subparagraph; or***

- (b) has not taken the precautionary measures referred to in Article 28(1); or*
- (c) has not taken measures pursuant to relevant previous requests from the competent authorities, control authorities or control bodies,*

the product shall not be marketed as an organic or in-conversion product or used in organic production.

- 3. The operator concerned shall be given an opportunity to comment on the results of the investigation. The competent authority or, where appropriate, the control authority or control body shall keep records of the investigation carried out. Where required, the operator concerned shall take the necessary corrective measures to avoid future contamination.*
- 4. Four years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the state of play of implementation of this Article, on the presence of products and substances not authorised in organic production pursuant to Article 9(3) first subparagraph and on the assessment of national rules referred to in paragraph 5. This report may be accompanied, if appropriate, by a legislative proposal to provide for further harmonisation.*

5. *Member States having in place rules providing for products containing non-
authorised products and substances above a certain level not to be marketed as
organic products, may continue to apply these rules provided that these rules do
not prohibit, restrict or impede the placing on the market as organic products of
products produced in other Member States in compliance with the requirements of
this Regulation. Member States who apply this provision shall inform the
Commission without delay.*
6. *The results of the investigations referred to in paragraph 1 shall be documented by
competent authorities, together with any measures taken with a view to
formulating best practices and further measures to avoid the presence of products
and substances not authorised in organic production pursuant to Article 9(3).
Member States shall make this information available to the other Member States
and to the Commission via a computer system enhancing exchanges of documents
and information made available by the Commission.*
7. *Member States may take appropriate measures on their territory to avoid the
unintended presence of non-
authorised products and substances in organic
agriculture. Such measures shall not prohibit, restrict or impede the placing on the
market as organic or in-conversion of products produced in other Member States
in compliance with the requirement of this Regulation. Member States which apply
this provision shall inform the Commission and the other Member States without
delay.*

8. *The Commission shall adopt implementing acts laying down uniform rules specifying:*
- (a) the methodology on detection and evaluation of the presence of non-authorized products and substances to be applied by competent authorities or, where appropriate, by control authorities or control bodies;*
 - (b) the details and format of the information to be transmitted by Member States to the Commission and other Member States as referred to in paragraph 6.*
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*
9. *By 31 March of each year, Member States shall transmit electronically to the Commission the relevant information, including information collected at border control posts, relating to the previous year concerning the nature of contamination detected, and in particular the cause, the source, the level of contamination and the volume and nature of products contaminated. This information on findings of non-authorized products and substances shall be collected by the Commission through the computer system made available by the Commission and shall be used to facilitate the formulation of best practices to avoid contamination.*

Chapter IV
Labelling
Article 30

Use of terms referring to organic production

1. For the purposes of this Regulation, a product shall be regarded as bearing terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials are described in terms suggesting to the purchaser that the product, its ingredients or feed materials have been obtained in accordance with this Regulation. In particular, the terms listed in Annex IV, their derivatives or diminutives, such as 'bio' and 'eco', alone or combined, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products *referred to in Article 2(1)* which comply with this Regulation.
2. For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising and commercial documents of a product which does not comply with this Regulation.
Furthermore, any terms, including terms used in trademarks *or company names*, or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation shall not be used.

3. ***Products produced during the conversion period shall not be labelled or advertised as organic or in-conversion products. However, plant reproductive material and food and feed products of plant origin produced during the conversion period which are in compliance with Article 10(4) may be labelled and advertised as in-conversion products, using the term "in-conversion", or a corresponding term, together with the terms referred to in paragraph***
4. ***The terms referred to in paragraph 1 and 3 shall not be used for a product for which it has to be indicated in the labelling or advertising, in accordance with Union law, that it contains GMOs, consists of GMOs or is produced from GMOs.***
5. As regards processed food, the terms referred to in paragraph 1 may be used:
 - (a) in the sales description, ***and in the list of ingredients where such a list is mandatory according to Union legislation***, provided that:
 - (i) the processed food complies with the production rules set out in Part IV of Annex II ***and with the rules laid down in accordance with Article 16(3)***;
 - (ii) at least 95 % by weight of its agricultural ingredients are organic;
 - (iii) ***and, in case of flavourings, only for natural flavouring substances and natural flavouring preparation labelled in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 and when all their flavouring components and carriers of flavouring components are organic***;
 - (b) only in the list of ingredients ***provided that***:
 - (i) less than 95 % ***by weight*** of agricultural ingredients are organic and provided that those ingredients comply with the production rules set out in this Regulation;

- (ii) *the processed food complies with the production rules set out in points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3);*
- (c) *in the sales description and in the list of ingredients provided that:*
 - (i) *the main ingredient is a product of hunting or fishing;*
 - (ii) *the term referred to in paragraph 1 is clearly related in the sales description to another ingredient which is organic and different from the main ingredient;*
 - (iii) *all other agricultural ingredients are organic;*
 - (iv) *the food complies with points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3).*

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

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

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

6. *As regards processed feed, the terms referred to in paragraph 1 may be used in the sales description and in the list of ingredients provided that:*
 - (a) *the processed feed complies with the production rules set out in Parts II, III and V of Annex II and with the specific rules laid down in accordance with Article 16(3);*
 - (b) *all ingredients of agricultural origin contained in the processed feed are organic;*
 - (c) *at least 95 % of the product's dry matter are organic.*
7. **The Commission is** empowered to adopt delegated acts in accordance with Article 54 **:**
 - (a) *amending this Article by adding further rules on the labelling of products listed in Annex I, or by amending those added rules;*
 - (b) *amending* the list of terms set out in Annex IV, taking into account linguistic developments within the Member States **.**

8. ***The Commission may adopt implementing acts to set detailed requirements for the application of paragraph 3.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).***

Article 31

Labelling of products and substances used in crop production

Notwithstanding the scope of this Regulation as set out in Article 2(1), a product or substance used in a plant protection product or as fertiliser, soil conditioner or nutrient authorised in accordance with Article 9 and Article 24 may bear a reference indicating that the product or substance is authorised for use in organic production in accordance with this Regulation.

Article 32

Compulsory indications

1. Where ***products bear*** terms as referred to in Article 30(1), ***including products labelled as in-conversion in accordance with Article 30(3):***
- (a) the code number of the control authority or control body to which the operator who has carried out the last production or preparation operation is subject, shall also appear in the labelling;
 - (b) in the case of pre-packed food, the organic production logo of the European Union referred to in Article 33 ■ shall also appear on the packaging, ***except in cases referred to in Article 30(3), (5)(b) and (c).***

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

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

The word 'Agriculture' may be replaced by 'Aquaculture' where appropriate.

The indication 'EU' or 'non-EU' may be replaced or supplemented by the name of a country ***or by the name of a country and a region*** if all agricultural raw materials of which the product is composed have been farmed in that country ***and, if applicable, that region.***

For the indication 'EU' or 'non-EU' *or of the name of the country and region as referred to in the third subparagraph*, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 5 % of the total quantity by weight of agricultural raw materials.

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

3. The indications referred to in paragraphs 1 and 2 of this Article and in Article 33(3) shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
4. **█** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 *amending* paragraph 2 of this Article and in Article 33(3) *by adding further* rules on labelling **█**, or by amending those added rules **█**.
5. The Commission shall adopt implementing acts relating to the following:
 - (a) **█** practical modalities as regards the *use*, presentation, composition and size of the indications referred to in point (a) of paragraph 1 and in paragraph 2 of this Article and in Article 33(3);

- (b) the assignment of code numbers to control authorities and control bodies;
- (c) the indication of the place where the agricultural raw materials have been farmed, in accordance with paragraph 2 of this Article and Article 33(3).

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

Article 33

Organic production logo of the European Union

1. The organic production logo of the European Union may be used in the labelling, presentation and advertising of products which comply with this Regulation.
The organic production logo may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that the use is not liable to mislead the consumer as regards the organic production of specific products and provided that the logo is reproduced in accordance with the rules set out in Annex V. In this case, the requirements of Article 32(2) and point 1.7 of Annex V shall not apply.
The organic production logo of the European Union shall not be used for processed food as referred to in Article 30(5)(b) and (c) or for in-conversion products as referred to in Article 30(3).

2. ***Except where used in accordance with the second sub-paragraph of paragraph 1,*** the organic production logo of the European Union is an official attestation in accordance with Article 85 and 90 of Regulation (EU) **2017/625**.
3. The use of the organic production logo of the European Union shall be optional for products imported from third countries. In addition, where that logo appears in the labelling, the indication referred to in Article 32(2) shall also appear in the labelling.
4. The organic production logo of the European Union shall follow the model set out in Annex V and shall comply with the rules set out in that Annex.
5. National and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation.
6. **■** ***The*** Commission ***is*** empowered to adopt delegated acts in accordance with Article 54 amending ***Annex V as regards*** the organic production logo of the European Union and the rules relating thereto **■** .

Chapter V
Certification
Article 34

Certification system

1. Operators or groups of operators *as referred to in Article 36 who* produce, prepare, *distribute* or store organic *or in-conversion* products, who import such products from a third country or export such products to a third country, or who place such products on the market **■**, prior to **■** placing on the market *any products as ‘organic’ or as ‘in-conversion’* or prior to *the conversion period shall* notify their activity to the *competent authorities of the* Member State *in which their* activity is carried out *and in which their undertaking is submitted to the control system.* *In case the competent authorities have conferred their responsibilities or delegated specific official controls tasks or other official activities to more than one control authority or control body, the operators or groups of operators shall indicate in the notification referred to in the first subparagraph, the control authority or the control body that verifies the compliance of their activity with this Regulation and provides the certificate referred to in Article 35(1).*

2. ***Operators who sell pre-packed organic products directly to the final consumer or user, provided that they do not produce, prepare or store such products other than in connection with the point of sale, do not import such products from a third country or have not subcontracted such activities to another operator, are exempted from the notification obligation referred to in paragraph 1 and from the obligation to be in the possession of a certificate referred to in Article 35(2).***
3. ***Where operators or groups of operators subcontract any of their activities to third parties, both the operators or groups of operators and the third parties to whom activities have been subcontracted, shall comply with paragraph 1, except where the operator or groups of operators declares in the notification referred to in paragraph 1 that the responsibility as regards organic production remains with the operator or groups of operators and is not transferred to the subcontractor. In such cases the compliance of the subcontracted activities with this Regulation is verified by the competent authorities, or where appropriate by the control authority or control body, in the framework of the control of the operators or groups of operators who have subcontracted their activities.***
4. ***Member States may designate an authority or approve a body to receive the notifications referred to in paragraph 1.***

5. Operators **■**, groups of operators, *and subcontractors* shall keep records in accordance with this Regulation on the different activities they engage in **■**.
6. *Member States* shall keep **■** updated *lists* containing the names and addresses of operators and groups of operators that have notified their activities in accordance with paragraph 1 and shall make **■** public *in an appropriate manner, including by means of links to a single internet website, a comprehensive list of this data,* together with the information relating to their **■** certificates as referred to in Article 35(1). *Member States* shall respect the requirements of the protection of personal data under *Regulation (EU) 2016/679* of the European Parliament and of the Council.
7. Member States shall ensure that *any operator or group of operators who complies with this Regulation, and who, if a fee is collected in accordance with Articles 78 and 80 of Regulation (EU) 2017/625, pays a reasonable fee covering the cost of controls, is entitled to be covered by the control system and that fees that may be collected* are made public.
8. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 *amending Annex II as regards the requirements for keeping records.*

9. The Commission may adopt implementing acts to provide details and specifications regarding:
- (a) *the format and technical means of the notification referred to in paragraph 1,*
 - (b) *the modalities of the publication of the lists referred to in paragraph 6, and*
 - (c) *the procedures and modalities of publication of the fees referred to in paragraph 7.*

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

Article 35

Certificate

1. ***Competent authorities or, where appropriate, control authorities or control bodies shall provide a certificate to any operator or group of operators that have notified their activity in accordance with Article 34(1) and comply with this Regulation. The certificate shall be issued in electronic form wherever possible, shall at least allow the identification of the operator or group of operators including the list of the members, the category of products covered by the certificate and its period of validity and shall certify that the notified activity is in compliance with this Regulation and shall be issued in accordance with the model set out in Annex VI.***

2. ***Without prejudice to paragraph 8 of this Article and to Article 34(2), operators and groups of operators shall be in possession of a certificate as referred to in paragraph 1 prior to the placing on the market of products referred to in Article 2(1) as organic or in-conversion.***
3. ***The certificate referred to in this Article shall be an official certificate within the meaning of Article 86(1)(a) of Regulation (EU) 2017/625.***
4. Operators and groups of operators shall not be entitled to be provided with a **█** certificate by ***more than one control body for activities carried out in one Member State, as regards*** the same ***category*** of products, including when those operators and groups of operators engage in different stages of production, preparation and distribution.
5. Members of a group of operators shall not be entitled to be provided with an individual **█** certificate for any of the activities covered by the certification of the group.
6. Operators shall **█** verify the **█** certificate of operators that are their suppliers.

7. *The categories of products referred to in paragraphs 1 and 4 are the following:*
- (a) unprocessed plants and plant products, including seed and other plant reproductive material;*
 - (b) livestock and unprocessed livestock products;*
 - (c) algae and unprocessed aquaculture products;*
 - (d) processed agricultural products, including aquaculture products, for use as food;*
 - (e) feed;*
 - (f) wine,*
 - (g) other products listed in Annex I to this Regulation or not covered by the previous categories.*
8. *Member States may exempt from the obligation to be in the possession of a certificate, as referred to in paragraph 2, operators who sell directly to the final consumer unpacked organic products other than feed:*
- (a) up to 5000 kilogrammes per year, or*

(b) representing an annual turnover not exceeding 20 000 EUR on unpacked organic products, or

(c) with a potential certification cost exceeding 2 % of the total turnover on unpacked organic products,

provided that those operators do not produce, prepare or store such products other than in connection with the point of sale, do not import such products from a third country or have not subcontracted such activities to a third party.

In case Member States decide to exempt the operators referred to in the first subparagraph, they may set lower limits than those set in the first subparagraph. Member States shall inform the Commission and the other Member States of their decision to exempt operators as referred to in the first subparagraph and on the limits up to which such operators are exempted.

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

- 10. The Commission shall adopt implementing acts to provide details and specifications regarding the form of the certificate referred to in paragraph 1 and the technical means by which it is issued.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).**

Article 36

Group of operators

1. Each group of operators shall:
- (a) only be composed of farmers or operators producing algae or aquaculture animals and who in addition may be engaged in processing, preparation or marketing of food or feed;**
 - (b) only be composed of members:**
 - (i) of which the individual certification cost represents more than 2 % of its turnover or standard output of organic production and whose annual turnover of organic production is not more than 25 000 EUR or whose standard output from of organic production is not more than 15 000 EUR per year; or**

- (ii) *which have each holdings of maximum:*
 - 5 hectares, or
 - 0,5 hectares, in the case of greenhouses, or
 - 15 hectares, exclusively in the case of permanent grassland;
 - (c) *be established in a Member State or a third country;*
 - (d) *have legal personality;*
 - (e) *only be composed of members whose production activities take place in geographical proximity to each other;*
 - (f) *set up a joint marketing system for the products produced by the group; and*
 - (g) *establish a system for internal controls comprising a documented set of control activities and procedures, in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group.*
2. Deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators that affect the integrity of organic *and in-conversion* products, *shall* result in the withdrawal of the *certificate referred to in Article 35* for the whole group.

3. **■** *The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 1 and 2 of this Article by adding provisions, or by amending those added provisions, in particular as regards:*
- (a) *the responsibilities of the individual members of a group of operators;*
 - (b) *the criteria to determine the geographical proximity of the members of the group, such as the sharing of facilities or sites;*
 - (c) *the set-up and functioning of the ■ system for internal control, including the scope, content and frequency of the controls to be carried out and the criteria to identify deficiencies in the set-up or functioning of the system for internal controls.*
4. The Commission may adopt implementing acts *laying down specific rules* concerning:
-
- (a) *the composition and dimension of a group of operators;*
 - (b) *the documents and record keeping systems, the system for internal traceability and the list of operators;*
 - (c) *the exchange of information between a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission.*
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

Chapter VI
Official controls and other official activities

Article 37

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

Article 38

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

- 1. Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with the requirements laid down in this Regulation shall include, in particular,***
 - (a) the verification of the application by operators of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of this Regulation, at all stages of production, preparation and distribution;***

- (b) in the cases where the holding includes non-organic and/or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units, between products produced by the organic, in-conversion and/or non-organic production units, and of the substances and products used for organic and non-organic production units; such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period and checks on the non-organic production units;**
- (c) in the cases where organic, in-conversion and non-organic products are collected simultaneously by operators, or prepared or stored in the same preparation unit or area or premise, or transported to other operators or units, the verification of the records and of the measures or procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and, as appropriate, measures to prevent substitution of products are implemented, that organic products are identified at all times and stored, before and after the preparation operations, separated by place or time from non-organic products;**

- (d) the set-up and functioning of the internal control system of groups of operators;*
 - (e) in the cases where operators are exempted from the notification obligation as provided for in Article 34(2), and where operators are exempted from the obligation to be in the possession of a certificate as provided for in Article 35(8) of this Regulation, the verification that the requirements for the exemption are fulfilled and the verification of the products sold by these operators.*
- 2. Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with the requirements laid down in this Regulation shall be performed throughout the entire production process at all stages of production, preparation and distribution on the basis of the likelihood of non-compliance as defined in Article 3(57), which shall be determined taking into account, in addition to the elements referred to in Article 9 of Regulation (EU) 2017/625, in particular the following elements:**
 - (a) the type, size and structure of the operators and groups of operators;*
 - (b) the length of time during which operators and groups of operators have been in organic production, preparation and distribution;*
 - (c) the results of the controls performed in accordance with this Article;*
 - (d) the point in time relevant for the activities carried out;*

- (e) the product categories;*
 - (f) the type, quantity and value of products and their development over time;*
 - (g) the possibility of commingling of products or contamination with unauthorised products or substances;*
 - (h) the application of derogations or exceptions to the rules by operators and groups of operators;*
 - (i) the critical points for non-compliance and likelihood of non-compliance at all stages of production, preparation and distribution;*
 - (j) subcontracting activities.*
- 3. In any case, all operators and groups of operators with the exception of those referred to in Articles 34(2) and 35(8) shall be subject to a verification of compliance at least once a year.**
- The verification of compliance shall include a physical on-the-spot inspection except when operators and groups of operators comply with the following conditions:**
- (a) the previous controls of the operator or group of operator concerned have not revealed any non-compliance affecting the integrity of organic or in-conversion products during at least three consecutive years; and*

(b) the operator or groups of operators concerned have been assessed on the basis of the elements referred to in paragraph 2 and in Article 9 of Regulation (EU) 2017/625 as presenting low likelihood of non-compliance.

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

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

(a) be performed in accordance with Article 9(4) of Regulation (EU) 2017/625 while ensuring that a minimum percentage of all official controls of operators or groups of operators are carried out without prior notice;

(b) ensure that a minimum percentage of additional controls to those referred in paragraph 3 are carried out;

(c) be carried out by taking a minimum number of the samples taken in accordance with Article 14(h) of Regulation (EU) 2017/625;

(d) ensure that a minimum number of operators that are members of a group of operators are controlled in the framework of the verification of compliance referred

- to in paragraph 3.*
5. *The delivery or the renewal of the certificate referred to in Article 35(1) shall be based on the results of the verification of compliance as described in paragraphs 1 to 4.*
 6. *The written record to be drawn up on each official control performed to verify compliance with the rules laid down in this Regulation in accordance with paragraph 1 of Article 13 of Regulation (EU) 2017/625 shall be countersigned by the operator or groups of operators to confirm the receipt of that written record.*
 7. *Paragraph 1 of Article 13 of Regulation (EU) 2017/625 shall not apply to the audits and inspections carried out by competent authorities in the context of their supervisory activities over control bodies to which specific official control tasks and other official activities were delegated.*
 8. *The Commission is empowered to adopt delegated acts in accordance with Article 54:*
 - (b) *supplementing this Regulation by laying down specific criteria and conditions for the performance of official controls aimed at ensuring the traceability at all stages of production, preparation and distribution, and compliance with the requirements laid down in this regulation, as concerns:*
 - (i) *checks of documentary accounts;*
 - (ii) *controls performed on specific categories of operators;*

Article 39

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

- 1.** *In addition to the obligations laid down in Article 15 of Regulation (EU) 2017/625, operators and groups of operators shall:*
- (a) keep records to demonstrate compliance with the requirements of this Regulation;*
 - (b) make all necessary declarations and other communications to support official controls;*
 - (c) take relevant practical measures to ensure compliance with the requirements of this Regulation;*
 - (d) provide, in form of a declaration to be signed and updated as necessary:*
 - (i) the full description of the organic or in-conversion production unit and of the activities to be performed in accordance with this Regulation;*
 - (ii) the relevant practical measures to be taken to ensure compliance with the requirements of this Regulation;*
 - (iii) an undertaking:*

- *in the event of a substantiated suspicion of non-compliance, a suspicion of non-compliance that cannot be eliminated, or of an established non-compliance affecting the integrity of the products, to inform in writing and without due delay buyers of the products and to exchange relevant information with the competent authority or, where appropriate, with the control authority or control body,*
- *to accept the transfer of the control file in case of change of control authority or control body or, in case of withdrawal from organic production, the keeping of the control file for at least five years by the last control authority or control body,*
- *in the event of withdrawal from organic production to immediately inform the competent authority or the authority or body designated according to the provisions of Article 34(4),*
- *in case subcontractors are checked by different control authorities or control bodies to accept the exchange of information among these authorities or bodies.*

2. *The Commission may adopt implementing acts to provide details and specifications regarding:*
- (a) *the records to demonstrate compliance with the requirements of this Regulation;*

- (b) the necessary declarations and other communications to support official controls;**
- (c) the relevant practical measures to ensure compliance with the requirements of this Regulation.**

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

Article 40

Additional rules on the delegation of certain tasks related to official controls and other official activities

- 1. Competent authorities may delegate to control bodies specific official control tasks and other official activities only if the following conditions, in addition to those set out in Chapter III of Regulation (EU) 2017/625, are complied with:**
 - (a) the delegation contains a detailed description of the delegated control tasks and other official activities, including reporting and other specific obligations, and of the conditions under which the control body may carry them out. In particular the control body shall submit to the competent authorities for prior approval:**
 - (i) its risk assessment procedure, determining in particular the basis for the intensity and frequency of the verification of compliance of the operators and groups of operators and established on the basis of the elements referred to in Article 9 of Regulation (EU) 2017/625 and of Article 38 of this Regulation, to be followed for the performance of official controls on operators and groups of operators;**

- (ii) the standard control procedure in place, containing a detailed description of the control measures that the control body undertakes to apply to operators and groups of operators subject to its controls;*
- (iii) a list of measures, in conformity with the common catalogue as referred to in Article 41, to be applied to operators and groups of operators in case of established non-compliance as well as in case of suspicion of non-compliance;*
- (iv) the arrangements for effective monitoring and reporting on the official control tasks and other official activities performed on operators and groups of operators.*

Any subsequent amendment of the elements referred to in points (i) to (iv) shall be notified by the control body to the competent authority;

- (b) competent authorities have procedures and arrangements in place to ensure the supervision of control bodies, including the verification of the effectiveness, independence and objectiveness of the way in which the delegated tasks are carried out, in particular as regards the intensity and frequency of the verification of compliance;*

- (c) competent authorities organise at least once a year audits pursuant to Article 33(a) of Regulation (EU) 2017/625 of the control bodies to whom they have delegated official control tasks and other official activities.*
- 2. *By way of derogation from Article 31(3) of Regulation (EU) 2017/625, competent authorities may delegate to a control body the decision concerning the tasks provided for in point (b) of Article 138(1) and in Article 138(2) and (3) of that Regulation.***
- 3. *For the purpose of Article 29(b)(iv) of Regulation (EU) 2017/625, the relevant standard in the area covered by this Regulation for the delegation of specific official control tasks and other official activities to verify compliance with this Regulation is the most recently notified version of the international harmonised standard ‘General requirements for bodies operating product certification systems’, the reference of which has been published in the Official Journal of the European Union.***
- 4. *Competent authorities shall not delegate to control bodies:***
- (a) the supervision and audit of other control bodies or control authorities;*
 - (b) the possibility to grant derogations except for the use of plant reproductive material not obtained from organic production;*

- (c) the reception of the notification of the activity by operators or groups of operators, as referred to under Article 34(1) of this Regulation;*
 - (d) the assessment of the likelihood of non-compliance with the provisions laid down in this Regulation determining the frequency rate of the physical checks to be performed on organic consignments prior to their release for free circulation into the Union according to Article 54 of Regulation (EU) 2017/625;*
 - (e) the establishment of the common catalogue of measures as referred to in Article 41.*
- 5. Competent authorities shall not delegate to natural persons tasks related to official controls and other official activities.*
 - 6. Competent authorities shall ensure that information received from control bodies on the basis of Article 32 of Regulation (EU) 2017/625 and information on the measures applied by control bodies in case of established or likely non-compliance is collected and used by the competent authorities in order to supervise the activities of those controls bodies.*
 - 7. In case of full or partial withdrawal of the delegation of specific official control tasks and other official activities in accordance with Article 33 of Regulation (EU) 2017/625, competent authorities shall decide on the validity of the certificates beyond the date of the decision on partial or full withdrawal issued by the control bodies concerned before the date of that partial or full withdrawal and shall inform the operators.*

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

- (a) for a time period that shall not exceed 12 months and during which the control body shall take action to remedy shortcomings identified during audits and inspections or address non-compliances for which information is exchanged with other control authorities and control bodies, competent authorities as well as with the Commission according to Article 43; or**
- (b) for the time period during which accreditation as referred to in Article 29(b)(iv) of Regulation (EU) 2017/625 and Article 40(3) of this Regulation is suspended.**

In case of suspension of the delegation on official controls and other official activities, control bodies concerned shall not issue organic certificates for the parts for which the delegation has been suspended. Competent authorities shall decide on the validity beyond the date of suspension of the certificates issued before the partial or full suspension and shall inform the operators concerned on this decision.

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

9. *Where a control body to whom competent authorities have delegated specific official control tasks or other official activities has also been recognised by the Commission in accordance with Article 46(1) of this Regulation for carrying out control activities in third countries, and the Commission intends to withdraw or has withdrawn the recognition of this control body, competent authorities shall organise audits and inspections on the control body as regards its activities in the Member State(s) concerned, in accordance with Article 33 of Regulation (EU) 2017/625.*
10. *The control bodies shall transmit to the competent authorities:*
 - (a) *by 31 January of each year, a list of the operators which were subject to their controls on 31 December of the previous year;*
 - (b) *by 31 March of each year, information on the official controls and other official activities carried out in the previous year to support the preparation of the part on organic production and labelling of organic products of the annual report referred to in Article 113 of Regulation (EU) 2017/625.*

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

Article 41

Additional rules on actions in case of non-compliance

1. *Subject to Article 29, where a competent authority or, where appropriate, a control authority or control body suspects or receives substantiated information, including from other competent authorities or where appropriate from control authorities or control bodies, that an operator intends to use or to place on the market a product that may not be in compliance with the requirements of this Regulation but bearing terms referring to the organic production, or is informed by an operator in accordance with Article 27:*
- (a) it shall immediately carry out an official investigation in accordance with Regulation (EU) 2017/625 to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case, with a view to verify compliance with the requirements of this Regulation;*
 - (b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in-conversion products and their use in organic production while expecting the results of the investigation referred to in point (a). Before taking such a decision, the competent authority or, where appropriate, the control authority or control body shall give the operator an opportunity to comment.*

2. *In case the results of the investigation referred to in paragraph 1(a) do not show any non-compliance affecting the integrity of organic or in-conversion products, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products.*
3. *Member States shall take any measures and provide for sanctions required to prevent fraudulent use of the indications referred to in Chapter IV of this Regulation.*
4. *Competent authorities shall provide a common catalogue of measures for cases of suspicion of non-compliance and established non-compliance to be applied in their territory including by control authorities and control bodies.*
5. *The Commission may adopt implementing acts to specify uniform arrangements for the cases where competent authorities are to take measures in relation to suspicion of non-compliance or to established non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*

Article 42

Additional rules on measures in case of non-compliance

- 1. In the event of non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, such as due to use of non-authorized products and substances and techniques or commingling with non-organic products, competent authorities and, as appropriate, control authorities and control bodies shall ensure, in addition to the measures to be taken in accordance with Article 138 of Regulation (EU) 2017/625 that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned.***
- 2. In the event of serious, or repetitive or continued non-compliance, competent authorities and, as appropriate, control authorities and control bodies shall ensure that the operators or the groups of operators concerned, in addition to the measures specified in paragraph 1 and any appropriate measures taken in particular in accordance with Article 138 of Regulation (EU) 2017/625, are prohibited from marketing products which refer to organic production for a given period, and that their organic certificate be suspended or withdrawn as appropriate.***

Article 43

Additional rules on the exchange of information

- 1. *In addition to the obligations laid down in Article 105(1) and Article 106(1) of Regulation (EU) 2017/625, competent authorities, shall immediately share information with other competent authorities, as well as with the Commission on any suspicion of non-compliance affecting the integrity of organic or in-conversion products.
Competent authorities shall share that information with other competent authorities and the Commission via a computer system enabling electronic exchanges of documents and information made available by the Commission.***
- 2. *In case of suspicion of non-compliance or established non-compliance identified with regard to products under the control of other control authorities or control bodies, control authorities and control bodies shall immediately inform those other control authorities or control bodies.***
- 3. *Control authorities and control bodies shall exchange other relevant information with other control authorities and control bodies.***
- 4. *Upon a request duly justified by the need to guarantee that a product has been produced in accordance with this Regulation, control authorities and control bodies shall exchange information on the results of their controls with other competent authorities, as well as with the Commission.***

5. *Competent authorities shall exchange information on the supervision of the control bodies with the national accreditation bodies as referred to in Article 2(11) of Regulation (EC) No 765/2008 of the European Parliament and of the Council¹.*
6. *Competent authorities shall take appropriate measures and establish documented procedures in order to ensure that information on the results of controls is communicated to the paying agency in accordance with the needs of that paying agency for the purpose of Article 58 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council² and the acts adopted on the basis thereof.*
7. *The Commission may adopt implementing acts specifying the information to be provided by the competent authorities, the control authorities and control bodies in charge of the official controls and other official activities in accordance with this Article, the relevant recipients of this information and the procedures in accordance with which this information shall be provided, including the functionalities of the computer system referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*

¹ *Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).*

² *Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).*

Chapter VII
Trade with third countries
Article 44

Export of organic products

1. A product may be exported from the Union as an organic product and may bear the organic production logo of the European Union if it complies with the rules for organic products under this Regulation.
2. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 *supplementing this Regulation as regards* documents intended for customs authorities in third countries, in particular **■** an organic export certificate issued in electronic form wherever possible and providing assurance that exported organic products comply with this Regulation.

Article 45

Import of organic products

1. A product may be imported from a third country in order to be placed on the market within the Union as *an* organic product *or as an in-conversion product* if the following conditions are met:
 - (a) the product is *a* product as referred to in Article 2(1);
 - (b) the product:

(i) complies with Chapters II, III and IV and all operators, **and groups of operators as referred to in Article 36** including the exporters in the third country concerned, have been subject to the control of control authorities or control bodies recognised in accordance with Article 46 **and are provided by these authorities or bodies with a certificate confirming that all operators or groups of operators are in compliance with this Regulation;**

or

(ii) **comes from a third country which is recognised in accordance with Article 47 and complies with the conditions laid down in the relevant trade agreement;**

or

(iii) comes from a third country which is recognised in accordance with Article 48 **and complies with the equivalent production and control rules of that third country and is imported with a certificate of inspection issued by the competent authorities, control authorities or control bodies of that third country confirming this compliance;**

(c) the operators in third countries are able to provide at any time, to the importers **and** the national authorities in the Union **and in the third countries**, information **enabling** the identification of the operators **that are their suppliers and control authorities or control bodies of those suppliers**, with a view to ensuring the traceability of the organic **or in-conversion** product **concerned. That information shall also be made available to the control bodies or the control authorities of the importers.**

2. *The Commission may in accordance with the procedure set out in Article 24(9) grant specific authorisations for the use of products and substances in third countries and in the outermost regions of the Union, taking into account differences in the ecological balance in plant or animal production, specific climatic conditions, traditions and local conditions in these areas. Such specific authorisations may be granted for a renewable period of two years and shall be subject to the principles laid down in Chapter II and to the criteria of Article 24(3) and (6).*
3. *When providing for the criteria for situations to qualify as catastrophic circumstances and laying down specific rules on how to deal with them in accordance with Article 22, the Commission shall also take into account differences in the ecological balance, climate and local conditions in third countries and in the outermost regions of the Union;*
4. **■** *The Commission shall **■** adopt implementing acts laying down specific rules concerning the content of the certificates referred to in paragraph 1, the procedure to be followed for their issuance, their verification and the technical means by which the certificate is issued, in particular as regards the role of competent authorities, control authorities and control bodies, ensuring the traceability and compliance of imported products intended to be placed on the Union market as organic products or as in-conversion products as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).*

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

Article 46

Recognition of control authorities and control bodies

1. The Commission may adopt implementing acts recognising, or withdrawing the recognition of, control authorities and control bodies **■** competent to carry out controls **and to issue an organic certificate** in third countries, and establishing a list of those control authorities and control bodies.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).
2. **Control authorities or control bodies shall be recognised as referred to in paragraph 1 for the control of import of the categories of products listed in Article 35(7) if they fulfil the following criteria:**

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

3. The accreditation referred to in paragraph 2(d) may only be granted by:
 - (a) a national accreditation body in the Union in accordance with Regulation (EC) No 765/2008 **■** ; or
 - (b) an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.
4. ***Control authorities and control bodies shall submit to the Commission a request for recognition consisting of a technical dossier containing all the information needed to ensure that the criteria set out in paragraph 2 are met.***

The **■** control bodies or control authorities shall provide the ***accreditation*** certificate issued by the accreditation body or respectively the ***latest*** assessment report issued by the competent authority, and, as appropriate, ***latest*** reports on the regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities.
5. Based on the information referred to under paragraph 4 ***and on any other relevant information related to the control authority or control body***, the Commission shall ensure appropriate supervision of the recognised control authorities and control bodies by regularly reviewing their ***performance and*** recognition. For the purposes of that supervision, the Commission may request additional information from the accreditation bodies or, ***where*** appropriate, the competent authorities.

6. The nature of the supervision shall be determined on the basis of an assessment of the *likelihood* of non-compliance *taking into account in particular the activity of the control authority or control body, the type of products and operators under its control and the changes in the production standard and control measures.*
The recognition of control authorities or of control bodies referred to in paragraph 1 shall in particular be withdrawn without delay in accordance with the procedure referred to in paragraph 1 when serious or repetitive infringements as regards the certification or the controls and actions laid down in accordance with paragraph 7a have been detected and when the control body or control authority concerned fails to take appropriate and timely remedial action after request of the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days.
7. *The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraph 2 of this Article by adding further criteria to those laid down therein to be applied to the recognition, or the withdrawal of the recognition, of the control authorities and control bodies referred to in paragraph 1 of this Article, or by amending those added criteria.*

8. ***The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards the exercise of the supervision of the control authorities and control bodies recognised by the Commission in accordance with paragraph 1, including through on-the-spot examination, and as regards the controls and other actions to be performed by those control authorities and control bodies.***
9. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance, ***in particular those*** affecting the integrity of organic ***or in-conversion*** products imported under the recognition provided for in this Article **■** or suspicion of such cases. Such measures may consist in particular in the verification of the integrity of **■** organic ***or in-conversion*** products before placing the products on the market within the Union and, where appropriate, the suspension of the authorisation of placing on the market within the Union of such products as organic ***products or in-conversion products***.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).
10. On duly justified imperative grounds of urgency relating to the protection against 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, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 55(3) to take the measures referred to in paragraph 9 of this Article or to decide on the withdrawal of the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article.

Article 47

Equivalence under a trade agreement

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

■

Article 48

Equivalence under Regulation (EC) No 834/2007

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

The recognition of the third countries referred to in the first subparagraph shall expire on [**5 years following the date of application of *this* Regulation**].

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

█

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

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

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

5. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance, *in particular those* affecting the integrity of organic *or in-conversion* products imported from third countries referred to in this Article **■** or suspicion of such cases. Such measures may consist in particular in the verification of the integrity of **■** organic *or in-conversion* products before placing the products on the market within the Union and, where appropriate, the suspension of the authorisation of placing on the market within the Union of such products as organic *products or in-conversion products*.

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

Article 49

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

Chapter VIII

General provisions

SECTION 1

Free movement of organic products

Article 50

Non-prohibition and non-restriction of the marketing of organic products

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

█

SECTION 2

Information, ■ reporting and related derogations

Article 51

Information relating to the organic sector and trade

1. Each year Member States shall transmit to the Commission the information necessary for the implementation and monitoring of the application of this Regulation. ***As far as possible, such information shall be based on established sources of data. The Commission shall take into account the data needs and synergies between potential data sources, in particular their use for statistical purposes when appropriate.***
2. The Commission shall adopt implementing acts as regards the system to be used for transmitting the information referred to in paragraph 1, the details of information to be transmitted, and the date by which that information is to be transmitted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

Article 52

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

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

Insofar as this is not already required under Article 4(4) of Regulation (EU) 2017/625, Member States shall transmit these lists, and any change thereof, to the Commission and make them public.

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

Article 53

Derogations, authorisations and report

- 1.** *The derogations to the use of organic plant reproductive material and of animals, provided in points 1.8.52 of Part I of Annex II and points 1.3.4.3 and 1.3.4.4 of Part II of Annex II, with the exception of point 1.3.4.4.2 of Part II of Annex II, shall end 15 years after the date of application.*
- 2.** *As of 7 years after the date of application, based on the conclusions as regards availability of organic plant reproductive material and animals presented in the report provided for under paragraph 3, the Commission shall be empowered to adopt delegated acts in accordance with Article 54 amending this Regulation as follows:*
 - (a) ending at an earlier date or extending the derogations referred to in points in point 1.8.5 of Part I of Annex II and in points 1.3.4.3 and 1.3.4.4 of Annex II, Part II, with the exception of point 1.3.4.4.2 of Part II of Annex II, beyond 15 years after the date of application or;*
 - (b) ending the derogation referred to in point 1.3.4.4.2 of Part II of Annex II.*

3. *As of 5 years after the date of application, the Commission shall be empowered to adopt delegated acts in accordance with Article 54:*
- (a) amending Article 26(2)(b) to extend the scope of the information system referred to in Article 26(2) to pullets and point 1.3.4.3 Annex II, part II to base the derogations concerning pullets on the data collected in accordance with this system;*
 - (b) based on the information as regards availability of organic protein feed for poultry and porcine animals made available by Member States in accordance with paragraph 5 or presented in the report provided for under paragraph 6, ending at an earlier date than the date laid down in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II or extending beyond this date, the authorisations to use non-organic protein feed in the nutrition of poultry and porcine animals referred to in these points.*
4. *When extending the derogations or authorisations referred to in paragraphs 2 and 3, the Commission shall do so only for as long as it has information, in particular provided by Member States in accordance with paragraph 5, that confirms the unavailability on the market.*

5. ***By 30th June of each year, Member States shall make available to the Commission and to the other Member States information provided in the database, as referred to in Article 26, paragraph 1 and in the systems referred to in paragraph 2 thereof and, if relevant, in the systems referred to in Article 26(3), information relating to the derogations granted in accordance with point 1.8.5 of Part I of Annex II and points 1.3.4.3 and 1.3.4.4 of Part II of Annex II and information on the availability on the market of the Union of organic protein feed for poultry and porcine animals and on the authorisations granted in accordance with points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II.***
6. ***5 years after the date of application, the Commission shall present a report to the European Parliament and the Council on the availability on the Union market of and, if relevant on the causes of limited access to:***
 - (a) organic plant reproductive material,***
 - (b) organic animals covered by the derogations referred to in points 1.3.4.3 and 1.3.4.4 of Part II of Annex II,***
 - (c) organic protein feed intended for the nutrition of poultry and porcine animals and the authorisations referred to in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II.***

In drawing up this report, the Commission shall take into account in particular the data collected in accordance with Article 26 and the information related to the derogations and the authorisations referred to in paragraph 5 of this Article.

Chapter IX

Procedural, transitional and final provisions

SECTION 1

Procedural provisions

Article 54

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. ***The power to adopt delegated acts referred to in Articles 2(6), 9(11), 10(5), 12(2), 13(3), 14(2), 15(2), 16(2), 17(2), 18(2), 19(2), 21(1), 22(1), 23(2), 24(6), 26(5), 30(7), 32(4), 33(6), 34(8), 35(9), 36(3), 38(8), 40(11), 44(2), 46(7) and (8), 48(4), 53(2) and (3), 57(3) and 58(2) shall be conferred on the Commission for a period of five years from the date of application of this Regulation. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in *Articles 2(6), 9(11), 10(5), 12(2), 13(3), 14(2), 15(2), 16(2), 17(2), 18(2), 19(2), 21(1), 22(1), 23(2), 24(6), 26(5), 30(7), 32(4), 33(6), 34(8), 35(9), 36(3), 38(8), 40(11), 44(2), 46(7) and (8), 48(4), 53(2) and (3), 57(3) and 58(2)* may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. ***Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter institutional Agreement of 13 April 2016 on Better Law-Making.***
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to *Articles 2(6), 9(11), 10(5), 12(2), 13(3), 14(2), 15(2), 16(2), 17(2), 18(2), 19(2), 21(1), 22(1), 23(2), 24(6), 26(5), 30(7), 32(4), 33(6), 34(8), 35(9), 36(3), 38(8), 40(11), 44(2), 46(7) and (8), 48(4), 53(2) and (3), 57(3) and 58(2)* shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 55

Committee procedure

1. The Commission shall be assisted by a *committee* called the ‘Organic **Production** Committee’. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.
4. ***In the case of implementing acts referred to in this Regulation where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***

SECTION 2

Repeal, ■ transitional and final provisions

Article 56

Repeal

Regulation (EC) No 834/2007 is repealed.

However, Regulation (EC) No 834/2007 shall continue to apply for the purposes of completing the examination of pending applications from third countries, as provided for in Article 42 of this Regulation.

■

Article 57

Transitional measures relating to control authorities and control bodies recognised under

Article 33(3) of Regulation (EC) No 834/2007

1. The recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007 shall expire ***at the latest three years after the date of application of this Regulation.***

2. The Commission shall, by means of an implementing act, establish a list of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and may amend that list by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).
3. **■** *The Commission is* empowered to adopt delegated acts in accordance with Article 54 *supplementing this Regulation as regards* the information to be sent by *the* control authorities and control bodies *referred to in paragraph 2 of this Article which is* necessary for the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.

Article 58

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

1. The Commission shall complete the examination of applications from third countries submitted under Article 33(2) of Regulation (EC) No 834/2007 which are pending at the date of entry into force of this Regulation. Regulation (EC) No 834/2007 shall apply to the examination of such applications.

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

Article 59

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

By way of derogation from the date of application referred to in Article 61, Article 46 shall apply already from the date of entry into force of this Regulation insofar as necessary in order to allow a timely recognition of control authorities and control bodies.

Article 60

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

Products produced in accordance with Regulation (EC) No 834/2007 **■** *before the date of application of this Regulation* may **■** *be placed on the market* after that date until stocks are exhausted.

■

Article 61

Entry into force and application

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

It shall apply from 1 **January 2021**.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

OTHER PRODUCTS REFERRED TO IN ARTICLE 2(1)

- Yeasts used as food or feed,
- maté, *sweetcorn, vine leaves, palm hearts, hop shoots, and other similar edible parts of plants and products produced therefrom,*
- sea salt *and other salts for food and feed,*
- *silkworm cocoon suitable for reeling,*
- natural gums and resins,
- beeswax,

- essential oils,

- *cork stoppers of natural cork, not agglomerated and without any binding substances,*

- *cotton, not carded or combed,*

- *wool, not carded or combed,*

- *raw hides and untreated skins,*

- *plant-based traditional herbal preparations.*

Detailed production rules referred to in Chapter III

Part I: Plant production rules

In addition to the production rules laid down in Articles 9 to 12, the rules set out in this Part shall apply to organic plant production.

1. General requirements
 - 1.1 Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock.***
 - 1.2 Hydroponic production, which is a method of growing plants, which are not naturally growing in water, with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.***
 - 1.3 By way of derogation from point 1.1, the production of sprouts by moistening of seeds and the obtaining of chicory heads including by dipping in clear water, shall be allowed.***
 - 1.4 By way of derogation from point 1.1, the following practices shall be allowed:***

- (a) *growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer;*
- (b) *growing seedlings or transplants in containers for further transplanting.*

1.5 *By way of derogation from point 1.1, growing crops in demarcated beds shall only be allowed for the surfaces that have been certified as organic for this practice before 28 June 2017 in Finland, Sweden and Denmark. Any extension of these surfaces shall not be permitted.*

This derogation shall end 10 years from the date of application of this Regulation.

Five years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the use of demarcated beds in organic agriculture. This report may be accompanied, if appropriate, by a legislative proposal as regards the use of demarcated beds in organic farming.

1.6 All plant production techniques used shall prevent or minimise any contribution to the *contamination* of the environment.

1.7 **Conversion**

- 1.7.1 For plants and plant products to be considered organic, the production rules laid down in this Regulation must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as **organic feed**, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.
- 1.7.2 The **competent** authority may decide, in the cases where the land **or one or more parcels thereof have** been contaminated with products not authorised for organic production, to extend the conversion period **for the land or parcels concerned** beyond the period referred to in point 1.7.1.
- 1.7.3 In the case of treatment with a product not authorised for organic production, the competent authority shall require a new conversion period in accordance with point 1.7.1.
That period may be shortened in the following two cases:

- (a) treatment with a product not authorised for organic production as part of a compulsory control measure for pests or weeds, including quarantine organisms or invasive species, imposed by the competent authority of the Member State;
 - (b) treatment with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State.
- 1.7.4 In the cases referred to in points 1.7.2 and 1.7.3, the length of the conversion period shall be fixed taking into account the following factors:
- (a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;
 - (b) the harvest following the treatment may not be sold *as organic or as in-conversion products*.
- 1.7.4.1 Member States shall inform the Commission and the other Member States of any decision taken by them which lays down compulsory measures related to treatment with a product non-authorised for organic production;**

- 1.7.4.2 In the case of treatment with a product which is not authorised for organic production, the provisions of point 1.7.5.2 shall not apply.**
- 1.7.5 The specific conversion rules for land associated with organic livestock production should be as follows:
- 1.7.5.1 The conversion rules shall apply to the whole area of the production unit on which animal feed is produced.
- 1.7.5.2 Notwithstanding point 1.7.5.1, the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.
- 1.8 Origin of plants including plant reproductive material
- 1.8.1 For the production of plants and plant products ***other than plant reproductive material, only organic*** plant reproductive material shall be used. ■

1.8.2 *To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.*

I

1.8.3 *When choosing organic plant reproductive material operators shall give preference to organic plant reproductive material suitable for organic agriculture.*

1.8.4 *For the production of organic varieties, the organic breeding activities shall be conducted under organic conditions and focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.*

All multiplication practices except meristem culture shall be under certified organic management.

1.8.5 *Use of non-organic plant reproductive material*

1.8.5.1 *By way of derogation from point 1.8.1, where the data collected in the database referred to in Article 26a(1) or the system referred to in Article 26(2)(a) shows that the qualitative or quantitative needs of the operator regarding relevant organic plant reproductive material, excluding seedlings, are not met, competent authorities may authorise the use of in-conversion or non-organic plant reproductive material under the conditions laid down under points 1.8.5.3 to 1.8.5.4*

Prior to requesting any such derogation the operator shall consult the database as referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) in order to verify whether his or her request is justified.

1.8.5.2 *For operators in third countries, control authorities or control bodies recognised in accordance with Article 46(1) may authorise the use of in-conversion or non-organic plant reproductive material on an organic production unit, when organic plant reproductive material is not available in sufficient quality or quantity in the territory of the country where the operator is located and under the conditions laid down under points 1. 8.5.3 to 1. 8.5.4.*

- 1.8.5.3 *Non-organic plant reproductive material shall not be treated with plant protection products, other than those authorised for treatment of seed in accordance with Article 24(1) of this Regulation, unless chemical treatment is prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authority of the Member State for all varieties of a given species in the area where the plant reproductive material is to be used.***
- 1.8.5.4 *The authorisation shall be granted before the sowing of the crop.***
- 1.8.5.5 *The authorisation shall be granted only to individual users for one season at a time and the competent authority responsible for authorisations shall list the quantities of plant reproductive material authorised.***
- 1.9 Soil management and fertilisation
- 1.9.1 Organic plant production shall use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.

- 1.9.2 **The** fertility and biological activity of the soil shall be maintained and increased
- (a) **except in the case of grassland or perennial forage**, by multiannual crop rotation including **mandatory leguminous crops as the main or cover crop for rotating crops** and other green manure crops; and
 - (b) **in the case of greenhouses or perennial crops other than forage, by short term green manure crops and legumes as well as the use of plant diversity; and**
 - (c) **in all cases** by the application of livestock manure or organic **matter**, both preferably composted, from organic production.
- 1.9.3 **Where** the nutritional needs of plants cannot be met by measures provided for in points 1.9.1 and 1.9.2 only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 24 may be used and only to the extent necessary. **Operators shall keep records of the use of these products.**
- 1.9.4 The total amount of livestock manure, as defined in **Directive 91/676/EEC**, applied on the **in-conversion and organic production units**, shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrements, including poultry manure, composted farmyard manure and liquid animal excrements.

- 1.9.5 *Agricultural* holdings may establish written cooperation agreements exclusively with other agricultural holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production *units*. The maximum limit as referred to in point 1.9.4 shall be calculated on the basis of all of the organic production units involved in such cooperation.
- 1.9.6 Preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.
- 1.9.7 For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.
- 1.9.8 Mineral nitrogen fertilisers shall not be used.
- 1.9.9 *Biodynamic preparations may be used.***
- 1.10 Pest and weed management
- 1.10.1 The prevention of damage caused by pests and weeds shall rely primarily on the protection by:

- natural enemies,
 - the choice of species, varieties and heterogeneous material,
 - crop rotation,
 - cultivation techniques such as biofumigation, ***mechanical and physical methods***, and
 - thermal processes such as solarisation and, ***in the case of protected crops***, shallow steam treatment of the soil (to a maximum depth of 10 cm).
- 1.10.2 Where plants cannot be protected adequately from pests by measures provided for in point 1.10.1 or in the case of an established threat to a crop, only products authorised for use in organic production pursuant to ***Articles 9 and 24*** may be used and only to the extent necessary. ***Operators shall keep records proving the need for the use of such products.***
- 1.10.3 ***In relation to products used in traps or dispensers of products other than pheromones, the traps and/or dispensers*** shall prevent the substances from being released into the environment and ***shall*** prevent contact between the substances and the crops being cultivated. ***All traps including pheromone*** traps shall be collected after use and ***safely*** disposed of **█**.
- 1.11 Products used for cleaning and disinfection
With regard to cleaning and disinfection, only the products for cleaning and disinfection in plant production authorised for use in organic production pursuant to Article 24 shall be used.

- 1.12 **Record-keeping obligation**
Operators shall keep records on the parcels concerned and on the amount of the harvest.
- 1.13 **Preparation of unprocessed products**
If preparation operations, other than processing, are carried out on plants, the general requirements laid down in points 1.6, 1.7, 1.8, 1.9 and 2.2.3 of Part IV shall apply mutatis mutandis to such prepared products.
2. **Detailed rules** for specific plants *and* plant products
- 2.1 Rules on mushroom production
For the production of mushrooms, substrates may be used, if they are composed only of the following components:
- (a) farmyard manure and animal excrements:
 - (i) either from **■** organic production *units or from in-conversion units in their second year of conversion*; or
 - (ii) referred to in point 1.9.3, only when the product referred to in point (i) is not available, provided that these farmyard manure and animal excrements do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;

- (b) products of agricultural origin, other than those referred to in point (a), from organic production *units*;
- (c) peat not chemically treated;
- (d) wood, not treated with chemical products after felling;
- (e) mineral products referred to in point 1.9.3, water and soil.

2.2 Rules concerning the collection of wild plants

The collection of wild plants and parts thereof, growing naturally in natural areas, forests and agricultural areas is considered as organic production provided that:

- (a) those areas have not, for a period of at least three years before the collection, received treatment with products other than those authorised for use in organic production pursuant to *Articles 9 and 24*;
- (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

Part II: Livestock production rules

In addition to the production rules laid down in Articles 9, 10, 11 and 14, the rules laid down in this Part shall apply to **organic** livestock production.

1. General requirements

- 1.1 ***Except in the case of beekeeping, landless livestock production shall be prohibited, where the farmer intending to produce organic livestock does not manage agricultural land and has not established a written cooperation agreement with a farmer as regards the use of organic production units or in-conversion production units for that livestock.***

1.2 Conversion

- 1.2.1 ***In the case of simultaneous start of conversion of the production unit, including, pasturage and of the animals existing on this production unit at the beginning of the conversion period of this production unit as referred to in points 1.7.1 and 1.7.5.2 of Part I, animals and animal products may be considered organic at the end of the conversion period of the production unit, including in cases where the conversion period laid down in point 1.2.2 for the type of animal concerned is longer than the conversion period for the production unit.***

By derogation from point 1.4.3.1, during the conversion period of the production unit, animals existing on this production unit at the beginning of the conversion period may be fed with in-conversion feed produced on the in-conversion production unit during the first year of conversion and/or with feed in accordance with point 1.4.3.1 and/or with organic feed.

Non-organic animals may be introduced on an in-conversion production unit after the start of the conversion period in accordance with point 1.3.4.

1.2.2 *Conversion periods specific to the type of animal production are set out as follows:*

- (a) 12 months in the case of bovine and equine animals for meat production, and in any case at least three quarters of their lifetime;*
- (b) six months in the case of ovine, caprine and porcine animals and animals for milk production;*
- (c) 10 weeks for poultry for meat production, except for Peking ducks, brought in before they are three days old;*
- (d) seven weeks for Peking ducks, brought in before they are three days old;*
- (e) six weeks in the case of poultry for egg production, brought in before they are three days old;*
- (f) 12 months for bees.*

During the conversion period, the wax shall be replaced with wax coming from organic beekeeping.

However, non-organic beeswax may be used:

(i) where beeswax from organic beekeeping is not available on the market;

(ii) where it is proven free of contamination by products or substances not authorised for organic production; and

(iii) provided that it comes from the cap;

(g) three months for rabbits;

(h) twelve months for cervine animals.

1.3 Origin of animals

1.3.1 ***Without prejudice to the rules on conversion, organic*** livestock shall be born ***or hatched*** and raised on organic ***production units***.

1.3.2 With regard to the breeding of organic animals:

(a) reproduction shall use natural methods; however, artificial insemination shall be allowed;

- (b) reproduction shall not be induced ***or impeded*** by treatment with hormones or ***other*** substances ***with a similar effect***, unless as a form of veterinary therapeutic treatment in case of an individual animal;
- (c) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;
- (d) the choice of breeds shall be appropriate, ***shall ensure a high standard of animal welfare*** and shall contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals.

1.3.3 ***When choosing*** breeds or strains, ***operators shall consider giving preference to breeds or strains, with a high degree of genetic diversity***, the capacity of animals to adapt to local conditions, ***their breeding value, their longevity***, their vitality and their resistance to disease ***or health problems, all without impairment of their welfare***. In addition, breeds or strains of animals shall be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production, such as porcine stress syndrome, ***possibly leading to*** pale-soft-exudative (PSE) ***meat***, sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference shall be given to indigenous breeds and strains.

To choose the breeds and strains in accordance with the first subparagraph, operators shall use the information available in the systems referred to in Article 26(3).

1.3.4 Use of non-organic animals

- 1.3.4.1** *By way of derogation from point 1.3.1, for breeding purposes, non-organically raised animals may be brought onto an organic production unit when breeds are in danger of being lost to farming in accordance with Article 28(10)(b) of Regulation (EU) No 1305/2013 and acts adopted on the basis thereof. In that case animals of those breeds must not necessarily be nulliparous.*
- 1.3.4.2** *By way of derogation from point 1.3.1, for the renovation of apiaries, 20 % per year of the queen bees and swarms may be replaced by non-organic queen bees and swarms in the organic production unit provided that the queen bees and swarms are placed in hives with combs or comb foundations coming from organic production units. In any case, one swarm or queen bee may be replaced per year by a non-organic swarm or a queen bee.*
- 1.3.4.3** *By way of derogation from point 1.3.1, when a flock is constituted for the first time, renewed or reconstituted, where qualitative and quantitative needs of farmers cannot be met, the competent authority may decide that non-organically reared poultry may be brought into an organic poultry production unit, provided that the pullets for the production of eggs and poultry for meat production are less than three days old. Products derived from them may only be considered as organic provided that the conversion period specified in point 1.2 of Part II of this Annex is respected.*

1.3.4.4 *By way of derogation from point 1.3.1, where the data collected according to the system referred to in Article 26(2)(b) shows that the qualitative or quantitative needs of the farmer regarding organic animals are not met, competent authorities may authorise the introduction of non-organic animals onto an organic production unit, subject to the following conditions provided for in points 1.3.4.4.1 to 1.3.4.4.4.*

Prior to requesting any such derogation the farmer shall consult the data collected as laid out in Article 26(2)(b) in order to verify whether his or her request is justified.

For operators in third countries, control authorities or control bodies recognised in accordance with Article 46(1) may authorise the introduction of non-organic animals onto an organic production unit, when organic animals are not available in sufficient quality or quantity in the territory of the country where the operator is located.

1.3.4.4.1 *For breeding purposes, non-organic young animals may be introduced when a herd or flock is constituted for the first time. They shall be reared in accordance with the organic production rules immediately after they are weaned. Moreover, the following restrictions shall apply at the date on which those animals enter the herd or flock:*

- (a) bovine, equine and cervine animals shall be less than six months old;*
- (b) ovine and caprine animals shall be less than 60 days old;*
- (c) porcine animals shall weigh less than 35 kg.*
- (d) rabbits shall be less than 3 months old.*

1.3.4.4.2 For breeding purposes, non-organic adult male and nulliparous female animals may be introduced for the renewal of a herd or flock. They shall be reared subsequently in accordance with the organic production rules. Moreover, the number of female animals shall be subject to the following restrictions per year:

- (a) up to a maximum of 10 % of adult equine or bovine animals and 20 % of the adult porcine, ovine, caprine animals, rabbits and cervine animals;*
- (b) for units with fewer than 10 equine, cervine or bovine animals or rabbits, or with fewer than five porcine, ovine or caprine animals, any renewal as mentioned above shall be limited to a maximum of one animal per year.*

1.3.4.4.3. The percentages referred to in sub-point 1.3.4.4.2 may be increased up to 40%, provided that the competent authority has confirmed that the one of following conditions is fulfilled:

- (a) a major extension to the farm has been undertaken;*
- (b) a breed has been changed;*
- (c) a new livestock specialisation has been initiated.*

1.3.4.4.4 *In the cases referred to in points 1.3.4.4.1 to 1.3.4.4.3, non-organic animals may only be considered as organic provided that the conversion period specified in point 1.2 of Part II of this Annex is respected. This conversion period laid down in point 1.2.2 shall start at the earliest when the animals are introduced on the in-conversion production unit.*

1.3.4.4.5 *In the cases referred to in points 1.3.4.4.1 to 1.3.4.4.4, non-organic animals shall either be kept separate from other livestock or shall be identifiable until the end of the conversion period referred to in point 1.3.4.4.4.*

1.4 Nutrition

1.4.1 General nutrition requirements

With regard to nutrition the following rules shall apply:

- (a) feed for livestock shall be obtained primarily from the agricultural holding where the animals are kept or from **organic or in-conversion production units** of other holdings in the same region;
- (b) livestock shall be fed with organic **or in-conversion** feed that meets the animal's nutritional requirements at the various stages of its development. Restricted feeding shall not be permitted in livestock production **unless justified for veterinary reasons**;
- (c) the keeping of livestock in conditions, or on a diet which may encourage anaemia, shall be prohibited;
- (d) fattening practices shall **always respect the normal nutrition patterns for each species and animals' welfare** at any stage of the rearing process. Force-feeding is forbidden;

- (e) with the exception of bees, *porcine and poultry*, livestock shall have permanent access to pasture *whenever conditions allow or to* roughage;
- (f) growth promoters and synthetic amino-acids shall not be used;
- (g) suckling animals shall be fed in preference on maternal milk for a minimum period *laid down by the Commission in accordance with Article 14; milk replacers containing chemically synthesised components or components of plant origin shall not be used during this period;*
- (h) feed materials *of plant, algae, animal or yeast origin shall be organic;*
- (i) *non-organic feed materials of plant, algae, animal or yeast origin, feed materials of microbial or* of mineral origin, feed additives ■ and processing aids *may* be used only if they have been authorised for use in organic production pursuant to Article 24.

1.4.2 Grazing

1.4.2.1 Grazing on organic land

Without prejudice to point 1.4.2.2, organic animals shall graze on organic land. However, non-organic animals may use organic pasturage for a limited period of time each year, provided that such animals have been raised in an environmental friendly way supported under Articles 23, 25, 28, 30, 31 and 34 of Regulation (EU) No 1305/2013 and that non-organic animals are not present on the organic land at the same time as organic animals.

1.4.2.2 Grazing *on* common land and transhumance

1.4.2.2.1 Organic animals may *graze* on common land, provided that:

- (a) the common land *has not been treated with products not authorised for organic production for at least three years*;
- (b) any non-organic animals which use the land concerned *have been raised in an environmental friendly way supported under Articles 23, 25, 28, 30, 31 and 34 of Regulation (EU) No 1305/2013*¹;
- (c) any livestock products from organic animals, whilst using this land, *are* not regarded as ¹ organic *products*, unless adequate segregation from non-organic animals can be proved.

1.4.2.2.2 During the period of transhumance animals may graze on non-organic land when they are being moved on foot from one grazing area to another. *During that period, organic livestock shall be kept separate from other livestock.* The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, shall be allowed:

- (a) for a maximum of 35 days covering both the outward and return journeys;
or
- (b) *for a maximum of 10 % of the total feed ration per year calculated as percentage of the dry matter of feeding stuffs from agricultural origin.*

¹

1.4.3 In-conversion feed

1.4.3.1 For *agricultural holdings that produce organic livestock*:

(a) *up to 25 % on average of the feed formula of rations may comprise in-conversion feed from the second year of conversion. When this in-conversion feed comes from the holding where the livestock is kept, this percentage may be increased to 100 %; and*

(b) *up to 20 % of the total average amount of feed fed to livestock may originate from the grazing or harvesting of permanent pastures, perennial forage parcels or protein crops, sown under organic management on lands in their first year of conversion, provided that they are part of the holding itself.* █

When both *types of* in-conversion feed *referred to in points (a) and (b)* are being used *for feeding*, the total combined percentage of such feed shall not exceed the *percentage* fixed in point (a).

█

1.4.3.2 The figures in *point 1.4.3.1* shall be calculated annually as a percentage of the dry matter of feed of plant origin.

█

1.5 Health care

- 1.5.1 Disease prevention
 - 1.5.1.1 Disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions.
 - 1.5.1.2 The use of immunological veterinary medicinal products shall be allowed.
 - 1.5.1.3 The use of chemically synthesised allopathic veterinary medicinal products, **including bolus of synthesised allopathic chemical molecules**, or antibiotics for preventive treatment shall be prohibited.
 - 1.5.1.4 The use of substances to promote growth or production (including antibiotics, coccidiostatics and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction or for other purposes (e.g. induction or synchronisation of oestrus), shall be prohibited.
 - 1.5.1.5 Where livestock is obtained from non-organic **production** units, special measures such as screening tests or quarantine periods shall apply, depending on local circumstances.
 - 1.5.1.6 With regard to cleaning and disinfection, only the products for cleaning and disinfection in livestock buildings and installations authorised for use in organic production pursuant to Article 24 shall be used.

- 1.5.1.7 Housing, pens, equipment and utensils shall be properly cleaned and disinfected to prevent cross-infection and the build-up of disease carrying organisms. Faeces, urine and uneaten or spilt feed shall be removed as often as necessary to minimise smell and to avoid attracting insects or rodents. Rodenticides (to be used only in traps), and the products authorised for use in organic production pursuant to *Articles 9 and 24* may be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.
- 1.5.2 Veterinary treatment
- 1.5.2.1 Where despite preventive measures to ensure animal health animals become sick or injured they shall be treated immediately.
- 1.5.2.2 Disease shall be treated immediately to avoid suffering of the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.

- 1.5.2.3 Feed materials of mineral origin and nutritional additives authorised for use in organic production pursuant to Article 24 and phytotherapeutic and homeopathic products shall be used in preference to chemically-synthesised allopathic veterinary treatment including antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.
- 1.5.2.4 With the exception of vaccinations, treatments for parasites and compulsory eradication schemes where an animal or group of animals receive more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products including antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year, the livestock concerned, or produce derived from them, shall not be sold as organic products, and the livestock shall undergo the conversion periods referred to in *point 1.2*.
- 1.5.2.5 The withdrawal period between the last administration of *a chemically synthesised* allopathic veterinary medicinal product *or an antibiotic* to an animal under normal conditions of use, and the production of organically produced foodstuffs from such *an animal, shall* be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC *and at least* 48 hours.
- 1.5.2.6 Treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed.

- 1.6 Housing and husbandry practices
- 1.6.1 Insulation, heating and ventilation of the building shall ensure that air circulation, dust level, temperature, relative air humidity and gas concentration, are kept within limits which ensure the well-being of the animals. The building shall permit plentiful natural ventilation and light to enter.
- 1.6.2 Housing for livestock shall not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors. Animals shall have access to shelters or shady areas to protect them from adverse weather conditions.
- 1.6.3 The stocking density in buildings shall provide for the comfort, the well-being and the species-specific needs of the animals which, in particular, shall depend on the species, the breed and the age of the animals. It shall also take account of the behavioural needs of the animals, which depend in particular on the size of the group and the animals' sex. The density shall ensure the animals' welfare by providing them with sufficient space to stand naturally, move, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.

- 1.6.4 The minimum *surfaces* for indoor and outdoor areas ***and the technical details relating to housing, as laid down in the implementing acts referred to in Article 14(3), shall be respected.***
- 1.6.5 Open air areas may be partially covered. Verandas shall not be considered as open air areas.
- 1.6.6 The total stocking density shall not exceed the limit of 170 kg of organic nitrogen per year and hectare of agricultural area.
- 1.6.7 To determine the appropriate density of livestock referred to in point 1.6.6, the competent authority shall set out the livestock units equivalent to the limit referred to in point 1.6.6, following the figures laid down in each of the specific requirement by animal production.
- 1.6.8 The use of cages, boxes and flat decks to raise livestock shall not be permitted for any livestock species.***
- 1.6.9 When livestock is treated individually for veterinary reasons, it shall be kept in spaces that have a solid floor and must be provided with straw or appropriate bedding. The animal shall be able to turn around easily and to lie down comfortably at full length.***
- 1.6.10 Organic livestock rearing in a pen on very wet or marshy soil shall not be allowed.***

- 1.7 Animal welfare
- 1.7.1 All persons involved in keeping animals ***and in handling animals during transport and slaughter*** shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals ***and shall have followed adequate training as required in particular in Council Regulation (EC) No 1/2005¹ and Council Regulation No (EC) 1099/2009², to ensure proper application of the rules set out in this Regulation.***
- 1.7.2 Husbandry practices, including stocking densities and housing conditions shall ensure that the developmental, physiological and ethological needs of animals are met.
- 1.7.3 ***Livestock*** shall have permanent access to open air areas ***allowing the animals to exercise***, preferably pasture, whenever weather ***and seasonal*** conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Union legislation.
- 1.7.4 The number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure.

¹ ***Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).***

² ***Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).***

- 1.7.5 Tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time, and in so far as this is justified for veterinary reasons. ***Isolation of livestock may be authorised, for a limited period of time, only when workers safety is compromised and for animal welfare reasons.*** Competent authorities may authorise cattle in ***farms with a maximum of 50 animals (excluding young stock)*** to be tethered if it is not possible to keep the cattle in groups appropriate to their behaviour requirements, provided they have access to pastures during the grazing period, and at least twice a week access to open air areas when grazing is not possible.
- 1.7.6 Duration of transport of livestock shall be minimised.
- 1.7.7 Any suffering, ***pain and distress*** shall be ***avoided and*** kept to a minimum during the entire life of the animal, including at the time of slaughter.
- 1.7.8 ***Without prejudice to further developments in Union legislation on animal welfare, tail-docking for sheep, beak trimming when undertaken in the first three days of life, dehorning may be exceptionally allowed only on a case-by-case basis when they improve the health, welfare or hygiene of the livestock or when workers safety is compromised. Disbudding may be allowed only on a case by case basis when it improves the health, welfare or hygiene of the livestock or when workers' safety is compromised. These operations shall be authorised by a competent authority and carried out by qualified personnel only when the operator has duly justified and notified the reasons to the competent authority.***

- 1.7.9 Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out **any** operation only at the most appropriate age by qualified personnel.
- 1.7.10 Physical castration shall be allowed in order to maintain the quality of products and traditional production practices but only under **the conditions set out in point 1.7.9**.
- 1.7.11 Loading and unloading of animals shall be carried out without the use of any type of electrical **or other painful** stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, shall be prohibited.

I

- 1.8** *Preparation of unprocessed products*
If preparation operations, other than processing, are carried out on livestock, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply mutatis mutandis to such prepared products.
- 1.9** *Additional general rules*
- 1.9.1** *For bovine, ovine, caprine and equine animals*
- 1.9.1.1** Nutrition

With regard to nutrition, the following rules shall apply:

- (a) ***at least 60 % of the feed shall come from the farm itself, or, in case this is not available/feasible be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region. This percentage shall be raised to 70 % two years after the date of application of this Regulation;***
- (b) animals shall have access to pasturage for grazing whenever conditions allow;
- (c) notwithstanding point (b), male bovine animals over one year old shall have access to pasturage or an open air area;
- (d) in cases where **█** animals have access to pasturage during the grazing period and where the winter- housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived;
- (e) rearing systems **█** shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year; at least 60 % of the dry matter in daily rations of bovine, ovine and caprine, **equine** animals, shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation shall be allowed

1.9.1.2 *Housing and husbandry practices*

With regard to housing *and husbandry practices*, the following rules shall apply:

- (a) *the* housing shall have smooth, but not slippery floors ;
- (b) the housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 24.

Notwithstanding point (a) of the first subparagraph of Article 3(1) and the second subparagraph of Article 3(1) of Council Directive 2008/119/EC³, the housing of calves in individual boxes shall be forbidden after the age of one week, unless for individual animals for a limited period of time, and in so far as this is justified for veterinary reasons.

When a calf is treated individually for veterinary reasons, it shall be kept in spaces that have a solid floor and must be provided with straw bedding. The calf shall be able to turn around easily and to lie down comfortably at full length.

³ Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).

1.9.2 For cervine animals

1.9.2.1 Nutrition

With regard to nutrition, the following rules shall apply:

- (a) ***at least 60 % of the feed shall come from the farm itself or, in case this is not available/feasible be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region. This percentage shall be raised to 70 % two years after the date of application of this Regulation;***
- (b) animals shall have access to pasturage for grazing whenever conditions allow;
- (c) in cases where animals have access to pasturage during the grazing period and where the winter-housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived;

- (d) *rearing systems shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year;*
- (e) rearing systems ■ shall be based on maximum use of grazing pasturage according to the *availability* of pastures in the different periods of the year; *at least 60 % of the dry matter in daily rations of cervine animals, shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50 % for female cervine animals in milk production for a maximum period of three months in early lactation shall be allowed;*

1.1.1. ■

- (f) *for cervine animals, natural grazing must be ensured in a pen during the period of vegetation. Pens that cannot provide feed by grazing during the period of vegetation shall not be allowed;*
- (g) *for cervine animals, feeding shall only be allowed in the event of a shortage of grazing due to poor weather conditions;*
- (h) *for cervine animals, farmed animals in a pen must be provided with clean and fresh water. If a natural source of water that is easily accessible to animals is not available, watering places must be provided.*

1.9.2.2 *Housing and husbandry practices*

With regard to **█** housing *and husbandry practices*, the following rules shall apply:

- (a) *cervine animals must be provided with hiding places, shelters and fences that do not harm animals;*
- (b) *in red deer pens, animals must be able to roll in the mud to ensure skin grooming and body temperature regulation;*
- (c) *any* housing of *cervine* animals shall have smooth, but not slippery floors **█** ;
- (d) *any* housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;

- (e) *for cervine animals, feeding places must be installed in areas protected from the weather and accessible both to animals and to persons attending to them. The soil where feeding places are located must be consolidated, and the feeding apparatus must be equipped with a roof;*

- (f) *for cervine animals, if permanent access to feed cannot be ensured, the feeding places must be designed so that all animals can feed at the same time.*

1.9.3 For porcine animals █

1.9.3.1 Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least **30** % of the feed shall come from the farm itself or, in case this is not *available*/feasible, be produced in █ cooperation with other organic █ or *in-conversion production units and* feed operators *using feed and feed material from the same region*;
- (b) *roughage*, fresh or dried fodder, or silage shall be added to the daily ration █ ;

█

- (c) *where farmers are unable to obtain protein feed exclusively from organic production for porcine animals and the competent authority has confirmed that organic protein feed is not available in sufficient quantity, non-organic protein feed may be used until five years after the date of application of this Regulation provided that the following conditions are fulfilled:*
- (i) *it is not available in organic form;*
 - (ii) *it is produced or prepared without chemical solvents;*
 - (iii) *its use is limited to piglets up to 35 kg and specific protein compounds; and*
 - (iv) *the maximum percentage authorised per period of 12 months for those animals does not exceed 5 %. The percentage of the dry matter of feed from agricultural origin shall be calculated.*

1.9.3.2 Housing and husbandry practices

With regard to **■** housing *and husbandry practices*, the following rules shall apply:

- (a) housing of porcine animals shall have smooth, but not slippery floors **■** ;
- (b) the housing of porcine animals shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 24;

- (c) *there shall always be a straw bed made of straw or other suitable material large enough to ensure that all pigs in a pen can lie down at the same time in the most space-consuming way;*
- (d) sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period, *during which time the sow shall be able to move freely in her pen and shall only be tethered for short times;*
- (e) *without prejudice to any additional requirements for straw, a few days before expected farrowing, sows must be provided with a quantity of straw or other suitable natural material sufficient to enable them to build nests;*
- (f) ■ exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

■
1.9.4 For poultry
■

1.9.4.1 Origin of *animals*

To prevent the use of intensive rearing methods, poultry shall either be reared until they reach a minimum age or else shall come from slow-growing poultry strains ***adapted to outdoor rearing***.

The competent authority shall define the criteria of slow-growing strains or draw up a list thereof and provide this information to operators, other Member States and the Commission.

Where slow-growing poultry strains are not used by the farmer the minimum age at slaughter shall be as follows:

- (a) 81 days for chickens;
- (b) 150 days for capons;
- (c) 49 days for Peking ducks;
- (d) 70 days for female Muscovy ducks;
- (e) 84 days for male Muscovy ducks;
- (f) 92 days for Mallard ducks;
- (g) 94 days for guinea fowl;
- (h) 140 days for male turkeys and roasting geese; and
- (i) 100 days for female turkeys.

1.9.4.2 Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least **30 %** of the feed shall come from the farm itself or, in case this is not **available/feasible**, be produced in **cooperation** with other organic **or in-conversion production units and** feed operators **using feed and feed material from the same region**;
- (b) roughage, fresh or dried fodder, or silage shall be added to the daily ration;
- (c) **where farmers are unable to obtain protein feed exclusively from organic production for poultry species and the competent authority has confirmed that organic protein feed is not available in sufficient quantity, non-organic protein feed may be used until five years after the date of application of this Regulation, provided that the following conditions are fulfilled:**

- (i) it is not available in organic form;*
- (ii) it is produced or prepared without chemical solvents;*
- (iii) its use is limited to young poultry and specific protein compounds; and*
- (iv) the maximum percentage authorised per period of 12 months for those animals does not exceed 5 %. The percentage of the dry matter of feed from agricultural origin shall be calculated.*

1.9.4.3 Animal welfare

Live plucking of poultry shall be prohibited.

1.9.4.4 Housing and husbandry practices

With regard to ■ housing *and husbandry practices*, the following rules shall apply:

- (a)** at least one third of the floor area shall be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;
- (b)** in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens shall be available for the collection of bird droppings;

(c) buildings shall be emptied of livestock between each batch of poultry reared. The buildings and fittings shall be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs shall be left empty during a period to be established by the Member States in order to allow vegetation to grow back. These requirements shall not apply where poultry are not reared in batches, are not kept in runs and are free to roam, throughout the day ■ ;

■
(d) poultry shall have access to an open air area for at least one third of their life. ■

However, laying hens and finisher poultry shall have access to an open air area for at least one third of their life, except in the case of temporary restrictions imposed on the basis of Union legislation;

(e) continuous daytime open air access shall be provided from as early an age as practically possible, whenever physiological and physical conditions allow, except in the case of temporary restrictions imposed on the basis of Union legislation;

■

- (f)** *by way of derogation from point 1.6.5, in the case of breeding birds and pullets aged under 18 weeks and when the conditions specified in point 1.7.3 as regards restrictions and obligations related to the protection of human and animal health imposed on the basis of Union legislation are met and prevent breeding birds and pullets aged under 18 weeks from having access to open air areas, verandas shall be considered as open air areas and in such cases shall have a wire mesh barrier to keep other birds out;*
- (g)** *open air areas for poultry shall permit fowl to have easy access to adequate numbers of drinking troughs;*
- (h)** *open air areas for poultry shall be mainly covered with vegetation;*
- (i)** *under conditions where feed availability from the range area is limited, due for instance to long term snow cover or arid weather conditions, supplementary feeding of roughage must be included as part of poultry diets;*

(j) where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs;

(k) *water fowl shall have access to a stream, pond, lake or a pool whenever the weather and hygienic conditions permit in order to respect their species-specific needs and animal welfare requirements; when weather conditions do not permit, they shall have access to water which enables them to dip their head therein so as to clean plumage;*

(l) *natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours;*

(m) *the total usable surface area of poultry houses for fattening poultry of any production unit shall not exceed 1 600 m²;*

(n) *not more than 3 000 laying hens shall be allowed in one compartment of a poultry house.*

1.9.5 For rabbits

1.9.5.1 Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least 70 % of the feed shall come from the farm itself, or, in case this is not available/feasible be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region;*
- (b) rabbits shall have access to pasturage for grazing whenever conditions allow;*
- (c) rearing systems shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year;*
- (d) for rabbits, fibrous feed such as straw or hay must be provided when grass is not sufficient. Forage shall comprise at least 60 % of the diet.*

1.9.5.2 Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) the housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 24;*

- (b) *rabbits shall be kept in groups.*
- (c) *rabbit farms shall use robust breeds adapted to outdoor conditions;*
- (d) *rabbits shall have access to:*
 - (i) *covered shelter including dark hiding places;*
 - (ii) *an outdoor run with vegetation, preferably pasture;*
 - (iii) *a raised platform on which they can sit, either inside or out;*
 - (iv) *nesting material for all nursing does.*

1.9.6 For bees

1.9.6.1 Origin of animals

For beekeeping, preference shall be given to the use of *Apis mellifera* and their local ecotypes.

1.9.6.2 Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at the end of the production season hives shall be left with sufficient reserves of honey and pollen to survive the winter;
- (b) the feeding of bee colonies shall only be permitted where the survival of the hives is endangered due to climatic conditions. Feeding shall be with organic honey, organic sugar syrups, or organic sugar.

1.9.6.3 Health care

With regard to *health care*, the following rules shall apply:

- (a) for the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides **■**, used **■** in traps **■**, and appropriate products authorised for use in organic production pursuant to *Articles 9 and 24* shall be permitted;
- (b) physical treatments for disinfection of apiaries such as steam or direct flame shall be permitted;
- (c) the practice of destroying the male brood shall be permitted only to isolate the infestation of *Varroa destructor*;
- (d) if despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, the colonies may be placed in isolation apiaries;
- (e) formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with *Varroa destructor*;
- (f) if a treatment is applied with chemically synthesised allopathic products *other than products authorised for use in organic production pursuant to Articles 9 and 24*, during such a period, the colonies treated shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of **12 months** laid down in point **1.2.2** shall apply to those colonies **■**.

█

1.9.6.4 *Animal welfare*

With regard to beekeeping, the following additional general rules shall apply:

- (a) *the destruction of bees in the combs as a method associated with the harvesting of beekeeping products shall be prohibited;*
- (b) *mutilation such as clipping the wings of queen bees shall be prohibited.*

1.9.6.5 *Housing and husbandry practices*

With regard to █ housing *and husbandry practices*, the following rules shall apply:

- (a) apiaries shall be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods;
 - (b) apiaries shall be kept at sufficient distance from sources that may lead to the contamination of beekeeping products or to the poor health of the bees;
 - (c) the siting of the apiaries shall be such that, within a radius of 3 km from the apiary site, nectar and pollen sources consist essentially of organically produced crops or spontaneous vegetation or crops treated with low environmental impact methods equivalent to those as provided for in Articles 28 and 30 of Regulation (EU) No 1305/2013 which cannot affect the qualification of beekeeping production as being organic. These requirements do not apply where flowering is not taking place, or the hives are dormant;
 - (d) the hives and materials used in beekeeping shall be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products;
- █

- (e) the beeswax for new foundations shall come from organic production units;
- (f) only natural products such as propolis, wax and plant oils may be used in the hives;
- (g) the use of chemical synthetic repellents shall be prohibited during honey extraction operations;
- (h) the use of brood combs shall be prohibited for honey extraction;
- (i) beekeeping shall not be considered as organic when practiced in regions or areas designated by Member States as regions or areas where organic beekeeping is not practicable.



Part III: Production rules for ■ *algae* and aquaculture animals



- 1. General requirements
- 1.1 Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for use in organic production, or pollutants that would compromise the organic nature of the products.

- 1.2 Organic and non-organic production units shall be separated adequately and in accordance with the minimum separation distances set by Member States, where such minimum separation distances have been set. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. *Algae and aquaculture* production shall not be considered as organic when practiced at locations or in areas designated by Member State authorities as locations or areas which are unsuitable for *such activities*.
- 1.3 An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control authority or control body. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU of the European Parliament and of the Council¹. If the *production* unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.

¹ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

- 1.4** *For organic aquaculture production, mangrove destruction shall not be permitted.*
- 1.5 The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and *algae* harvesting.
- 1.6 The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.
- 1.7** *Defensive and preventive measures taken against predators according to Council Directive 92/43/EEC and national rules shall be recorded in the sustainable management plan.*
- 1.8** *Where applicable, coordination shall take place with the neighbouring operators in drawing up the management plan.*
- 1.9 Aquaculture and *algae* business operators shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources. ■
- 1.10** *Preparation of unprocessed products*
If preparation operations, other than processing, are carried out on algae or aquaculture animals, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply mutatis mutandis to such prepared products.

2. Requirements for *algae*

In addition to the general production rules laid down in Articles 9, 10, 11 and 15, and where relevant in Section 1, the rules laid down in this Section shall apply to the *organic* collection and production of *algae*. Those rules shall apply mutatis mutandis to the production of [] phytoplankton [] .

2.1 Conversion

2.1.1 The conversion period for a *production unit for algae* harvesting [] shall be six months.

2.1.2 The conversion period for a *production unit for algae* cultivation [] shall be a period of six months or one full production cycle, whichever is the longer.

[]

2.2 Production rules for *algae*

2.2.1 The collection of wild *algae* and parts thereof [] is considered as organic production provided that:

- (a) the growing areas are of high ecological status as defined by Directive 2000/60/EC¹, **or have a quality equivalent:**
- **to the production zones classed as A and B in Regulation (EC) No 854/2004¹, until the repeal of that Regulation, or**
 - **to the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation (EU) 2017/625, as of the date of application of that Regulation,**
- and are not unsuitable from a health point of view¹;

- (b) the collection does not affect significantly the stability of the natural ecosystem or the maintenance of the species in the collection area.

2.2.2 The cultivation of *algae* shall take place in¹ areas with environmental and health characteristics at least equivalent to those outlined in point 2.2.1(a) in order to be considered organic. In addition the following production rules shall apply:

- (a) sustainable practices shall be used in all stages of production, from collection of juvenile *algae* to harvesting;

¹

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

- (b) to ensure that a wide gene-pool is maintained, the collection of juvenile *algae* in the wild shall take place on a regular basis *so as to maintain and increase the diversity of* indoor culture stock;
- (c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose *pursuant to Article 24*.

2.3 *Algae* cultivation

2.3.1 *Algae* culture at sea shall only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal production, preferably located nearby as part of a polyculture system.

2.3.2 In facilities on land where external nutrient sources are used, the nutrient levels in the effluent water shall be verifiably the same, or lower, than the inflowing water. Only nutrients of plant or mineral origin authorised for use in organic production pursuant to Article 24 may be used.

2.3.3 Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of *algae* which can be supported without negative effects on the environment is not exceeded.

- 2.3.4 Ropes and other equipment used for growing *algae* shall be re-used or recycled where possible.
- 2.4 Sustainable harvesting of wild *algae*
 - 2.4.1 A once-off biomass estimate shall be undertaken at the outset of *algae* harvesting
 - 2.4.2 Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild *algae* produced in accordance with this Regulation.
 - 2.4.3 Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that *algae* can regenerate and by-catches are prevented, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining *algae*.
 - 2.4.4 If *algae* is harvested from a shared or common harvest area, documentary evidence ***produced by the relevant authority designated by the Member State concerned*** shall be available, ***showing*** that the total harvest complies with this Regulation.

3. Requirements for aquaculture animals

In addition to the general production rules laid down in Article 9, 10, 11 and 15, **and where relevant in Section 1 of this Part**, the rules laid down in this **point** shall apply to **the organic production of** species of fish, crustaceans, echinoderms and molluscs **■**. Those rules also shall apply mutatis mutandis to **the production of** zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

3.1 General requirements

3.1.1 Conversion

■ The following conversion periods for aquaculture production units shall apply for the following types of aquaculture facilities including the existing aquaculture animals:

- (a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;
- (b) for facilities that have been drained, or fallowed, a conversion period of 12 months;
- (c) for facilities that have been drained, cleaned and disinfected a conversion period of six months;
- (d) for open water facilities including those producing bivalve molluscs, a conversion period of three months.

I

3.1.2 Origin of aquaculture animals

3.1.2.1 With regard to the origin of the aquaculture animals the following rules shall apply:

- (a) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock, and organic ***production units***;
- (b) locally grown species shall be used and breeding shall aim to give strains which are more adapted to production conditions, ensuring good animal health and welfare and good utilisation of feed resources. Documentary evidence of their origin and treatment shall be provided for ***the competent authority or, where appropriate***, the control authority or control body;
- (c) species shall be chosen which are robust and can be produced without causing significant damage to wild stocks;

- (d) *for breeding purposes*, wild caught or non-organic aquaculture animals may be brought into a holding *only in duly justified cases where no organic breed is available or where new genetic stock for breeding purposes is brought into the production unit after an authorisation has been granted by the competent authority*, with a view to improving *the suitability of* genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding. *For animals that are on the IUCN Red List of endangered species, the authorisation to use wild caught specimens may only be granted in the context of conservation programmes recognised by the relevant public authority in charge of the conservation effort;*
- (e) *for on-growing purposes the collection of wild aquaculture juveniles shall be specifically restricted to the following cases:*
- (i) *natural influx of fish or crustacean larvae and juveniles when filling ponds, containment systems and enclosures;*

- (ii)** *restocking of wild fry or crustacean larvae of species that are not on the IUCN Red List of endangered species in extensive aquaculture farming inside wetlands, such as brackish water ponds, tidal areas and costal lagoons, provided that:*
- *the restocking is in line with management measures approved by the relevant authorities to ensure the sustainable exploitation of the species concerned, and*
 - *the animals are fed exclusively with feed naturally available in the environment.*
- (f)** *By way of derogation from point (a), Member States may authorise the introduction for on-growing purposes on an organic production unit of a maximum of 50 % of non-organic juveniles of species that were not developed as organic in the Union by the date of application of this Regulation, provided that at least the latter two thirds of the duration of the production cycle are managed under organic management. Such derogation may be granted for a maximum period of 2 years and is not renewable.*
- For aquaculture holdings situated outside the Union, such derogation may only be granted by control authorities or control bodies recognised in accordance with Article 46(1) for species that were not developed as organic in the territory of the country where the holding is located, nor in the Union. Such derogation may be granted for a maximum period of 2 years and is not renewable.*

3.1.2.2 The following rules shall apply with regard to breeding:

- (a) the use of hormones and hormone derivatives shall be prohibited;
- (b) artificial production of monosex strains, except by hand sorting, induction of polyploidy, artificial hybridisation and cloning shall not be used;
- (c) the appropriate strains shall be chosen.

3.1.3 Nutrition

3.1.3.1 With regard to feed for fish and crustaceans and echinoderms: the following rules shall apply:

- (a) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
- (b) feeding regimes shall be designed with the following priorities:
 - (i) animal health and welfare;
 - (ii) high product quality, including the nutritional composition which shall ensure high quality of the final edible product;
 - (iii) low environmental impact;
- (c) the plant fraction of feed shall **be** organic and the feed fraction derived from aquatic animals shall originate from organic aquaculture or **from fisheries certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013**;

- (d) **■** non-organic feed materials from plant, *animal, algae or yeast* origin, feed materials *of* mineral *or of microbial* origin, feed additives **■** and processing aids shall be used only if they have been authorised for use in organic production under this Regulation **■**.
- (e) growth promoters and synthetic amino-acids shall not be used **■**
■.

3.1.3.2 The following rules shall apply with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:

- (a) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;
- (b) the growing areas shall be of high ecological status as defined by Directive 2000/60/EC, *or of good environmental status as defined by Directive 2008/56/EC, or have a quality equivalent:*
 - *to the production zones classed as A in Regulation (EC) No 854/2004, until the repeal of that Regulation, or*
 - *to the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation (EU) 2017/625, as of the date of application of that Regulation,*
and shall not be unsuitable from a health point of view.

3.1.3.3 Specific rules on feed for carnivorous aquaculture animals

Feed for carnivorous aquaculture animals shall be sourced with the following priorities:

- (a) organic feed of aquaculture origin;
- (b) fish meal and fish oil from organic aquaculture trimmings sourced from fish, crustaceans or molluscs;
- (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish, crustaceans or molluscs already caught for human consumption in sustainable fisheries;
- (d) fish meal and fish oil and ingredients of fish origin derived from whole fish, crustaceans or molluscs caught in sustainable fisheries and not used for human consumption;
- (e) organic feed materials of plant or animal origin; plant material shall not exceed 60 % of total ingredients.

3.1.3.4 Specific rules on feed for certain aquaculture animals

In the grow-out phase, fish in inland waters, penaeid shrimps and freshwater prawns and tropical freshwater fish shall be fed as follows:

- (a) they shall be fed with feed naturally available in ponds and lakes;
- (b) where natural feed is not available in sufficient quantities as referred to in point (a), organic feed of plant origin, preferably grown on the farm itself or ***algae*** may be used. Operators shall keep documentary evidence of the need to use additional feed;

- (c) where natural feed is supplemented in accordance with point (b) :
- (i) ***the feed ration of penaeid shrimps and freshwater prawns (Macrobrachium spp.) may comprise a maximum of 25 % fishmeal and 10 % fish oil derived from sustainable fisheries;***
 - (ii) ***the feed ration of siamese catfish (Pangasius spp.) may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.***

3.1.4 Health care

3.1.4.1 Disease prevention

With regard to disease prevention the following rules shall apply:

- (a) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, taking into account, inter alia, the species' requirements as to good water quality, flow and exchange rate, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;
- (b) the use of immunological veterinary medicines is allowed;
- (c) an animal health management plan shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal health services who shall visit the farm at a frequency of not less than once per year ***or, in the case of bivalve shellfish***, not less than once every two years ;

- (d) holding systems, equipment and utensils shall be properly cleaned and disinfected;
- (e) bio-fouling organisms shall be removed only by physical means or by hand and where appropriate returned to the sea at a distance from the farm;
- (f) only substances for cleaning and disinfection of equipment and facilities authorised for use in organic production pursuant to Article 24 may be used **■**;
- (g) with regard to fallowing the following rules shall apply:
 - (i) the competent authority *or, where appropriate, control authority or control body* shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea;
 - (ii) it shall not be mandatory for bivalve mollusc cultivation;
 - (iii) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again;
- (h) where appropriate, uneaten fish-feed, faeces and dead animals shall be removed promptly to avoid any risk of significant environmental damage as regards water status quality, minimise disease risks, and to avoid attracting insects or rodents;
- (i) ultraviolet light and ozone may be used only in hatcheries and nurseries;
- (j) for biological control of ectoparasites preference shall be given to the use of cleaner fish *and to the use of freshwater, marine water and sodium chloride solutions*.

3.1.4.2 Veterinary treatments

The following rules shall apply with regard to veterinary treatments:

- (a) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. Where appropriate, restrictions with respect to courses of treatment and withdrawal periods shall be defined;
- (b) treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed;

- (c) when despite preventive measures to ensure animal health, according to point 3.1.4.1, a health problem arises, veterinary treatments may be used in the following order of preference:
 - (i) substances from plants, animals or minerals in a homoeopathic dilution;
 - (ii) plants and their extracts not having anaesthetic effects; and
 - (iii) substances such as trace elements, metals, natural immunostimulants or authorised probiotics;
- (d) the use of allopathic treatments shall be limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of a production cycle of less than a year a limit of one allopathic treatment applies. If the indicated limits for allopathic treatments are exceeded the aquaculture animals concerned shall not be sold as organic products;
- (e) the use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months;
- (f) the withdrawal period for allopathic veterinary treatments and parasite treatments in accordance with point (d), including treatments under compulsory control and eradication schemes, shall be twice the withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period *is* not specified, 48 hours;
- (g) whenever veterinary medicinal products are used, such use shall be declared ***to the competent authority or, where appropriate,*** to the control authority or the control body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

3.1.5 Housing conditions and husbandry practices

3.1.5.1 Closed recirculation aquaculture animal production facilities shall be prohibited, with the exception of hatcheries and nurseries or for the production of species used for organic feed organisms.

3.1.5.2 Artificial heating or cooling of water shall only be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.

3.1.5.3 The husbandry environment of the aquaculture animals shall be designed in such a way that, in accordance with their species specific needs, the aquaculture animals shall:

- (a) have sufficient space for their wellbeing and ***have the relevant*** stocking density ***as laid down in the implementing acts referred to in Article 15(3)***;
- (b) be kept in water of good quality with, inter alia, an adequate flow and exchange rate, sufficient oxygen levels and keeping a low level of metabolites;
- (c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location.

In considering the effects of the stocking density on the welfare of produced fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored and taken account of.

In the case of freshwater fish, the bottom type shall be as close as possible to natural conditions.

In the case of carp *and similar species*:

- the bottom shall be natural earth;
- *organic and mineral fertilisation of the ponds and lakes shall be carried out with only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 24 with a maximum application of 20 kg nitrogen/ha;*
- *treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters shall be prohibited.*

3.1.5.4 The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.

The specific characteristics for production systems and containment systems for species or group of species as laid down in the implementing acts referred to in Article 15(3) have to be respected.

3.1.5.5 Rearing units on land shall meet the following conditions:

- (a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;
- (b) at least **10 %** of the perimeter ('land-water interface') area shall have natural vegetation.

3.1.5.6 Containment systems at sea shall meet the following conditions:

- (a) they shall be located where water flow, depth and water-body exchange rates are adequate to minimise the impact on the seabed and the surrounding water body;
- (b) they shall have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.

- 3.1.5.7 Containment systems shall be designed, located and operated to minimise the risk of escape incidents.
- 3.1.5.8 If fish or crustaceans escape, appropriate action shall be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Records shall be maintained.
- 3.1.5.9 For aquaculture animal production in fishponds, tanks or raceways, farms shall be equipped with either natural-filter beds, settlement ponds, biological filters or mechanical filters to collect waste nutrients or use *algae* or animals (bivalves and algae) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.

█

3.1.6 Animal welfare

- 3.1.6.1 All persons involved in keeping aquaculture animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals.
- 3.1.6.2 Handling of aquaculture animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in a manner to minimise physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.
- 3.1.6.3 The following restrictions shall apply to the use of artificial light:
- (a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of produced animals, this maximum shall not exceed **14** hours per day, except for reproductive purposes;
 - (b) abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.
- 3.1.6.4 Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources.
- 3.1.6.5 The use of oxygen is only permitted for uses linked to animal health and welfare requirements and critical periods of production or transport, in the following cases:
- (a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental **water** pollution;
 - (b) occasional stock management procedures such as sampling and sorting;
 - (c) in order to assure the survival of the farm stock.

3.1.6.6 appropriate measures shall be taken to keep the duration of transport of aquaculture animals to a minimum.

3.1.6.7 Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.

3.1.6.8 Eyestalk ablation, including all similar practices such as ligation, incision and pinching, is prohibited.

3.1.6.9 Slaughter techniques shall render fish immediately unconscious and insensible to pain. Handling prior to slaughter shall be performed in a way that avoids injuries while keeping suffering and stress at a minimum. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.

3.2 **Detailed** rules for molluscs

3.2.1 Origin of seed

With regard to the origin of seed the following rules shall apply:

- (a) wild seed from outside the boundaries of the production unit may be used in the case of bivalve shellfish, provided that there is no significant damage to the environment, it is permitted by local legislation and the wild seed comes from:
 - (i) settlement beds which are unlikely to survive winter weather or are surplus to requirements; or
 - (ii) natural settlement of shellfish seed on collectors;
- (b) for the cupped oyster, *Crassostrea gigas*, preference shall be given to stock which is selectively bred to reduce spawning in the wild;
- (c) records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area;
- (d) **wild seed may be collected only after the authorisation has been granted by the competent authority.**

3.2.2 Housing conditions and husbandry practices

With regard to the housing conditions and husbandry practices the following rules shall apply:

- (a) production may be carried out in the same area of water as organic finfish and *algae* production in a polyculture system to be documented in the sustainable management plan. Bivalve molluscs may also be grown together with gastropod molluscs, such as periwinkles, in polyculture;
- (b) organic bivalve mollusc production shall take place within areas delimited by posts, floats or other clear markers and shall, as appropriate, be restrained by net bags, cages or other man made means;
- (c) organic shellfish farms shall minimise risks to species of conservation interest. If predator nets are used their design shall not permit diving birds to be harmed.

3.2.3 Cultivation

With regard to cultivation the following rules shall apply:

- (a) cultivation on mussel ropes and other methods listed in *the implementing acts referred to in Article 15(3)* may be *used in* organic production;
- (b) bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. *A survey and report supporting the* evidence of minimal environmental impact **■** shall be added as a separate chapter to the sustainable management plan *and provided by the operator to the competent authority or, where appropriate, the control authority or control body before starting operations.*

3.2.4 Management

With regard to management the following rules shall apply:

- (a) production shall use a stocking density not in excess of that used for non-organic molluscs in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass and to ensure animal welfare and high product quality;
- (b) biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from mollusc farms. Molluscs may be treated once during the production cycle with a lime solution to control competing fouling organisms.

3.2.5 Specific cultivation rules for oysters

Cultivation in bags on trestles shall be permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the requirements set out in *the implementing acts referred to in Article 15(3)*.

Part IV: Processed food ■ production rules

In addition to the general production rules laid down in Articles 9, 11 and 16, the rules laid down in this Part shall apply to *the organic production of* processed food ■ .

1. General requirements for the production of processed food ■
 - 1.1 Food ■ additives, processing aids and other substances and ingredients used for processing food ■ and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice¹.
 - 1.2 Operators producing processed food ■ shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
 - 1.3 The application of the procedures referred to in point 1.2 shall guarantee at all times that the produced processed products comply with this Regulation.

¹ Good manufacturing practices (GMPs) as defined in Article 3(a) of Commission Regulation (EC) *No* 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, p. 75).

- 1.4 Operators shall comply with and implement the procedures referred to in point 1.2, and in particular shall ***without prejudice to Article 28***:
- (a) take ***precautionary*** measures ■ ;
 - (b) implement suitable cleaning measures, monitor their effectiveness and record these operations;
 - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
- 1.5 The preparation of processed organic, ***in-conversion and non-organic*** products shall be kept separate ***from each other*** in time or space ■ . When non-organic ***or in-conversion*** products are also prepared or stored in the preparation unit concerned, the operator shall:
- (a) inform ***the competent authority or, where appropriate***, the control authority or control body accordingly;
 - (b) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on ***in-conversion or*** non-organic products;
 - (c) store ***organic, in-conversion and non-***organic products, before and after the operations, separate by place or time from ***each other***;

- (d) keep available an updated register of all operations and quantities processed;
 - (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with *in-conversion or* non-organic products;
 - (f) carry out operations on organic *or in-conversion* products only after suitable cleaning of the production equipment.
- 1.6 Products, substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of organic food or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food shall not be used.
2. **Detailed requirements** for the production of processed food
- 2.1 The following conditions shall apply to the composition of organic processed food:
- (a) the product shall be produced mainly from agricultural ingredients *or products intended for use as food listed in Annex I*; in order to determine whether a product is produced mainly from *those products*, added water and salt shall not be taken into account;

- (b) an organic ingredient shall not be present together with the same ingredient in non-organic form;
- (c) ***an in-conversion ingredient shall not be present together with the same ingredient in organic or non-organic form.***

2.2 Use of certain products and substances in processing of food

2.2.1 *Only those food additives, processing aids and non-organic agricultural ingredients authorised for use in organic production pursuant to Article 24 or Article 25, as well as the products and substances referred to in point 2.2.2 may be used in the processing of food, with the exception of products and substances of the wine sector, for which point 2 of Part VI shall apply, and of yeast for which point 1.3 of Part VII shall apply.*

2.2.2 In the processing of food, the use of the following products and substances shall be allowed:

- (a) preparations of micro-organisms and food enzymes normally used in food processing; however food enzymes to be used as food additives have to be authorised for use in organic production pursuant to Article 24;
- (b) substances, and products as defined in Article 3(2)(c) and (d)(i) of Regulation (EC) No 1334/2008 labelled as natural flavouring substances or natural flavouring preparations, in accordance with Article 16(2), (3) and (4) of that Regulation;

- (c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008 **■**;
- (d) ***natural colours and natural coating substances for the traditional decorative colouring of the shell of boiled eggs produced with the intention to place them on the market at a given period of the year;***
- (e) drinking water and ***organic or non-organic*** salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
- (f) minerals (trace elements included), vitamins, aminoacids **■** and micronutrients, only authorised **■** :

■

(i) *when their use in food for normal consumption is ‘directly legally required’, in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if the mineral, vitamin, aminoacid or micronutrient is not added;*

or

(ii) *as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers, in products as referred to in Article 1(1)(a) and (b) of Regulation (EU) No 609/2013 of the European Parliament and of the Council¹, provided that their use is authorised by that Regulation and acts adopted on the basis of its Article 11(1) for these products or by Commission Directive 2006/125/EC² provided that their use is authorised by that Directive.*

2.2.3 *With regard to cleaning and disinfection, only the products for cleaning and disinfection authorised for use in processing pursuant to Article 24 shall be used.*

¹ *Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).*

² *Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, OJ L 339, 6.12.2006, p. 16–35.*

2.2.4 For the purpose of the calculation referred to in Article 30(5), the following rules shall apply:

- (a) certain food additives authorised for use in organic production pursuant to Article 24 shall be calculated as agricultural ingredients;
- (b) preparations and substances referred to in *points (a), (c), (d), (e) and (f) of point 2.2.2* shall not be calculated as agricultural ingredients;
- (c) yeast and yeast products shall be calculated as agricultural ingredients.

█

Part V: Processed feed production rules

In addition to the general production rules laid down in Articles 9, 11 and 17, the rules laid down in this Part shall apply to the organic production of processed feed.

- 1. General requirements for the production of processed feed***
- 1.1 Feed additives, processing aids and other substances and ingredients used for processing feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.***
- 1.2 Operators producing processed feed shall establish and update appropriate procedures based on a systematic identification of critical processing steps.***
- 1.3 The application of the procedures referred to in point 1.2 shall guarantee at all times that the produced processed products comply with this Regulation.***

- 1.4** *Operators shall comply with and implement the procedures referred to in point 1.2, and in particular shall without prejudice to Article 28:*
- (a) take precautionary measures;*
 - (b) implement suitable cleaning measures, monitor their effectiveness and record these operations;*
 - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.*
- 1.5** *The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space. When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:*

- (a) *inform the control authority or control body accordingly;*
█
- (b) *carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;*
█
- (c) *store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other;*
- (d) *keep available an updated register of all operations and quantities processed;*
- (e) *take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;*
- (f) *carry out operations on organic or in-conversion products only after suitable cleaning of the production equipment.*

2. **Detailed requirements** for the production of processed feed
- 2.1 Organic feed materials, or in-conversion feed materials, shall not enter simultaneously with the same feed materials produced by non-organic means into the composition of the organic feed product.
- 2.2 Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.
- 2.3 **Only non-organic feed material of plant origin, algae, animal or yeast origin, feed material of mineral origin, feed additives and processing aids authorised for use in organic production pursuant to Article 24, may be used in the processing of feed.**
- 2.4 **With regard to cleaning and disinfection, only the products for cleaning and disinfection authorised for use in processing pursuant to Article 24 shall be used.**

Part VI: Wine

1. Scope
 - 1.1. In addition to the general production rules laid down in Articles 9, 10, **11**, **16** and 18, the rules laid down in this Part shall apply to the organic production of the products of the wine sector as referred to in point (1) of Article 1(2) of Regulation (EU) No 1308/2013.
 - 1.2. Commission Regulations (EC) No 606/2009¹ and (EC) No 607/2009² shall apply, save as explicitly provided otherwise in this Part.
2. Use of certain products and substances
 - 2.1. Products of the wine sector shall be produced from organic raw material.
 - 2.2. Only products and substances authorised for use in organic production pursuant to Article 19 may be used for the making of products of the wine sector, including during the processes and oenological practices, subject to the conditions and restrictions laid down in Regulation (EU) No 1308/2013 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.
3. Oenological practices and restrictions

¹ Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).

² Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (OJ L 193, 24.7.2009, p. 60).

- 3.1 Without prejudice to Sections 1 and 2 and to specific prohibitions and restrictions provided for in points 3.2 to 3.4, only oenological practices, processes and treatments, including the restrictions provided for in Article 80 and 83(2) of Regulation (EU) No 1308/2013, and in Article 3, Articles 5 to 9 and Articles 11 to 14 of Regulation (EC) No 606/2009, and in the Annexes to those Regulations, used before 1 August 2010, shall be permitted.
- 3.2 The use of the following oenological practices, processes and treatments shall be prohibited:
- (a) partial concentration through cooling according to point (c) of Section B.1 of Part I of Annex VIII to Regulation (EU) No 1308/2013;
 - (b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009;
 - (c) electro dialysis treatment to ensure the tartaric stabilisation of the wine according to point 36 of Annex I A to Regulation (EC) No 606/2009;
 - (d) partial dealcoholisation of wine according to point 40 of Annex I A to Regulation (EC) No 606/2009;
 - (e) treatment with cation exchangers to ensure the tartaric stabilisation of the wine according to point 43 of Annex I A to Regulation (EC) No 606/2009.

- 3.3 The use of the following oenological practices, processes and treatments is permitted under the following conditions:
- (a) for heat treatments according to point 2 of Annex I A to Regulation (EC) No 606/2009, the temperature shall not exceed **75 °C**;
 - (b) for centrifuging and filtration with or without an inert filtering agent according to point 3 of Annex I A to Regulation (EC) No 606/2009, the size of the pores shall be not smaller than 0,2 micrometer.

- █**
- 3.4 Any amendment introduced after 1 August 2010, as regards the oenological **practices**, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009, may be applicable in the organic production of wine only after **those measures have been included as permitted** in this Section **█** and, if required, an evaluation according to Article 24 of this Regulation.

Part VII: Yeast used as food or feed

In addition to the general production rules laid down in Articles 9, **11, 16, 17** and 19, the rules laid down in this Part shall apply to **the organic production of** yeast used as food or feed.

1. General requirements
 - 1.1 For the production of organic yeast only organically produced substrates shall be used. **However, until 31 December 2020, the addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in weight of dry matter) is allowed for the production of organic yeast, where operators are unable to obtain yeast extract or autolysate from organic production.**
 - 1.2 Organic yeast shall not be present in organic food or feed together with non-organic yeast.
 - 1.3 The following substances may be used in the production, confection and formulation of organic yeast:
 - (a) processing aids authorised for use in organic production pursuant to Article 24;
 - (b) products and substances referred to in point 2.2.2(a), **(b)** and (e) of Part IV.
 - 1.4 **With regard to cleaning and disinfection, only the products for cleaning and disinfection authorised for use in processing pursuant to Article 24 shall be used.**
-

COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS

1. Collection of products and transport to preparation units
Operators may carry out simultaneous collection of organic, *in-conversion* and non-organic products only where appropriate measures are taken to prevent any possible mixture or exchange *between organic, in-conversion and* non-organic products and to ensure the identification of the organic *and in-conversion* products. The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the control authority or control body.
2. Packaging and transport of products to other operators or units
- 2.1 Operators shall ensure that organic *and in-conversion* products are transported to other operators or units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by Union law:
 - (a) the name and address of the operator and, where different, of the owner or seller of the product;
 - (b) the name of the product or a description of the compound feedingstuff accompanied by a reference to organic production;

- (c) the name or the code number of the control authority or control body to which the operator is subject; and
- (d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the control authority or control body and which permits to link the lot with the records referred to in Article 34(5).

The information referred to in points (a) to (d) may also be presented on an accompanying document, if such a document can be undeniably linked with the packaging, container or vehicular transport of the product. This accompanying document shall include information on the supplier or the transporter.

2.2 The closing of packaging, containers or vehicles shall not be required where:

- (a) **the transport** is direct between an operator and another operator who are both subject to the organic control system;
- (b) **the transport includes only organic or only in-conversion products;**
- (c) the products are accompanied by a document giving the information required under point 2.1; and
- (d) both the expediting and the receiving operators keep documentary records of such transport operations available for the control authority or control body.

3. Special rules for transporting feed to other **■** production or preparation units or storage premises

When transporting feed to other production or preparation units or storage premises, operators shall ensure that the following conditions are met:

- (a) during transport, organically produced feed, in-conversion feed, and non-organic feed ***are*** effectively physically separated;
- (b) vehicles or containers which have transported non-organic products ***are*** only **■** used to transport organic ***or in-conversion*** products if:
 - (i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic ***or in-conversion*** products and the operators record these operations;
 - (ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with control arrangements and, where necessary, operators **■** guarantee that non-organic products cannot be placed on the market with an indication referring to organic production;

- (iii) the operator *keeps* documentary records of such transport operations available for the control authority or control body;
 - (c) the transport of finished organic *or in-conversion* feed *is* separated physically or in time from the transport of other finished products;
 - (d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round *is* recorded.
- 4. Transport of live fish
- 4.1 Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.
- 4.2 Before transport of organic fish and fish products, tanks shall be thoroughly cleaned, disinfected and rinsed.
- 4.3 Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.
- 4.4 Documentary evidence shall be maintained for operations referred to in points 4.1, 4.2 and 4.3.

5. Reception of products from other operators of units
On receipt of an organic *or in-conversion* product, the operator shall check the closing of the packaging **■**, container *or vehicle* where it is required and the presence of the indications provided for in Section 2.
The operator shall crosscheck the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article **34(5)**.
6. Special rules for the reception of products from a third country
Where organic *or in-conversion* products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot and with the certificate of control for import from third countries as appropriate.
On receipt of an organic *or in-conversion* product imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing, shall check the closing of the packaging or container and, in the case of products imported in accordance with Article 45(1)(b)(iii), shall check that the certificate of inspection referred to in that *Article covers* the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the records referred to in Article **34(5)**.

7. Storage of products

- 7.1 For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products or substances not in compliance with the organic production rules. Organic ***and in-conversion*** products shall be clearly identifiable at all times.
- 7.2 In case of organic ***or in-conversion*** plant and livestock production units, storage of input products other than those authorised for use in organic production pursuant to Article 24 is prohibited in the production unit.
- 7.3 The storage of allopathic veterinary medicinal products and antibiotics is permitted on agricultural and aquaculture holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in points 1.5.2.2 of Part II and 3.1.4.2(a) of Part III of Annex II, that they are stored in a supervised location and that they are entered in the livestock ***records*** referred to in Article ***34(5)***.

- 7.4 Where operators handle **■** non-organic **■**, organic *or in-conversion* products *in any combination* and the *organic or in-conversion products* are stored in storage facilities in which also other agricultural products or foodstuffs are stored:
- (a) the organic *or in-conversion* products shall be kept separate from the other agricultural products or foodstuffs;
 - (b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;
 - (c) suitable cleaning measures, the effectiveness of which has been checked, *shall* have been carried out before the storage of organic *or in-conversion* products and the operators shall record these operations.
- 7.5 *With regard to cleaning and disinfection, only the products for cleaning and disinfection authorised for use in organic production pursuant to Article 24 shall be used in storage facilities.*
-

TERMS REFERRED TO IN ARTICLE 30

BG:	биологичен.
ES:	ecológico, biológico, <i>orgánico</i> .
CS:	ekologické, biologické.
DA:	økologisk.
DE:	ökologisch, biologisch.
ET:	mahe, ökoloogiline.
EL:	βιολογικό.
EN:	organic.
FR:	biologique.
GA:	orgánach.
HR:	ekološki.
IT:	biologico.
LV:	bioloģisks, ekoloģisks.
LT:	ekologiškas.
LU:	<i>biologesch, ökologesch.</i>
HU:	ökológiai.

MT: organiku.
NL: biologisch.
PL: ekologiczne.
PT: biológico.
RO: ecologic.
SK: ekologické, biologické.
SL: ekološki.
FI: luonnonmukainen.
SV: ekologisk.

ORGANIC PRODUCTION LOGO OF THE EUROPEAN UNION AND CODE NUMBERS

1. Logo

- 1.1 The organic production logo of the European Union shall comply with the model below:

LOGO to be inserted

- 1.2 The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.

- 1.3 The organic production logo of the European Union may also be used in black and white as shown, only where it is not practicable to apply it in colour:

LOGO to be inserted

- 1.4 If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.

- 1.5 If a logo is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the logo can be used to improve contrast with the background colours.

- 1.6 *Where* there are indications in a single colour on the packaging, the organic production logo of the European Union may be used in the same colour.

- 1.7 The organic production logo of the European Union must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.

1.8 The organic production logo of the European Union may be associated with graphical or textual elements referring to organic production, under the condition that they do not modify or change the nature of the organic production logo of the European Union, nor any of the indications defined in accordance with Article 32. When associated to national or private logos using a green colour different from the reference colour provided for in point **1.2**, the organic production logo of the European Union may be used in that non-reference colour.

2. Code numbers

The general format of the code numbers shall be as follows:

AB-CDE-999

where:

- (a) 'AB' is the ISO code for the country where the controls take place;
- (b) 'CDE' is a term, indicated in three letters to be decided by the Commission or each Member State, like "bio" or "öko" or "org" or "eko" establishing a link with organic production; and
- (c) '999' is the reference number, indicated in maximum three digits, to be assigned by:
 - (i) each Member State's competent authority to the control authorities or control bodies to which *it has* delegated control tasks;
 - (ii) the Commission, to:
 - the control authorities and control bodies recognised by the Commission pursuant to Article 46,
 - to the competent authorities of third countries recognised by the Commission pursuant to Article 48.

Model of certificate
Certificate according to Article 35(1) of Regulation (EU) XXX/XXX
[Organic production and labelling of organic products Regulation]

1. Document number:	
2. (tick one box as appropriate) <input type="checkbox"/> Operator <input type="checkbox"/> Group of operators – see annex	3. Name and address of operator or group of operators:
4. Activit(y)(ies) of the operator or group of operators (choose as appropriate): <input type="checkbox"/> Agricultural production <input type="checkbox"/> Preparation <input type="checkbox"/> Distribution <input type="checkbox"/> Storing <input type="checkbox"/> Import <input type="checkbox"/> Export <input type="checkbox"/> Placing on the market	5. Name, address and code number of control authority or control body of the operator or group of operators:

<p>6. Categor(y)(ies) of products as referred to in Article 35(7) of Regulation (EU) XXX/XXX and production methods (choose as appropriate):</p>	
<p>- <i>unprocessed plants and plant products, including seed and other plant reproductive material</i></p> <p><i>Production method:</i></p> <p><input type="checkbox"/> <i>organic production excluding during the conversion period</i></p> <p><input type="checkbox"/> <i>production during the conversion period</i></p> <p><input type="checkbox"/> <i>organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</i></p>	<p><i>Certificate validity period from to</i></p>
<p>- <i>livestock and unprocessed livestock products</i></p> <p><i>Production method:</i></p> <p><input type="checkbox"/> <i>organic production excluding during the conversion period</i></p> <p><input type="checkbox"/> <i>production during the conversion period</i></p> <p><input type="checkbox"/> <i>organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</i></p>	<p><i>Certificate validity period from to</i></p>

<p>- <i>algae and unprocessed aquaculture products</i></p> <p><i>Production method:</i></p> <p><input type="checkbox"/> <i>organic production excluding during the conversion period</i></p> <p><input type="checkbox"/> <i>production during the conversion period</i></p> <p><input type="checkbox"/> <i>organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</i></p>	<p><i>Certificate validity period from to</i></p>
<p>- <i>processed agricultural products, including aquaculture products, for use as food</i></p> <p><i>Production method:</i></p> <p><input type="checkbox"/> <i>production of organic products</i></p> <p><input type="checkbox"/> <i>production of in-conversion products</i></p> <p><input type="checkbox"/> <i>organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</i></p>	<p><i>Certificate validity period from to</i></p>
<p>- <i>feed</i></p> <p><i>Production method:</i></p> <p><input type="checkbox"/> <i>production of organic products</i></p> <p><input type="checkbox"/> <i>production of in-conversion products</i></p> <p><input type="checkbox"/> <i>organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</i></p>	<p><i>Certificate validity period from to</i></p>

<p>- wine</p> <p>Production method:</p> <p><input type="checkbox"/> production of organic products</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p><i>Certificate validity period from to</i></p>
<p>- other products listed in Annex I to Regulation (EU) XXX/XXX [Organic production and labelling of organic products Regulation] or not covered by previous categories (please specify):</p> <p>Production method:</p> <p><input type="checkbox"/> production of organic products</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> organic production with non-organic production (pursuant to Article 9(7) of Regulation (EU) XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p><i>Certificate validity period from to</i></p>
<p><i>This document has been issued in accordance with the provisions of Regulation (EU) XXX/XXX [Organic production and labelling of organic products Regulation] to certify that the operator or group of operators (choose as appropriate) meets the requirements of that Regulation.</i></p>	
<p><i>Date, place:</i></p> <p><i>Signature on behalf of the issuing control authority or control body:</i></p>	

Annex – List of members of group of operators as defined in Article 36 of Regulation (EU) XXX/XXX

<i>Name of member</i>	<i>Address</i>
