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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 <i>- Council General approach</i>

Delegations will find attached the final text of the general approach which was reached at the "Agriculture and Fisheries" Council meeting on 16 June 2015.

The text incorporates the modifications to articles 26b, 26e and 26f introduced by the room document circulated during the Council meeting.

2014/0100 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on organic production and labelling of organic products 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 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,

Whereas:

¹ OJ C , , p. .

² OJ C , , p. .

- (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 policy³, 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 Council⁴ and Regulation (EU) No 228/2013 of the European Parliament and of the Council⁵, 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.

³ COM (2009) 234 final.

⁴ 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).

⁵ 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, and promotes sustainable agricultural production. That is why, measures financially supporting organic production have been introduced under the CAP, most recently under Regulation (EU) No 1307/2013 of the European Parliament and of the Council⁶, and in particular strengthened in the recent reform of the legal framework for rural development policy as established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council⁷.

⁶ 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).

⁷ 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 Strategy⁸, the Green Infrastructure Communication⁹, the Soil Thematic Strategy¹⁰ and environmental legislation such as the Birds¹¹ and Habitats¹² Directives, the Nitrates Directive¹³, the Water Framework Directive¹⁴, the National Emissions Ceiling Directive¹⁵ and the Directive on the sustainable use of pesticides¹⁶.
- (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.

⁸ COM(2011) 244 final, 'Our life insurance, our natural capital: an EU biodiversity strategy to 2020'.

⁹ SWD(2013) 155 final, 'Green Infrastructure (GI) – Enhancing Europe's Natural Capital'.

¹⁰ COM(2006) 231 final, 'Thematic Strategy for Soil Protection'.

¹¹ 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).

¹² 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).

¹³ 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).

¹⁴ 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).

¹⁵ 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).

¹⁶ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)

- (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’¹⁷ 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) Given the dynamic evolution of the organic sector, Council Regulation (EC) No 834/2007¹⁸ 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.

¹⁷ COM(2010)2020 final.

¹⁸ 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).

- (9) This new Regulation should cover agricultural products, including aquaculture products, 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 because those other products either constitute a major outlet for agricultural products or form an integral part of the production process. Finally, salt should be included in the scope of this Regulation because it is produced by applying natural production techniques and its production contributes to the development of rural areas, and thus falls within the objectives of this Regulation
- (10) 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. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (11) 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 view of supplementing the list of other products falling within the scope of this Regulation. Only products which are closely linked to agricultural products should be eligible for inclusion in that list.

- (12) 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. Products of hunting and fishing of wild animals should not be considered as organic products since the production process cannot be fully controlled.
- (13) 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.
- (14) This Regulation should apply without prejudice to related legislation, such as in the field of safety of the food chain, animal health and welfare, plant health, plant reproductive material, labelling and the environment. More specifically, as regards the authorisation of products and substances that may be used for the production of organic products, it is important to highlight that such products and substances have to be authorised at Union level first. Therefore this Regulation should apply without prejudice to other specific Union provisions relating to the authorisation and placing on the market of those products and substances.
- (15) As a matter of principle, the general production rules of this Regulation should include a prohibition on the use of ionising radiation, animal cloning and genetically modified organisms (GMOs) and products produced from or by GMOs. Organic operators should take appropriate preventive measures at all stages of production, preparation and distribution in order to ensure prevention and control of pests and weeds and in particular to avoid contamination with products and substances that are not authorised in organic production.

- (16) All operators who aim to become organic should manage their entire holding in compliance with the requirements applicable to organic production. However, to facilitate entering the organic scheme and to favour the development of environmental practices in agriculture, a holding may be split into separated units which are not all managed according to this Regulation.
- (16a) The conversion to the organic production method requires certain periods of adaptation. Specific time periods for the various production sectors should be laid down. Organic agricultural and aquaculture holdings should undergo the same conversion periods in all Member States and third countries. To facilitate entering the organic scheme and to favour the development of environmental practices in agriculture, under certain conditions, previous periods may be recognised retroactively as being part of the conversion period.
- (16b) Products produced during the relevant conversion periods cannot be marketed as organic. Products of plant origin containing only one crop ingredient of agricultural origin can be marketed as in-conversion products and can be allowed in organic production under the condition that a 12 months conversion period has been respected, since these products can usefully contribute to supplying livestock with feed from the farm or the region and are allowed to be used in organic production. However, products that are not of plant origin or products of plant origin that contain more than one crop ingredient of agricultural origin or that have been harvested before the 12 months conversion period, should not be marketed as in-conversion products as such products might create confusion in the market of organic products.
- (17) 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 to ensure harmonisation and respect of the objectives and principles of organic production.

- (18) As organic plant production is based on nourishing plants, which grow naturally in soil, primarily through the soil ecosystem, hydroponic production should not be allowed. In addition, organic plant production should involve the use of production techniques that prevent or minimise any contribution to the contamination of the environment.
- (19) 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.
- (20) The use of pesticides, 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 of the European Parliament and of the Council¹⁹, 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.
- (22) As livestock production naturally involves the management of agricultural land, where the manure is used to nourish crop production, landless livestock production should be prohibited. The choice of breeds should take account of their capacity to adapt to local conditions, their vitality and their resistance to disease, and a wide biological diversity should be encouraged.

¹⁹ 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).

- (23) Organic livestock and aquaculture production housing, including where relevant the aquatic medium, should satisfy the behavioural needs of the animals. Specific housing conditions and husbandry 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.
- (24) In order to avoid environmental pollution of natural resources such as soil and water by nutrients, an upper limit for the use of manure per hectare and for keeping livestock per hectare should be set. That limit should be related to the nitrogen content of the manure.
- (25) Mutilations should be prohibited. However, tail docking, trimming of beaks, dehorning including disbudding and castration of piglets may be allowed only on a case by case basis and under certain conditions, when they improve the health, welfare or hygiene of the livestock or when workers' safety is compromised. These operations should be authorised by a competent authority and carried out by qualified personnel and by applying adequate anaesthesia and/or analgesia in order to reduce to a minimum any suffering to the animals.
- (26) 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, because of the limited availability of certain organic feed materials on the EU market, in certain cases, non-organic feed materials may be used in the feeding of organic animals and in the processing of organic feed. In addition, in order to provide for the basic nutritional requirements of livestock, certain minerals, trace elements and vitamins may need to be used under well-defined conditions.
- (27) 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, except in the event of sickness or injury of an animal requiring immediate treatment and 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, it should be possible to take restrictive measures such as doubling the official withdrawal period after use of such medicinal products as specified in the relevant Union legislation.

- (29) 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 Council and the European Parliament on Strategic Guidelines for the sustainable development of European aquaculture²⁰ 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.
- (30) 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.
- (32) 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 establishing rules amending or supplementing the specific rules for the production of aquaculture animals as regards disease prevention and veterinary treatment in particular.
- (33) 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 integrity and vital qualities of the products are maintained through all stages of organic production.

²⁰ COM(2013) 229 of 29.4.2013.

- (34) Provisions concerning the composition of organic processed food should be laid down. In particular, such food should be produced mainly from agricultural ingredients 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.
- (36) Provisions concerning the composition of organic processed feed and the use of certain substances and techniques in the production of that feed should be laid down.
- (37) 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 establishing rules amending or supplementing the production rules for processed food as regards the type, composition and condition of use of products and substances allowed for use in processed food and supplementing the production rules for processed feed.
- (38) 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.

- (40) 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 889/2008²¹ introduced the obligatory calculation of yeast and yeast products as agricultural ingredients for the purposes of organic production as of 31 December 2013. Accordingly, only organically produced substrates should be used in the production of organic yeast and only certain substances should be allowed for use in its production, confection and formulation. In addition, organic yeast should not be present in organic food or feed together with non-organic yeast. However, to ensure a smooth transition to the new production rules, it is necessary to allow, for a limited period of time, the use of a limited percentage of non-organic yeast extract for the production of organic yeast.
- (41) 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 establishing rules supplementing the specific production rules for organic yeast as regards the processing and the substrates used in its production.

²¹ 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).

(42) This Regulation covers a wide range of products and lays down production rules for different categories of products: plants, livestock, algae and aquaculture animals, as well as processed food, including wine, processed feed and yeast used as food and feed. In the cases where no specific production rules are laid down for plants or plant products, livestock, algae or aquaculture animals, it should be clarified that products marketed as organic have to comply with the production rules laid down for the relevant category of products, with the general production rules and with the principles of organic production. In the absence of specific production rules laid down in an implementing act for specific plants, plant products or plant production systems and implementing act for livestock species other than bovine, ovine, caprine, equine, porcine animals, poultry and bees, Member States may apply national rules for those products. However, the harmonisation achieved through this Regulation and in particular the free movements of products complying with this Regulation should not be endangered. National rules should therefore respect the principles and rules of this Regulation and should only apply to products produced in the Member States laying down national rules. They should not apply to products that are produced in accordance with this Regulation in other Member States

- (42a) In the cases where products are covered by the scope of the Regulation, but do not fall under one of the previously mentioned categories of products (plants, livestock, algae and aquaculture animals, as well as processed food, including wine, processed feed and yeast used as food and feed), it should be clarified that, pending the adoption of production rules for such products, they have to comply with the general production rules and with the principles of organic production in order to be marketed as organic. To be able to take account of any future need in the internal market to have production rules for such products, the power to adopt certain acts should be delegated to the Commission in respect of establishing production rules for such products. In the absence of these production rules laid down in a delegated act, Member States may apply national rules for such products. However, the harmonisation achieved through this Regulation and in particular the free movement of products complying with this Regulation should not be endangered. National rules should therefore respect the principles and rules of this Regulation and should only apply to products produced in the Member State laying down national rules. They should not apply to products that are produced in accordance with this Regulation in other Member States.
- (43) Regulation (EC) No 834/2007 provided for different exceptions from organic production rules. The experience gained from the diverse application of those provisions has shown that such exceptions have a negative impact on organic production, in particular, the management and control of exceptions entail considerable administrative burden, both for the national administrations and for operators. In addition, the existence of exceptions has created conditions for distortions in competition and has threatened to undermine consumer confidence. Accordingly, where exceptions have to be maintained, they should be applied in a harmonised way to all operators in all Member States and third countries.
- (45) Under certain conditions organic products and non-organic products can be collected and transported simultaneously. In order to ensure due separation of organic from non-organic products during handling and to avoid any commingling, specific provisions should be laid down.

- (46) 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 establishing rules amending or supplementing the specific rules on transport of organic products.
- (47) The use in organic production of products and substances such as plant protection products, fertilisers, soil conditioners, nutrients, components of animal nutrition, feed or food 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 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.
- (48) In order to ensure quality, traceability and compliance with this Regulation as regards organic production in general and the production of organic processed 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 organic processed food in particular, and other requirements for the use of such authorised products and substances.

- (52) 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 Council²², and in particular the provisions aimed at preventing labelling that may confuse or mislead consumers. In addition, specific provisions relating to the labelling of organic products and in-conversion products of plant origin 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 enjoying conditions of fair competition, and those of consumers in enabling them to make informed choices.
- (53) 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.
- (53a) 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 in the ingredients list of non-organic 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 the labelling of products of hunting and fishing.
- (53b) Processed feed should be labelled as organic only where all or almost all the ingredients of agricultural origin are organic.

²² 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).

- (54) 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 model of the organic production logo of the European Union should be set out in this Regulation.
- (55) 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 % of their ingredients of agricultural origin are organic.
- (56) 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.
- (57) 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 adapting 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.

- (58) Organic production is only credible if accompanied by effective verification and controls at all stages of production, processing and distribution. Organic production should be subject to official controls or other official activities carried out in accordance with Regulation (EU) No (XXX/XXXX) of the European Parliament and of the Council²³ to verify compliance with the rules on organic production and labelling of organic products. In addition to the rules of Regulation (EU) No XXX/XXX (Official controls Regulation), specific rules for official controls and other official activities in relation to organic production and labelling of organic products should be laid down in this Regulation.

²³ Regulation (EU) No XX/XXX of the European Parliament and of the Council of [...] 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, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 [Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation) (OJ L ...).

- (59) Specific requirements should be laid down to ensure compliance with the rules that are specific to organic production. In particular, provisions should be made for a certification system that allows the competent authorities to identify the operators or groups of operators whose activities relate to organic production so that these authorities or, as appropriate, the control authorities or control bodies verify their compliance with the rules governing organic production and labelling of organic products. In order to avoid disproportionate burden and costs, these notification and certification requirements should not apply to the retail operators who sell products directly to the final consumers or users and do not produce, prepare or store organic products other than at the point of sale, do not import organic products and have not contracted out those activities to third parties. Subcontractors of the operators should comply with the notification and certification requirements, unless the subcontracted activities are covered by the organic certification of the operators concerned. The transparency of the certification system should be ensured by requiring Member States to make public the list 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.
- (59a) The certification system should encompass the delivery of an organic certificate that, being an official certification within the meaning of Regulation (EU) No (XXX/XXXX) of the European Parliament and of the Council (Official controls Regulation), certifies the compliance of the notified activity with this Regulation, and should allow the identification of the operator or group of operators, the categories of products that are certified, as well as of the length of its validity.
- (60) Small-scale 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.

- (62a) Specific, additional provisions to define the aspects that should be included as part of verification of compliance should be laid down in this Regulation, as regards the essential elements for the risk-based approach underpinning the performance of official controls, the minimum frequency of verification of compliance for all organic operators or groups of operators, the specific conditions for the delegation of official control tasks, including in respect of the approval, supervision, and suspension or withdrawal of the delegated bodies, and measures in case of non compliance.
- (62b) As regards the measures to take when non-authorised substances or products are present in organic products, different approaches have been developed and implemented across the Union. This situation creates uncertainties for operators, control authorities and control bodies. It may also entail a different treatment of operators in the Union and affect consumers' confidence in organic products. It is therefore appropriate to lay down clear and uniform provisions requiring competent authorities or, where appropriate, control authorities or control bodies to carry out an investigation in order to determine the source and the cause of the presence of such substances or products in organic products and to conclude on whether such products can be placed on the market as organic. It is also appropriate that, based on information transmitted by Member States on the cases where non authorised products or substances have been detected, the Commission presents a report to the European Parliament and the Council by 2021. In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the methodology to be used in order to detect and evaluate the presence of products or substances that have not been authorised and the related procedures.
- (63) 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 a certificate of export and laying down provisions for export to third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007.

- (63a) The arrangements for import of organic products into the Union should be conducted within the framework of the principles and objectives of the Union's external action, and in particular with the goal of full coherence with the development cooperation, in accordance with existing or future negotiating directives and paying attention to regional standards as set out in Article 21(2)(d) and (e) of the Treaty on European Union.
- (64) 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.
- (65) 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.

- (66) 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.
- (67) 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.
- (68) 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.

- (69) In order to ensure fair competition among operators, the traceability of the imported products intended to be placed on the market within the Union as organic, the transparency of the recognition and supervision procedure for control authorities and control bodies within the context of import of compliant organic products, the effectiveness, efficiency and transparency of controls of imported products and 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 additional criteria for recognition or 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 on those control authorities and control bodies by the Commission, including through on-the-spot examination, in respect of the controls and other actions to be performed by control authorities and control bodies recognised for the import of compliant organic products, and in respect of the information to be sent by third countries recognised under that Regulation necessary for the supervision of their recognition and the exercise of that supervision by the Commission, including on-the-spot examination.
- (70) 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.
- (71) For the purpose of obtaining reliable information needed for the implementation of this Regulation, Member States should provide the Commission annually with the necessary information, including the relevant statistical data which shall be defined within the context of the European Statistical Programme. 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, and any change thereof, should be transmitted by the Member States to the Commission, that shall regularly publish them.

- (73) Furthermore, a date 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.
- (74) 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 and to facilitate the completion of the examination of applications from third countries for recognition for the purpose of equivalence that are pending at 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 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, as well as in respect of any procedural rules necessary for the examination of the pending applications from third countries.
- (75) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the following: the separation of the organic and non-organic units of a holding; the documents to be supplied in view of the retroactive recognition of a previous period as part of conversion; the requirements for specific plants, plant products or plant production systems, the technical details for the establishment of the database for the listing of the varieties and populations for which plant reproductive material, excluding seedlings, obtained by the organic production method is available, and the conditions for the use of non-organic plant reproductive material; specific rules for bovine, ovine, caprine, equine, porcine animals, poultry, bees, and other livestock species; the use of non-organic animals for breeding purposes; specific rules for algae cultivation and sustainable harvesting of wild algae; specific rules for different species of aquaculture animals;

the use of non-organic aquaculture juveniles; specific rules concerning the production methods and the techniques authorised in the processing of specific food or feed products; the identification of oenological practices, processes and treatments prohibited and restricted in the production of organic wine; specific rules on how to deal with catastrophic circumstances, possible exceptions to be applied in such cases for a limited period of time and monitoring and reporting requirements; 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, including 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; specific labelling rules for in-conversion products of plant origin; the specific and 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 and the assignment of code numbers to control authorities and control bodies; the requirements for the content, form and way of the notification to be made by operators or groups of operators, the keeping of records by operators or groups of operators, the publication by Member States of the list of operators or groups of operators, the requirements on the form and procedures to be applied for the publication of the fees that may be collected in relation to the controls for verifying compliance with the organic production rules and for the supervision by the competent authorities of the application of those fees; the content and the form of the organic certificate; the composition and dimension of the group of operators, the criteria for the geographical proximity of its members, the conditions for participation in the group including in respect of the product categories produced by its members, the set up and functioning of the group's system for internal controls, including the scope, content and frequency of the controls to be carried out, the responsibilities and obligations of the members of the group, and the exchange of information between the group and the competent authorities, control authorities and control bodies as well as between the Member States and the Commission;

the specific tasks of the competent authorities, the timing, methods and techniques for the controls to be performed, the modalities for sampling as regards in particular the range of samples to be taken and the stage of production, processing and distribution where samples shall be taken, the modalities for establishing the likelihood of non-compliance and the frequency of sampling, the reporting obligations for the competent authorities, the control authorities and the control bodies, the specific obligations, arrangements and undertakings by operators, the cases where competent authorities are to take which actions and measures in case of non compliance, the exchange of information between competent authorities, control authorities and control bodies concerning cases of non-compliance so as to be adapted to the specific needs of the organic production sector; the documents intended for customs authorities in third countries, in particular an organic export certificate, in electronic form wherever possible; the content of the certificates confirming that all operators or groups of operators are in compliance with this Regulation and of the certificates of inspection and the procedure to be followed for their issuance and verification; the recognition or withdrawal of the recognition of control authorities and control bodies which are competent to carry out controls in third countries and the establishment of the list of those control authorities and control bodies; the procedures for the recognition or withdrawal of those control authorities and control bodies, including the content of the technical dossier to be submitted, and rules to ensure the application of measures in relation to cases of non-compliance, or suspicion thereof, affecting the integrity of imported organic products; 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 as well as rules to ensure the application of measures in relation to cases of non-compliance, or suspicion thereof, affecting the integrity of organic products imported from those countries; the system to be used to transmit the information necessary for the implementation and monitoring of this Regulation, 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. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²⁴.

- (76) 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, affecting the integrity of imported organic products or to decide on the withdrawal of the recognition of the control authorities and control bodies.
- (78) The Commission should consider the situation of the availability of organic plant reproductive material, animals for breeding purposes and young stock of aquaculture animals and present a report to this end to the European Parliament and the Council in 2024.
- (79) 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. That provision should also apply to those products which require a specific refining or ageing period in case this period has already started at the date of application of this Regulation.

²⁴ 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).

- (81) 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.
- (82) 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, certification and controls and the use of indications referring thereto in labelling and advertising.

Article 2

Scope

1. This Regulation shall apply to the following products listed in Annex I to the TFEU or originating from such products, where they are produced, prepared, distributed, placed on the market, imported or exported or are intended to be produced, prepared, distributed, placed on the market, imported or exported:
 - (a) live or unprocessed agricultural products;
 - (b) processed agricultural products for use as food;
 - (c) feed;
 - (d) plant reproductive material.

This Regulation shall also apply to the other products listed in Annex I to this Regulation where such products are produced, prepared, distributed, placed on the market, imported or exported or are intended to be produced, prepared, distributed, placed on the market, imported or exported.

The products of hunting and fishing of wild animals shall not be considered as organic products.

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.

Mass catering operations carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council²⁵ shall not be subject to this Regulation.

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.

3. 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.

²⁵ 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).

4. 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 Council²⁶, and to Regulation (EU) No 1169/2011.
5. In order to take into account new information on production methods or material or international commitments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing the list of products set out in Annex I. Only products which are closely linked to agricultural products shall be eligible for inclusion in that list.

Article 3

Definitions

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

- (1) ‘organic production’ means the use of production methods compliant with this Regulation, at all stages of production, preparation and distribution;
- (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 in order to ensure soil quality as well as prevention and control of pests and weeds for plants, prevention and control of disease for animals, as well as to prevent in particular contamination with products or substances that are not authorised under this Regulation at all stages of production, preparation and distribution;

²⁶ 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).

- (5) ‘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 have been applied;
- (5a) ‘in-conversion products’ means products that are produced in accordance with Article 8 during the conversion period;
- (6) ‘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;
- (6a) ‘holding’ means all the production units operated under a single management for the purpose of producing products referred to in Article 2(1);
- (6b) ‘production unit’ means all assets to be used for a production sector such as primary production premises, land parcels, pasturages, open air areas, livestock buildings, 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 input relevant for this specific production sector;
- (6c) ‘plant reproductive material’ means plant(s) as well as all forms of plant(s) at any growth stage including seeds, capable of, and intended for, producing entire plants;
- (7) ‘group of operators’ means a group of which each member is a farmer or an operator producing algae or aquaculture animals who in addition may be engaged in processing of food or feed and whose turnover is less than 25.000 Euro per year or standard output is less than 15.000 Euro per year or who has a holding of up to 5 hectares;
- (8) ‘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;
- (9) ‘agricultural area’ means agricultural area as defined in point (e) of Article 4(1) of Regulation (EU) No 1307/2013;

- (9a) ‘populations’ means plant groupings which fulfil the requirements specified in temporary experiments allowed under Article 13a of Council Directives 66/401/EEC and 66/402/EEC, Article 14a of Council Directive 68/193/EEC, Article 19 of Council Directives 2002/54/EC and 2002/56/EC, Article 33 of Council Directive 2002/55/EC and Article 17 of Council Directive 2002/57/EC;
- (10) ‘plants’ means plants as defined in point 5 of Article 3 of Regulation (EC) No 1107/2009;
- (11) ‘plant production’ means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
- (12) ‘plant products’ means plant products as defined in point 6 of Article 3 of Regulation (EC) No 1107/2009;
- (13) ‘pest’ means a pest as defined in Article 1(1) of Regulation (EU) No XX/XXXX (protective measures against pests of plants);
- (14) ‘plant protection products’ means the products referred to in Article 2 of Regulation (EC) No 1107/2009;
- (15) ‘livestock production’ means the production of domestic or domesticated terrestrial animals, including insects;
- (16) ‘veranda’ means an additional, roofed, uninsulated, outdoor part of a livestock building, the longest side being usually equipped with wire fencing or netting with outdoor climate, natural and artificial illumination and a littered floor;
- (17) ‘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 Council²⁷;

²⁷ 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).

- (17a) ‘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;
- (17b) ‘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;
- (17c) ‘hatchery’ in the framework of aquaculture and algae production means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;
- (17d) ‘nursery’ in the framework of aquaculture and algae production means a place where an intermediate 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;
- (17e) ‘pollution’ in the framework of aquaculture and algae production means the direct or indirect introduction into the aquatic environment of substances or energy as defined in Directive 2000/60/EC of the European Parliament and of the Council²⁸ and in Directive 2008/56/EC of the European Parliament and of the Council²⁹, in the waters to which those Directives apply, respectively;
- (17f) ‘polyculture’ in the framework of aquaculture and algae production means the rearing of two or more species usually from different trophic levels in the same culture unit;

²⁸ 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).

²⁹ 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).

- (17g) ‘production cycle’ in the framework of aquaculture and algae production means the lifespan of an aquaculture animal or algae from the earliest life stage (fertilised eggs in the case of aquaculture animals) to harvesting;
- (17h) ‘locally grown species’ in the framework of aquaculture and algae production means species which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007³⁰, as well as the species listed in Annex IV to that Regulation;
- (17i) ‘stocking density’ in the framework of aquaculture and algae production 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;
- (18) ‘veterinary treatment’ means all courses of a curative or preventive treatment against one occurrence of a specific disease;
- (19) ‘veterinary medicinal products’ means veterinary medicinal products as defined in point 1 of Article 4 of Regulation (EU) No XX/XXX (veterinary medicinal products)³¹;
- (20) ‘preparation’ means the operations of preserving or processing of organic products, including slaughter and cutting for livestock products, packaging, labelling or alterations made to the labelling relating to organic production;
- (21) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council³²;
- (22) ‘feed’ means feed as defined in point 4 of Article 3 of Regulation (EC) No 178/2002;

³⁰ 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).

³¹ Regulation (EU) No XX/XXX of the European Parliament and of the Council [...] on veterinary medicinal products (OJ L...)

³² 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).

- (23) ‘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 Council³³;
- (25) ‘placing on the market’ means placing on the market as defined in point 8 of Article 3 of Regulation (EC) No 178/2002;
- (26) ‘traceability’ means traceability as defined in point 15 of Article 3 of Regulation (EC) No 178/2002;
- (27) ‘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;
- (29) ‘ingredient’ means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011;
- (30) ‘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;
- (31) ‘advertising’ means any presentation of products to the public, by any means other than a label, that is intended or is likely to influence and shape attitude, beliefs and behaviours in order to promote directly or indirectly the sale of organic products;
- (32) ‘competent authorities’ means competent authorities as defined in point 5 of Article 2 of Regulation (EU) No XXX/XXXX [Official controls Regulation];

³³ 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).

- (33) ‘control authority’ means control authority for organic production and labelling of organic products as defined in point 39 of Article 2 of Regulation (EU) No XXX/XXXX [Official controls Regulation];
- (34) ‘control body’ means a delegated body as defined in point 38 of Article 2 of Regulation (EU) No XXX/XXXX [Official controls Regulation], 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;
- (35) ‘non-compliance’ means non-compliance with this Regulation;
- (36) ‘genetically modified organism’ 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 Council³⁴ which is not obtained through the techniques of genetic modifications listed in Annex I.B to that Directive, hereinafter referred to as ‘GMO’;
- (37) ‘produced from GMOs’ means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (38) ‘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;
- (39) ‘food additive’ means a food additive as defined in point (a) of Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council³⁵;
- (40) ‘feed additive’ means a feed additive as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council³⁶;

³⁴ 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).

³⁵ 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).

³⁶ 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).

- (41) ‘equivalence’ means meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;
- (41a) ‘processing aid’ means processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008;
- (42) ‘food enzyme’ means a food enzyme as defined in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council³⁷;
- (43) ‘ionising radiation’ means ionising radiation as defined in Article 1 of Council Directive 96/29/Euratom³⁸.
- (43a) ‘pre-packed food’ means a pre-packed food as defined in Article 2(2)(e) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council;

³⁷ 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)

³⁸ 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).

Chapter II

Principles of organic production

Article 4

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) contribution to a high level of biodiversity;
- (c) responsible use of energy and natural resources, such as water, soil, organic matter and air;
- (d) respect of high animal welfare standards and, in particular, fulfilment of animals' species-specific behavioural needs;
- (e) 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 land-related crop cultivation and 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 and preventive measures, when appropriate;
- (f) restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in point (e) do not exist, these shall be limited to:
 - (i) inputs from organic production;
 - (ii) natural or naturally-derived substances;
 - (iii) low solubility mineral fertilisers;
- (g) 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;
- (ga) exclusion of animal cloning, rearing artificially induced polyploid animals and ionising radiation from the whole organic food chain;
- (gb) production of a wide variety of food and other agricultural 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;
- (gc) ensuring the integrity of organic production at all stages of production, processing and distribution of food and feed.

Article 5

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 populations resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests;
- (e) choice of breeds having regard to the capacity of animals to adapt to local conditions, their vitality and their resistance to disease or health problems; the practice of site-adapted and land-related livestock production; 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, where appropriate;
- (f) observance of a high level of animal welfare respecting species-specific needs;
- (g) feeding of livestock with organic feed composed of agricultural ingredients from organic production and of natural non-agricultural substances;

- (i) continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems;
- (j) 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.

Article 6

Specific principles applicable to the processing of organic food and feed

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

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

Chapter III

Production rules

Article 7

General production rules

1. Operators shall comply with the following general production rules:
 - (a) the entire agricultural or aquaculture holding shall be managed in compliance with the requirements applicable to organic production.
 - (b) for the purposes mentioned in Article 19 and in point 2.2 of Part IV and point 1.3 of Part VI of Annex II, only products and substances authorised pursuant to these provisions may be used in organic agriculture and aquaculture, provided that the product or substance in question has been authorised for use in agriculture and aquaculture, in accordance with the relevant provisions of Union law and, where necessary, in the Member States concerned, in accordance with national provisions based on Union law; the use of products and substances used for other purposes than those mentioned in Article 19 and point 2.2 of Part IV and point 1.3 of Part VI of Annex II are allowed provided that their use respects the principles laid down in Chapter II.
 - (c) 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;
 - (ca) the use of animal cloning and the rearing of artificially induced polyploid animals is prohibited;
 - (cb) preventive measures shall be taken as appropriate at all stages of production, preparation and distribution

1a. By way of derogation from paragraph 1 (a), a holding may be split into clearly and effectively separated units or aquaculture production sites which are not all managed under organic production, provided that:

(i) as regards livestock, different species shall be involved;

(ii) as regards plants, different varieties that can be easily differentiated shall be involved.

As regards aquaculture, the same species may be involved, provided that there is a clear and effective separation between the production sites.

In case of research and educational centers, nurseries, seed multipliers, hatcheries in the framework of aquaculture and algae production and breeding operations, the requirements concerning different species and varieties referred to in points (i) and (ii) shall not apply.

1b. In the case referred to in paragraph 1a, the operator shall keep the organic production and the products used for this organic production separate from the non-organic production and the products used for the non organic production. The operator shall keep adequate records to show the effective separation.

2. The Commission shall, by way of implementing acts, lay down more specific rules on the application of paragraphs 1a and 1b.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 8

Conversion

1. Farmers and operators producing algae or aquaculture animals shall respect a conversion period. During the whole conversion period they shall apply the rules on organic production laid down in this Regulation and, in particular, the relevant rules on conversion set out 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 24(1) and his holding is submitted to the organic certification and control system.
3. No previous retroactive period may be part of the conversion period, except where:
 - (a) the land parcels were subject of measures defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 provided that these measures ensure that products or substances not authorised for organic production have not been used on those land parcels; or
 - (b) proof can be provided by the operator that the land parcels were natural or agricultural areas which were not treated with products or substances not authorised for organic production for a period of at least three years.
- 3a. The operator shall keep the organic products separate from the in-conversion products and shall keep adequate records to show the effective separation.

4. Products produced during the conversion period shall not be marketed as organic.

Products of plant origin produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products provided a conversion period of at least 12 months before the harvest has been complied with and the product contains only one crop ingredient of agricultural origin.

The Commission shall, where appropriate, adopt implementing acts laying down specific rules regarding the documents to be supplied in view of the recognition of previous retroactive period, as referred to in Article 8.3 (a) and (b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 9

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 and animals in organic production.
2. For the purposes of paragraph 1, with regard to GMOs or products produced from or by 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 Council³⁹ or Regulation (EC) No 1830/2003 of the European Parliament and of the Council⁴⁰.

³⁹ Regulation (EC) 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).

⁴⁰ Regulation (EC) 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 or by 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.
- 3a. For the purpose of the prohibition referred to in paragraph 1, with regard to products not being food or feed, or products produced by GMOs, operators using such 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 10

Plant production rules

1. Operators producing plants or plant products shall in particular comply with the production rules set out in Part I of Annex II and with the specific rules laid down in accordance with paragraph 4 (a) and (c).
2. Each Member State shall ensure that a computerised database is established for listing the varieties and populations, for which plant reproductive material, excluding seedlings, obtained by the organic production method is available on its territory.
4. The Commission shall adopt implementing acts laying down:
 - (a) requirements for specific plants, plant products or plant production systems;
 - (b) the technical details for establishing the database referred to in paragraph 2;

- (c) the conditions for the implementation of point 1.4.2 of Part. I of Annex II, including the list of varieties or species for which point 1.4.2.1 cannot be applied.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 11

Livestock production rules

1. Livestock operators shall in particular comply with the production rules set out in Part II of Annex II and with the specific rules laid down in accordance with paragraphs 2a, 2b and 2c.
- 2a. The Commission shall adopt implementing acts laying down specific rules on nutrition requirements, housing conditions, stocking density, disease prevention, veterinary treatments, animal welfare and husbandry practices for the following specific livestock species:
 - (a) bovine, ovine and caprine animal;
 - (b) equine animal;
 - (c) porcine animal;
 - (d) poultry;
 - (e) bees;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

- 2b. The Commission may adopt implementing acts laying down specific rules on nutrition requirements, housing conditions, stocking density, disease prevention, veterinary treatments, animal welfare, husbandry practices and conversion periods for livestock species other than those referred to in paragraph 2a.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

- 2c. The Commission shall, where appropriate, adopt implementing acts laying down specific rules on the application of point 1.3.5. of Part II of Annex II.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 12

Production rules for algae and aquaculture animals

1. Operators producing algae and aquaculture animals shall in particular comply with the production rules set out in Part III of Annex II and with the specific rules laid down in accordance with paragraph 3a.
3. In order to ensure quality, traceability and compliance with this Regulation as regards organic aquaculture animals production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing the production rules for aquaculture animals as regards disease prevention and veterinary treatment as referred to in points 4.1.4.1 and 4.1.4.2 of Part III of Annex II.
- 3a. The Commission shall adopt implementing acts laying down specific rules on:
- (a) algae cultivation and sustainable harvesting of wild algae;

- (b) origin of seed, nutrition requirements, housing conditions, stocking density, disease prevention, veterinary treatments, animal welfare and husbandry practices for the different species of aquaculture animals.
- (c) the conditions for the implementation of point 4.1.2.1 (db) of part III of Annex II.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 13

Production rules for processed food and feed

1. Operators producing processed food and feed shall in particular comply with the production rules set out in Part IV of Annex II.
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic processed food production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the production rules for processed food as regards the type, composition and conditions of use of products and substances allowed for use in processed food as laid down in points 2.2.2 of Part IV of Annex II.
 - 2a. In order to ensure quality, traceability and compliance with this Regulation as regards organic processed feed production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing the production rules for processed feed as regards products other than those referred to in points 3.2a and 3.2b of Part IV of Annex II.

- 2b. The Commission may adopt implementing acts laying down specific rules concerning the production methods and the techniques authorised in the processing of specific food or feed products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 14

Production rules for wine

1. Operators producing products of the wine sector shall in particular comply with the production rules set out in Part V of Annex II.
2. Amongst the oenological practices, processes and treatments provided for in Regulations (EU) No.1308/2013 and 606/2009, the Commission shall by way of implementing acts, identify:
 - the oenological practices, processes and treatments prohibited in the production of products of the wine sector;
 - the oenological practices, processes and treatments permitted in the production of products of the wine sector, and the conditions of and restrictions to their use.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 15

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 production rules set out in Part VI of Annex II.
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic yeast production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing the production rules for yeast as regards the processing and the substrates used under point 1.3 of Part VI of Annex II.

Article 16

Absence of specific production rules

1. In the absence of specific production rules for plants, livestock, algae and aquaculture animals, operators shall comply with the principles laid down in Articles 4 to 6, with the general production rules laid down in Articles 7 to 9 and with the relevant requirements laid down in Parts I to III of Annex II.

Until the implementing acts referred to in Article 10.4(a), Article 11.2b and Article 12.3a are adopted, Member States may apply national rules provided that these rules comply with this Regulation and in particular with Article 32. Notably, Member States shall not prohibit or restrict the marketing of organic products produced outside the territory of the Member State concerned.

2. In the absence of production rules for products listed in Annex I to TFEU or in Annex I to this Regulation not falling within the categories referred in Articles 10 to 15, operators shall comply with the principles laid down in Articles 4 and 5, and *mutatis mutandis* with the principles in Article 6 and with the general production rules laid down in Articles 7 to 9.

Taking into account the future need to have specific production rules for the purpose of achieving fair competition, a proper functioning of the internal market and consumer confidence in organic production, the Commission shall be empowered to adopt delegated acts, in accordance with Article 36, laying down production rules for products listed in Annex I to TFEU or in Annex I to this Regulation not falling within the categories referred to in Articles 10 to 15. Those delegated acts have to be based on the principles of organic production laid down in Articles 4 to 6 and have to take into account general production rules laid down in Articles 7 to 9 and existing specific rules set out for similar products. They shall lay down general and specific requirements, concerning in particular allowed or prohibited treatments, practices, inputs or conversion.

Until those delegated acts are adopted, Member States may apply national rules to the products referred to in the first subparagraph, provided that these rules comply with this Regulation and in particular with Article 32. Notably, Member States shall not prohibit or restrict the marketing of organic products produced outside the territory of the Member State concerned.

Article 17

Adoption of exceptional production rules

1. To allow organic production to continue or recommence in the event of catastrophic circumstances deriving from an ‘adverse climatic event’, animal disease, an ‘environmental incident’, a ‘natural disaster’ or a ‘catastrophic event’ as defined respectively in points (h), (i), (j), (k) and (l) of Article 2(1) of Regulation (EU) No 1305/2013 and subject to the principles laid down in Chapter II, the Commission shall adopt implementing acts laying down specific rules on how to deal with such situations, and on monitoring and reporting requirements. Those implementing acts shall provide exceptions to the production rules set out in this Regulation, for a limited period of time.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

2. In cases where the Member State has formally recognised an event as a natural disaster as defined in point (k) of Article 2(1) of Regulation (EU) No 1305/2013 and this event makes it impossible to respect production rules laid down in this Regulation, Member States may take measures, subject to the principles laid down in Chapter II, that grant exceptions to these production rules for a limited period of time and until organic production can be re-established.

Article 18

Collection, packaging, transport and storage

1. Organic products shall be collected, packaged, transported and stored in accordance with the rules set out in Annex III.

2. In order to ensure the integrity of organic production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the rules set out in points 2, 3 and 4 of Annex III.

Article 19

Authorisation of products and substances used in organic production

1. The Commission shall authorise certain products and substances for use in organic production and include them in restricted lists, for the following purposes:
 - (a) as plant protection products;
 - (b) as fertilisers, soil conditioners and nutrients;
 - (c) as feed materials, including non-organic feed material of plant or animal origin, or feed material of 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.
- 1a. 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 include them in restricted lists, for the following purposes:
 - (a) as food additives, food enzymes and processing aids;

(aa) as non-organic agricultural ingredients to be used for the production of organic processed food;

(b) as processing aids for the production of yeast and yeast products.

2. 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) their use is necessary for sustained production and essential for its intended use;

(b) all products and substances are of plant, 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, the following shall apply:

(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 products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be authorised only if 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, the following shall apply:
 - (i) their use is necessary to maintain animal health, animal welfare and vitality and contribute 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 shall be 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;
 - (iia) the use of non-organic feed material of plant or animal origin may be authorised only when feed material of plant or animal origin produced in accordance with organic production rules is not available in sufficient quantity.

2a. The authorisation of the products and substances referred to in paragraph 1a 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) alternatives authorised in accordance with this Article 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 the 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;

- (ca) the organic ingredient is not available in sufficient quantity.
- 2b The authorisation of the use of chemically synthesised products or substances referred to in paragraphs 1 and 1a shall be strictly limited to cases where the use of external inputs referred to in Article 4(f) would contribute to unacceptable environmental impacts.
3. 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 Commission shall be empowered to adopt delegated acts in accordance with Article 36 providing for criteria additional to those referred to in paragraphs 2 and 2a for the authorisation or withdrawal of the authorisation of products and substances referred to in paragraphs 1 and 1a for use in organic production in general and in the production of processed organic food in particular.
4. 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 1a, or that the specifications of use mentioned in the production rules should be amended, the Member State concerned shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the other Member States.

Requests for amendment or withdrawal shall be published by the Commission.

5. The Commission shall adopt implementing acts authorising or withdrawing the authorisation of products and substances referred to in paragraphs 1 and 1a 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 37(2).

Chapter IV

Labelling

Article 21

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.

- 2a. Products of plant origin produced during the conversion period in compliance with Article 8(4) sub-paragraph 2 may be labelled as in-conversion products.
- 2b. The terms referred to in paragraph 1 and 2a shall not be used for a product for which it has to be indicated in the labelling or advertising that it contains GMOs, consists of GMOs or is produced from GMOs according to Union law.

3. 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 provided that:
 - (i) the processed food complies with the production rules set out in Part IV of Annex II and with the specific rules laid down in accordance with Article 13(2b);
 - (ii) at least 95% by weight of its agricultural ingredients 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), 2.2.1, and 2.1(c) of Part IV of Annex II and with the specific rules laid down in accordance with Article 13(2b);
 - (ba) 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 2.1(c) of part IV of Annex II.

The list of ingredients referred to in points (a), (b) and (ba) 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 (ba) 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 (ba) of the first subparagraph as well as the indication of the percentage referred to in points (b) and (ba) 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.

- 3a. 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 IV of Annex II and with the specific rules laid down in accordance with Article 13(2b);
 - (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.
4. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning adaptation of the list of terms set out in Annex IV, taking into account linguistic developments within the Member States.
- 4a. The Commission shall adopt implementing acts to set specific rules on the application of paragraph 2a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 22

Compulsory indications

1. Where products bear terms as referred to in Article 21(1) or are labelled as in conversion in accordance to Article 21(2a):
 - (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) the organic production logo of the European Union referred to in Article 23 as regards pre-packed food as defined in point (e) of Article 2(2) of Regulation (EU) No 1169/2011 shall also appear on the packaging except in cases referred to in Article 21 (2a), (3)(b) and (ba).

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 if all agricultural raw materials of which the product is composed have been farmed in that country.

For the indication 'EU' or 'non-EU' or of the name of the country as referred to in subparagraph 3, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 2% 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 23(3) shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
5. The Commission shall adopt implementing acts laying down specific rules on:
 - (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 23(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 23(3).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Organic production logo of the European Union

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

The organic production logo of the European Union shall not be used for processed food as referred to in Article 21(3)(b) and (ba) or for in-conversion products as referred to in Article 21(2a).

2. The organic production logo of the European Union is an official attestation in accordance with Articles 85 and 90 of Regulation (EU) No XXX/XXXX [Official controls Regulation].
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 22(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. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending the organic production logo of the European Union and the rules relating thereto set out in Annex V.

Chapter V

Certification

Article 24

Organic certification system

1. Operators or groups of operators that produce, prepare, distribute or store organic 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 shall, prior to the placing on the market as organic or prior to conversion period, notify their activity to the competent authorities of the Member State(s) where the activity is carried out and submit their holding to the organic certification and 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 group of operators shall indicate in the notification referred to in subparagraph 1 the control authority or the control body that verifies the compliance of the activity with this Regulation and provides the organic certificate referred to in Article 25(0a).

- 1a. Member States may exempt from the notification obligation referred to in paragraph 1 operators who sell products directly to the final consumer or user provided that they do not produce, prepare, store other than in connection with the point of sale, organic products or import such products from a third country or have not contracted out such activities to a third party.

2. 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 so that the compliance of the sub contracted activities with this Regulation is verified by the competent authorities.
3. Operators, groups of operators and subcontractors shall keep records on the different activities they engage in, in accordance with this Regulation.
4. Member States shall keep updated lists kept in an appropriate manner containing the names and addresses of operators and groups of operators that have notified their activities in accordance with paragraph 1 and shall make that list public, together with the information relating to their organic certificates as referred to in Article 25(1). Member States shall respect the requirements of the protection of personal data under Directive 95/46/EC of the European Parliament and of the Council⁴¹.
5. Member States shall ensure that the fees that may be collected by the competent authorities, control authorities or control bodies in accordance with Article 76 of Regulation (EU) No XX/XXXX (official controls Regulation) are made public.
7. The Commission may adopt implementing acts to provide details and specifications regarding:
 - the requirements, content, form and way of the notification referred to in paragraph 1;
 - the keeping of records referred to in paragraph 3,
 - the publication of the list referred to in paragraph 4;

⁴¹ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

- the requirements and procedures to be applied for the publication, including its form, of the fees referred to in paragraph 5, and for the supervision by the competent authorities of the application of those fees.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 25

Organic certificate

- 0a. Competent authorities or, where appropriate, control authorities or control bodies shall provide an organic certificate to any operator or group of operators that have notified their activity in accordance with Article 24(1) and comply with this Regulation. The organic certificate shall certify that the notified activity is in compliance with this Regulation.
- 0b. Operators and group of operators shall be in possession of an organic certificate as referred to in paragraph 0a prior to the placing on the market of products referred to in Article 2(1).
- 0c. The organic certificate is an official certification within the meaning of Articles 85 and 86 of Regulation (EU) No XXX/XXX (Official controls Regulation).
- 0d. The organic certificate, 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 organic certificate and its period of validity.
- 3. Operators and groups of operators shall not be entitled to be provided with an organic certificate by different control bodies 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.
- 4. Members of a group of operators shall not be entitled to be provided with an individual organic certificate for any of the activities covered by the certification of the group.

5. Operators shall verify the organic certificate of operators that are their suppliers.

5a. The categories of products referred to in paragraphs 0d and 3 are the following:

- plant and plant products;
- livestock and livestock products;
- algae and aquaculture animals;
- processed food and feed, including yeast;
- wine;
- other products listed in Annex I to this Regulation or not covered by previous categories.

6a. The Commission shall adopt implementing acts to provide details and specifications regarding the content and the form of the organic certificate referred to in paragraph 0a.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 26

Group of operators

1. Each group of operators shall:

- be established in a Member State or a third country;
- have a legal entity;
- set up a joint marketing system;

- establish a system for internal controls. This system shall consist of 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 products, may result in the withdrawal of the organic certificate referred to in Article 25 for the whole group.
- 2a. The members of the group of operators shall be located in geographical proximity.
- 2b. Member States shall have a choice to apply one or a combination of more criteria (turnover, standard output, area in ha) referred to in Article 3(7).
4. The Commission shall adopt implementing acts laying down specific rules concerning:
- the composition and dimension of a group of operators as well as the criteria to determine the geographical proximity of the members of the group;
 - the conditions for participation in a group of operators, including regarding the categories of products they produce;
 - the set-up and functioning of the group's system for internal controls, including the scope, content and frequency of the controls, the documentation and record keeping systems, the system for internal traceability and the list of operators;
 - the responsibilities and obligations of the individual members of a group of operators and

- 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 37 (2).

Chapter Va

Controls

Article 26a

General provision

In addition to the provisions laid down in Regulation (EU) No XX/XXXX (Official Controls Regulation), the specific rules provided for in this Chapter shall apply to the official controls and other official activities carried out in relation to organic production and labelling of organic products.

Article 26b

Official controls in relation to organic production and labelling of organic products

1. Official controls in relation to organic production and labelling of organic products shall be performed for the verification of compliance with the provisions of this Regulation and shall include, in particular, the verification of the application of preventive measures, as defined in Article 3(4), of the conditions for the exemption from the notification obligation referred to in Article 24(1a), and of the effective separation between organic and non-organic production and products, referred to in Articles 7 and 8, including through the control of the non-organic production units or sites.
2. The nature and frequency of the official controls shall be determined on the basis of the likelihood of non-compliance, taking into account in particular the following:
 - the type, size and structure of the operators and groups of operators;
 - the length of time during which operators and groups of operators have been in organic production, preparation and distribution;

- the product categories;
- the type, quantity and value of products and their development over time;
- the possibility of commingling of products;
- the application of derogations or exceptions to the rules by operators and groups of operators;
- the critical points for non-compliance and likelihood of non-compliance at any stage of production, preparation and distribution, as defined in Article 3(27).

In any case, all operators and groups of operators with the exception of those referred to in Article 24(1a) shall be subject to a verification of compliance at least once a year. The verification of compliance shall imply a physical on-the-spot inspection, except where Member States decide that in duly justified cases, taking into account the elements referred to in the first subparagraph, the operators and group of operators concerned present a proven low-risk profile and fulfill the criteria of compliant track-record of at least 3 years. In those duly justified cases, however, the period between two physical on-the-spot inspections shall not exceed thirty months.

3. For the purpose of paragraph 2 of Article 12 of Regulation (EU) No XX/XXXX (Official Controls Regulation), the written records on the official controls performed for the verification of compliance with the provisions of this Regulation shall be countersigned by the operator or group of operators concerned or by their representative.

Article 26c

Delegation of tasks to control bodies

1. Official control tasks or other official activities may only be delegated by the competent authorities in accordance with Chapter III of Regulation (EU) No XX/XXXX (Official Controls Regulation) if the following conditions are also met:
 - (a) the control bodies are accredited in accordance with the international harmonised standard ‘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;
 - (b) the delegation of the competent authorities contains a detailed description of delegated control tasks and other official activities, of the reporting obligations and other specific obligations;
 - (c) the control bodies submit to the competent authorities for prior approval:
 - (i) their risk assessment procedures determining in particular the basis for the intensity and frequency of the verification of compliance of the operators and group of operators;
 - (ii) the standard control procedure to be followed, containing a detailed description of the control measures and precautions that the body undertakes to impose on operators and groups of operators subject to its controls;
 - (iii) the measures that the control body intends to apply where non-compliances are found;

- (d) the 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.
2. The competent authorities shall not delegate to control bodies the competence to grant exceptions except for the use of plant reproductive material not obtained from organic production.
 3. For the purpose of Article 31 of Regulation (EU) No XX/XXXX (Official Controls Regulation), the competent authorities shall ensure that information on any non-compliance and likelihood of non-compliance identified by control bodies and on the measures applied is collected and used in order to supervise the activities of control bodies.
 4. In the cases where there is evidence that a control body is failing to properly perform the official control tasks delegated to it, the competent authorities may, before withdrawing the delegation in accordance with Article 32 of Regulation (EU) No XX/XXXX (Official Controls Regulation), fully or partly suspend it.

Article 26d

Measures in case of non-compliance

1. In the event of non-compliance that affects the organic status of the products throughout any of the stages of production, preparation and distribution, the competent authorities, or where appropriate, the control authorities or the control bodies shall ensure 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, repetitive or continued non-compliance, competent authorities or where appropriate, the control authorities or the control bodies shall ensure that the operators or the group of operators concerned, in addition to the measures referred to in paragraph 1 and any appropriate measures taken in particular in accordance with Article 135 of Regulation (EU) No XX/XXXX (Official Controls Regulation), are prohibited from marketing products which refer to organic production for a given period, and that their organic certificate be suspended or withdrawn accordingly.
3. In addition to the requirements laid down in Article 104(1) of Regulation (EU) No XX/XXXX (Official Controls Regulation), competent authorities, control authorities and control bodies shall immediately share information with other competent authorities, control authorities and control bodies as appropriate on any non-compliance or likelihood of non-compliance affecting the organic status of the products.

Article 26e

Presence of non-authorised products or substances

1. When a competent authority, or where appropriate, a control authority or a control body receives reliable and substantiated information or detects the presence of products or substances that have not been authorised in accordance with Article 19 for the purposes listed in Article 19, it must carry out without delay an investigation in order to determine the source and cause of contamination in view of verifying compliance with Article 7(1)(b).

Based on the results of this investigation, the competent authority or, where appropriate, the control authority or control body shall ensure that such products are not marketed as organic, if the presence is due to the deliberate use by the operator or due to avoidable contamination in the production process.

- 1a. A contamination shall be considered as avoidable when the operator:
- has not put in place or maintained appropriate, proportionate measures to identify and avoid the risks of contamination of organic products with non-authorised products and substances or;
 - has not regularly reviewed and adjusted such appropriate measures, while the risk for contamination has clearly been perceptible or;
 - has not taken appropriate measures pursuant to previous requests from the competent authorities or, where appropriate, from the control authority or control body to take steps to avoid contamination or;
 - has not complied with relevant requirements of this Regulation or has otherwise failed to take necessary steps in the production process to avoid contamination.
- 1b. On the basis of the results of the investigation referred to in paragraph 1, the competent authority, or where appropriate the control authority or control body shall identify the possible deficiencies and non-compliances that cause the presence of non-authorised products or substances. The operator concerned shall take the necessary corrective measures to avoid future contamination.
- 1c. By way of derogation from paragraphs 1, 1a and 1b, Member States that have, on 31 December 2015, rules in place providing that products containing non-authorised products and substances above a certain level cannot be marketed as organic, may continue to apply these rules until 31 December 2020 provided that these rules do not prohibit, restrict or impede the placing on the market as organic 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.

2. The control authority or control body shall keep records of the investigations carried out.

By 31 March of each year, Member States shall transmit 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.

By 31 December 2020 at the latest, the Commission shall present a report to the European Parliament and the Council on the state of play of implementation of this article and on the presence of products or substances not authorised in accordance with Article 19 which had been detected in organic products. This report may be accompanied, if appropriate, by a legislative proposal.

3. The Commission shall adopt implementing acts laying down uniform rules concerning:

- the methodology to be used in order to detect and evaluate the presence of products or substances that have not been authorised in accordance with Article 19;
- the procedures to be followed in case the presence of products or substances that have not been authorised in accordance with Article 19 is detected;
- the details of information referred to in paragraph 2 and the format in which it will be transmitted.
- measures to avoid the risks of contamination of organic products with non-authorised products or substances as referred to in paragraph 1a.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 26f

Implementing powers in relation to official controls for organic production and labelling of organic products

The Commission may, by means of implementing acts, lay down rules establishing uniform modalities and specific requirements for the performance of official controls and other official activities carried out in relation to organic production and labelling of organic products, as regards:

- (a) the specific tasks of the competent authorities;
- (b) methods and techniques for the performance of official controls;
- (c) the range of samples and the stage of production, processing and distribution where the sample shall be taken according to the methods to be used for sampling and laboratory analysis;
- (d) the modalities for establishing the likelihood of non-compliance and the frequency of sampling;
- (e) specific reporting obligations for the competent authorities, the control authorities and the control bodies;
- (f) specific obligations, arrangements and undertakings by operators;
- (g) the cases where the competent authorities, in relation to specific suspicion of non compliance and established non-compliance are to take one or more of the actions and measures referred to in Article 26d (1) and (2);

- (h) the exchange of information between competent authorities, control authorities and control bodies concerning cases of non-compliance or likelihood of non-compliance including the exchange of relevant information on the results of their controls upon a request duly justified by the need to guarantee that a product has been produced in accordance with this Regulation.
- (i) the elements referred to in subparagraph 1 of Article 26b(2) to determine the risk-profile referred to in subparagraph 2 of Article 26b(2) for those Member States that decide to exempt operators and groups of operators from the annual physical on-the-spot inspection in accordance with subparagraph 2 of Article 26b(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Chapter VI

Trade with third countries

Article 27

Export of organic products

1. A product may be exported from the Union as organic and bear the organic production logo of the European Union if it complies with this Regulation.

3. The Commission may adopt implementing acts laying down specific details concerning documents intended for customs authorities in third countries, in particular as regards an organic export certificate issued in electronic form wherever possible and providing assurance that exported organic products comply with this Regulation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

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 organic or as in conversion 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 group of operators 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 29 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 31 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; or
 - (ia) comes from a third country which is recognised in accordance with Article 30 and complies with the conditions laid down in the relevant trade agreement;
 - (c) the operators in third countries are able to provide at any time, to the importers or the national authorities information allowing the identification of the operator who carried out the last operation and his control authority or control body with a view to ensuring the traceability of the organic product. This information shall be made available also to the control bodies or the control authorities of the importers.

2. The traceability of imported products intended to be placed on the market within the Union as organic and their compliance with this Regulation have to be ensured. The Commission shall by way of implementing acts lay down specific rules concerning the content of the certificates referred to in paragraph 1 and the procedure to be followed for their issuance and verification, in particular as regards the role of competent authorities, control authorities and control bodies and the possibility to take into account regional differences in ecological balance, climate and local conditions, as well as specific production practices.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37 (2).

3. The respect of the conditions and measures for the import of organic products into the Union shall be ascertained at border control posts, in accordance with Article 45(1) of Regulation (EU) No XXX/XXX (Official controls regulation). The physical checks referred to in Article 47(3) of that Regulation shall be performed at a frequency dependent on the likelihood of non-compliance with this Regulation.

Article 29

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 37(2).
 - 1a. The control authorities or control bodies shall be recognised for the import of the categories of products as listed in Article 25(5a).

- 1b. In order to be recognised, the control authorities and control bodies shall fulfil the following criteria:
- (a) control authorities and control bodies shall be legally established in one Member State or third country;
 - (b) control authorities and control bodies shall have the capacity to carry out controls to ensure that the conditions set out in Article 28(1)(a), (b)(i) and (c) and in this Article are met for organic products intended for import into the Union;
 - (c) control authorities and control bodies shall offer adequate guarantees of objectivity and impartiality and be free from any conflict of interest as regards the exercise of control tasks;
 - (d) control bodies shall be 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) control authorities and control bodies shall have the expertise, equipment and infrastructure required to carry out control tasks and a sufficient number of suitable qualified and experienced staff;
 - (f) additional criteria that may be laid down in a delegated act, adopted pursuant to paragraph 7.
3. The accreditation referred to in paragraph 1b(d) may only be granted by:
- (a) a national accreditation body in the Union in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council⁴²; or

⁴² 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).

(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 1b are met. When examining requests for recognition, the Commission shall invite the control authority or control body to supply all the necessary information.

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 continuously reviewing their performance and recognition. For the purposes of that supervision, the Commission may request additional information from the accreditation bodies or, as 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.

7. In order to ensure the transparency of the recognition and supervision procedures, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing the criteria laid down in paragraph 1b to be applied to the recognition, or the withdrawal of the recognition, of the control authorities and control bodies referred to in paragraph 1, as well as laying down provisions concerning the exercise of the supervision by the Commission, including through on-the-spot examination.

- 7a. The Commission shall adopt implementing acts laying down specific rules concerning the procedure to be followed for the recognition of the control authorities and control bodies referred to in paragraph 1, including the content of the technical dossier to be submitted, as well as the procedure to be followed for the withdrawal of the recognition. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).
- 7b. In order to ensure effectiveness, efficiency and transparency of controls of imported products, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the controls and other actions to be performed by control authorities and control bodies recognised by the Commission for the purpose of this Article.
8. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance affecting the integrity of organic 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 the organic 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. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).
9. 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 37(3) to take the measures referred to in paragraph 8 of this Article or to decide on the withdrawal of the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article.

Article 30

Equivalence under a trade agreement

A recognised third country referred to in Article 28(1)(b)(ia) 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 31

Equivalence under Regulation (EC) No 834/2007

1. A recognised third country referred to in Article 28(1)(b)(ii) is a third country which has been recognised for the purpose of equivalence under Article 33(2) of Regulation (EC) No 834/2007, including those recognised under the transitional measure provided for in Article 42.

The recognition of the third countries referred to in the first subparagraph shall expire on 31 December 2022.

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 continuously reviewing their recognition. 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 that third country, the results of the monitoring and supervisory activities carried out by the competent authority and the results of previous controls.

3. The control bodies performing controls in the third countries referred to in paragraph 1 shall be 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*.
4. 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 37(2).
5. In order to ensure the management of the list of third countries referred to in paragraph 4, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the information to be sent by those third countries 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.
6. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance affecting the integrity of organic 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 the organic 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. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 31a

Report from the Commission on the application of Articles 30 and 31

By 31 December 2020 the Commission shall present a report to the European Parliament and the Council on the state of play concerning the application of Articles 30 and 31, in particular as regards the recognition of third countries for the purpose of equivalence.

Chapter VII

General provisions

SECTION 1

FREE MOVEMENT OF ORGANIC PRODUCTS

Article 32

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

1. 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) No XXX/XXX (Official controls Regulation) 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 AND REPORTING

Article 33

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, including the relevant statistical data which shall be defined within the context of the European Statistical programme. The information shall relate to the organic production of the Member States, in particular as regards numbers of organic operators and groups of operators, numbers of organic holdings including mixed holdings, volumes of organic crop production per type of crop, crop area under conversion and under organic production, organic livestock numbers and volumes of organic animal products, volumes of industrial production per type of activity, number of organic aquaculture animal production sites, volume of organic aquaculture production, number of organic algae production sites, volume of organic algae production.
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 37(2).

Article 34

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 and addresses of the control authorities and control bodies, and their code numbers.

Member States shall transmit these lists, and any change thereof, to the Commission.

2. 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 35

Report

By 31 December 2024, the Commission shall present a report to the European Parliament and the Council on the availability of organic plant reproductive material, animals for breeding purposes and young stock of aquaculture animals. This report shall be accompanied, if appropriate, by a legislative proposal.

Chapter VIII

Procedural, transitional and final provisions

SECTION 1

PROCEDURAL PROVISIONS

Article 36

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.
- 1a. The delegation of power referred to in Articles [.....] shall be conferred on the Commission for a period of 5 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 5-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.
2. The delegation of power referred to in [.....] 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.
3. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

4. A delegated act adopted pursuant to [...] 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 37

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.
- 3a. 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, AMENDMENTS, TRANSITIONAL AND FINAL PROVISIONS

Article 38

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 41

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 on [31 December 2019] at the latest.
2. The Commission shall, by means of an implementing act, establish a list of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and may amend that list by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

3. In order to ensure the management of the list of control authorities and control bodies referred to in paragraph 2, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the information to be sent by those control authorities and control bodies 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 42

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. In order to facilitate the completion of the examination of the applications referred to in paragraph 1, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the procedural rules necessary for the examination, including on the information to be submitted by the third countries.

Article 43

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

Products produced in accordance with Regulation (EC) No 834/2007 before 1 January 2018 [*date of application of this Regulation*] may be placed on the market after that date until stocks are exhausted.

Article 45

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 2018⁴³.

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

[...]

⁴³ At least 6 months after enter into force.

ANNEX I

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.

ANNEX II

PRODUCTION RULES REFERRED TO IN CHAPTER III

Part I: Plant production rules

In addition to the production rules laid down in Articles 7 to 10, the rules set out in this Part shall apply to organic plant production.

1. General requirements

- 1.1. 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.
- 1.2. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.
- 1.3. Conversion
 - 1.3.1. 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 feed from organic production, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.
 - 1.3.1a By way of derogation from article 7.1a.(ii), for the purpose of the conversion of perennial crops, which require a cultivation period of at least three years, varieties that cannot be easily differentiated may be involved provided that the production in question forms part of a conversion plan and the conversion to organic production of the last part of the area concerned begins within the shortest possible period and, in any event, does not exceed a maximum of five years.

In such cases:

- (i) appropriate measures have been taken to ensure the permanent separation of the products obtained from each unit concerned;
- (ii) the control authority or control body is notified of the harvest of each of the products concerned at least 48 hours in advance;
- (iii) upon completion of the harvest, the producer informs the control authority or control body of the exact quantities harvested on the units concerned and of the measures applied to separate the products;
- (iv) the conversion plan and the measures to ensure the permanent separation have been approved by the competent authority; this approval shall be confirmed each year after the start of the conversion plan.

1.3.2. The competent authority may decide, in the cases where the land has been contaminated with products not authorised for organic production, to extend the conversion period beyond the period referred to in point 1.3.1.

1.3.3. 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 1.3.1.

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.

- 1.3.4. In the cases referred to in points 1.3.2. and 1.3.3., 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 with reference to organic production.
- 1.3.5. The specific conversion rules for land associated with organic livestock production should be as follows:
- 1.3.5.1. The conversion rules shall apply to the whole area of the production unit on which animal feed is produced.
 - 1.3.5.2. Notwithstanding point 1.3.5.1., the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.
- 1.4. Origin of plants including plant reproductive material
- 1.4.1. For the production of plants and plant products other than plant reproductive material, only organically produced plant reproductive material shall be used. The plant intended for plant reproductive material production and, where relevant, the mother plant 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.
- 1.4.2. Use of plant reproductive material not obtained from organic production
- By way of derogation from point 1.4.1., for a limited period of time, where plant reproductive material is not available on the market in organic form,
- (a) plant reproductive material from a production unit in conversion to organic farming may be used.
 - (b) Where point (a) is not applicable, Member States may authorise the use of non-organic plant reproductive material, except for seedlings. However, for the use of such non-organic material, points 1.4.2.1 to 1.4.2.7 apply.

- 1.4.2.1. Non-organic plant reproductive material may be used, provided that the plant reproductive material is not treated with plant protection products, other than those authorised for treatment of seed in accordance with point 1.6.2., unless chemical treatment is prescribed in accordance with Regulation (EU) No XX/XXX of the European Parliament and of the Council (protective measures against pests of plants) 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.
- 1.4.2.2. Member States may confer the responsibility for granting the authorisation referred to in point 1.4.2.(b) to control authorities or delegate it to another public administration under their supervision or to control bodies.
- 1.4.2.3. Authorisation to use plant reproductive material not obtained by the organic production method may only be granted in the following cases:
- (i) where no variety of the species which the user wants to obtain is registered in the database referred to in Article 10;
 - (ii) where no supplier, meaning an operator who markets plant reproductive material to other operators, is able to deliver the plant reproductive material before sowing or planting in situations where the user has ordered the plant reproductive material in reasonable time;
 - (iii) where the variety which the user wants to obtain is not registered in the database referred to in Article 10, and the user is able to demonstrate that none of the registered alternatives of the same species are appropriate and that the authorisation therefore is significant for his production;
 - (iv) where it is justified for use in research, test in small-scale field trials or for variety conservation purposes agreed by the competent authority of the Member State.
- 1.4.2.4. The authorisation shall be granted before the sowing of the crop.
- 1.4.2.5. The authorisation shall be granted only to individual users for one season at a time and the authority or body responsible for the authorisations shall register the quantities of plant reproductive material authorised.

1.4.2.6. By way of derogation from point 1.4.2.5., the competent authority of the Member State may grant to all users a general authorisation:

- (i) for a given species when and in so far as the condition laid down in point 1.4.2.3.(i) is fulfilled;
- (ii) for a given variety when and in so far as the conditions laid down in point 1.4.2.3.(iii) are fulfilled.

The authorisations referred to in the first subparagraph shall be clearly indicated in the database referred to in Article 10.

1.4.2.7. Authorisation may only be granted during periods for which the database is updated.

1.5. Soil management and fertilisation

1.5.1. 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.

1.5.2. The fertility and biological activity of the soil shall be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production.

1.5.2a. The use of biodynamic preparations is allowed.

1.5.3. Where the nutritional needs of plants cannot be met by measures provided for in points 1.5.1. and 1.5.2. only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 19 may be used and only to the extent necessary. Operators shall keep records of the use of these products.

- 1.5.4. The total amount of livestock manure, as defined in Council Directive 91/676/EEC⁴⁴, applied on the agricultural holding, 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.
- 1.5.5. Organic 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. The maximum limit as referred to in point 1.5.4., shall be calculated on the basis of all of the organic production units involved in such cooperation.
- 1.5.6. 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.
- 1.5.7. For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.
- 1.5.8. Mineral nitrogen fertilisers shall not be used.
- 1.6. Pest and weed management
- 1.6.1. The prevention of damage caused by pests and weeds shall rely primarily on the protection by:
- natural enemies,
 - the choice of species, varieties and populations,
 - crop rotation,

⁴⁴ 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).

- cultivation techniques such as biofumigation, mechanical and physical methods, and
- thermal processes such as solarisation and shallow steam treatment of the soil (to a maximum depth of 10 cm).

1.6.2. Where plants cannot be protected adequately from pests by measures provided for in point 1.6.1. or in the case of an established threat to a crop, only products authorised for use in organic production pursuant to Article 19 may be used and only to the extent necessary. Operators shall keep records of the use of these products.

1.6.3. The traps or dispensers of products other than pheromones shall prevent the substances from being released into the environment and prevent contact between the substances and the crops being cultivated. The traps shall be collected after use and disposed of safely.

1.7. 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 19 shall be used.

Part II: Livestock production rules

In addition to the production rules laid down in Articles 7, 8, 9 and 11, the rules laid down in this Part shall apply to livestock production.

1. General requirements

1.1. Where the farmer producing organic livestock does not manage agricultural land and has not established a written cooperation agreement with another organic farmer, landless livestock production shall be prohibited.

1.2. Conversion

1.2.2. Conversion periods for the animal species referred to Article 11(3) from (a) to (e) are:

- (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) 7 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.

1.2.3. Animals and animal products produced during the conversion period shall not be marketed as organic.

1.2.4. Animals and animal products may be considered organic at the end of the conversion period if there is simultaneous conversion of the complete production unit, including livestock, pasturage or any land used for animal feed.

1.3. Origin of animals

1.3.1. Organic livestock shall be born and raised on organic agricultural holdings.

1.3.2. Animals existing on the agricultural holding at the beginning of the conversion period and their products may be deemed organic after compliance with the applicable conversion period referred to in point 1.2.2 and the provision of point 1.2.4.

1.3.3. With regard to the breeding of organic animals:

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

(b) reproduction cycles shall not be induced or impeded by treatment with hormones or similar substances, 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 and shall contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals.

1.3.4. In the choice of breeds or strains, account shall be taken of the capacity of animals to adapt to local conditions, without impairment of their welfare, their vitality and their resistance to disease. 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, pale-soft-exudative (PSE) syndrome, sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference shall be given to indigenous breeds and strains.

1.3.5. By way of derogation from point 1.3.1, non-organic animals may be brought onto a holding for breeding purposes, only when organic animals are not available in sufficient number and subject to the conditions provided for in points 1.3.5.1 to 1.3.5.5.

1.3.5.1. Non-organic young animals, when a herd or flock is constituted for the first time, 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 the animals enter the herd:

- (a) bovine and equine 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.

1.3.5.2 Non-organic adult male and nulliparous female animals, for the renewal of a herd or flock, shall be reared subsequently in accordance with the organic production rules. Moreover, the number of female mammals is 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 and caprine animals;

(b) for units with less than 10 equine or bovine animals, or with less than five porcine, ovine or caprine animals any renewal as mentioned above shall be limited to a maximum of one animal per year.

1.3.5.3. The percentages referred to in point 1.3.5.2 may be increased up to 40 %, subject to prior authorisation by the competent authority, in the following special cases:

(a) when a major extension to the farm is undertaken;

(b) when a breed is changed;

(c) when a new livestock specialisation is initiated;

(d) when breeds are in danger of being lost to farming as defined by Member States in accordance with Commission Delegated Regulation (EU) No 807/2014⁴⁵ and in that case animals of those breeds must not necessarily be nulliparous.

1.3.5.4. 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.

1.3.5.5. When a flock of birds is constituted for the first time, renewed or reconstituted, 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.

⁴⁵ Commission Delegated Regulation (EU) No 807/2014 of 11 March 2014 supplementing Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and introducing transitional provisions (OJ L 227, 31.7.2014, p. 1)

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 other organic holdings in the same region;
- (b) livestock shall be fed with organic or in-conversion feed as referred to in point 1.4.3, that meets the animal's nutritional requirements at the various stages of its development. Restricted feeding shall not be permitted in livestock production;
- (c) the keeping of livestock in conditions, or on a diet which may encourage anaemia, shall be prohibited;
- (d) fattening practices shall be reversible at any stage of the rearing process. Force-feeding is forbidden;
- (e) with the exception of bees, livestock shall have permanent access to pasture or 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;
- (h) feed materials of mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production pursuant to Article 19.

1.4.1a. Grazing on organic land

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 are derived from a farming system equivalent to one of those provided for in Articles 23, 25, 28, 30, 31 and 34 of Regulation (EU) No 1305/2013 and that organic animals are not present at the same time on that pasture.

1.4.2. Grazing of common land and transhumance

1.4.2.1. 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 are derived from a production system equivalent to one of those provided for in Articles 23, 25, 28, 30, 31 and 34 of Regulation (EU) No 1305/2013⁴⁶;
- (c) any livestock products from organic animals, whilst using this land, is not regarded as being from organic production, unless adequate segregation from non-organic animals can be proved.

1.4.2.2. 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. The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, shall be allowed for a maximum of 35 days covering both the outward and return journeys. During this period, organic livestock shall be kept separate from other livestock.

⁴⁶ 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).

1.4.3. In-conversion feed

1.4.3.1. For in-conversion agricultural holdings, 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 feed from parcels both in their first and second year of conversion are being used for feeding, the total combined percentage of such feed shall not exceed the maximum percentages fixed in point 1.4.3.2. Feed in their first year of conversion may not be used for the production of organic processed feed.

1.4.3.2. For organic agricultural holdings, up to 30% on average of the feed formula of rations may comprise feed from the second year of conversion. For in-conversion agricultural holdings, when the feed from the second year of conversion comes from the holding itself, this percentage may be increased to 100.

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

1.4.4. Use of certain feed materials and substances in feed

Only organic feed materials, as well as feed materials and feed additives authorised for use in organic production pursuant to Article 19 and to point 3 of part IV of Annex II may be used in the processing of organic feed and in the feeding of organic animals.

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 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 19 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 Article 19 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 19 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 points 1.2.
- 1.5.2.5. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to 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.
- 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 conditions 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.
- 1.6.5. 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.

- 1.7. Animal welfare
- 1.7.1. All persons involved in keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals.
- 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. The livestock shall have permanent access to open air areas, preferably pasture, whenever weather 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.
- 1.7.6. 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.
- 1.7.7. Duration of transport of livestock shall be minimised.
- 1.7.8. Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.
- 1.7.9. Mutilation of animals shall be prohibited.

- 1.7.9a. Tail-docking, trimming of beaks and dehorning, including disbudding are 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. These operations shall be authorised by a competent authority and carried out by qualified personnel.
- 1.7.10. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out an operation only at the most appropriate age by qualified personnel.
- 1.7.11 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 1.7.10.
- 1.7.12. 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.

Part III: Production rules for algae and aquaculture animals

2. General requirements

- 2.1. 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.
- 2.2. 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.
- 2.3. 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 Council⁴⁷. If the production unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
- 2.4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and algae harvesting.

⁴⁷ 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).

- 2.5. 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.
- 2.5a. 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.
- 2.5b. Where applicable, coordination shall take place with the neighbouring operators in drawing up the management plan.
- 2.6. 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.

3. Requirements for algae

In addition to the general production rules laid down in Articles 7, 8, 9 and 12, and where relevant in Section 2, the rules laid down in this Section 3 shall apply to the collection and production of algae. Those rules shall apply *mutatis mutandis* to the production of phytoplankton.

3.1. Conversion

- 3.1.1. The conversion period for an algae harvesting site shall be six months.
- 3.1.2. The conversion period for an algae production unit shall be a period of six months or one full production cycle, whichever is the longer.

3.2. Production rules for algae

3.2.1. 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/EC, and are not unsuitable from a health point of view.
- (b) the collection does not affect significantly the stability of the natural ecosystem or the maintenance of the species in the collection area.

3.2.2. The cultivation of algae shall take place in areas with environmental and health characteristics at least equivalent to those outlined in point 3.2.1(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;
- (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 to supplement 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 19.

4. Requirements for aquaculture animals

In addition to the general production rules laid down in Article 7, 8, 9, 12, and where relevant in Section 2, the rules laid down in this Section 4 shall apply to species of fish, crustaceans, echinoderms and molluscs.

Those rules also shall apply *mutatis mutandis* to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

4.1. General requirements

4.1.1. 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.

4.1.2. Origin of aquaculture animals

4.1.2.1. 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 holdings;
- (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 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) wild caught or non-organic aquaculture animals may be brought into a holding with a view to improving genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding;
- (da) for on growing purposes the collection of wild aquaculture juveniles is specifically restricted to the following cases:
- (i) natural influx of fish or crustacean larvae and juveniles when filling ponds, containment systems and enclosures;
 - (ii) European glass eel, provided that an approved eel management plan is in place for the location and artificial reproduction of eel remains unsolved;
 - (iii) restocking of wild fry of species other than European eel 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 fish are fed exclusively with feed naturally available in the environment.
- (db) for on-growing purposes and when organic aquaculture juvenile animals are not available, Member States may authorize the use of non-organic juveniles, provided that at least the latter two thirds of the duration of the production cycle is managed under organic management.

4.1.2.2. 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;
- (d) where appropriate, species-specific conditions for broodstock management, breeding and juvenile production shall be established.

4.1.3. Nutrition

4.1.3.1. 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 originate from organic production and the feed fraction derived from aquatic animals shall originate from organic aquaculture or sustainable exploitation of fisheries;

- (d) in the case of non-organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition 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;
- (f) only feed materials of mineral origin authorised for use in organic production pursuant to Article 19 may be used in organic aquaculture;
- (g) only feed additives, certain products used in animal nutrition and processing aids as referred to in point 1.4.4. of Part II may be used in organic aquaculture.

4.1.4. Health care

4.1.4.1. 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 and not less than once every two years in the case of bivalve shellfish;
- (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 19 may be used.
- (g) with regard to fallowing the following rules shall apply:
 - (i) the competent authority 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.

4.1.4.2. 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 4.1.4.1., 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 control authority or the control body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

4.1.5. Housing conditions and husbandry practices

- 4.1.5.1. 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.
- 4.1.5.2. 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.

4.1.5.3. 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, where appropriate, a minimum stocking density;
- (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.

4.1.5.4. 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.

4.1.5.5. 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 five percent of the perimeter ("land-water interface") area shall have natural vegetation.

4.1.5.6. 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.

4.1.5.7. Containment systems shall be designed, located and operated to minimise the risk of escape incidents.

4.1.5.8. If fish or crustaceans escape, appropriate action shall be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained.

4.1.5.9. 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 seaweeds 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.

4.1.5.10. Stocking density

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.

4.1.6. Animal welfare

4.1.6.1. 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

4.1.6.2. 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.

4.1.6.3. 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 16 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.

4.1.6.4. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources.

4.1.6.5. 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 pollution;
- (b) occasional stock management procedures such as sampling and sorting;
- (c) in order to assure the survival of the farm stock.

4.1.6.6. Appropriate measures shall be taken to keep the duration of transport of aquaculture animals to a minimum.

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

4.1.6.8. 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.

Part IV: Processed food and processed feed production rules

In addition to the general production rules laid down in Articles 7, 9 and 13, the rules laid down in this Part shall apply to processed food and processed feed.

1. General requirements for the production of processed food and feed

- 1.1. Food and feed additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.
- 1.2. Operators producing processed food or 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:
 - (a) take preventive measures to avoid the risk of contamination by unauthorised substances or products;
 - (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 products shall be kept separate in time or space from non-organic products. 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 products, before and after the operations, separate by place or time from non-organic products;
 - (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 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. 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; in order to determine whether a product is produced mainly from agricultural ingredients, added water and salt shall not be taken into account;

- (c) an organic ingredient shall not be present together with the same ingredient in conversion or in non-organic form;
- (d) food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.

2.2. Use of certain products and substances in processing of food

2.2.1. Only those food additives, processing aids and non-organic ingredients authorised pursuant to Article 19, 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 V shall apply, and of yeast for which point 1.3 of Part VI 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 19;
- (b) substances, and products as defined in Article 3(2)(c) and (d) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council⁴⁸ labelled as natural flavouring substances or natural flavouring preparations, in accordance Article 16(2) and (4) of that Regulation;.
- (c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁴⁹;

⁴⁸ 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).

⁴⁹ 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).

- (ca) 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;
- (d) drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
- (e) minerals (trace elements included), vitamins, aminoacids, and micronutrients, only authorised as far their use is legally required in the foodstuffs in which they are incorporated.

2.2.3. For the purpose of the calculation referred to in Article 21(3), the following rules shall apply:

- (a) certain food additives authorised for use in organic production pursuant to Article 19 shall be calculated as agricultural ingredients;
- (b) preparations and substances referred to in point 2.2.2. shall not be calculated as agricultural ingredients;
- (c) yeast and yeast products shall be calculated as agricultural ingredients.

3. Requirements for the production of processed feed

- 3.1. 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.
- 3.2. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.
- 3.2a. Salt may be used in the processing of organic feed and feeding organic animals.

- 3.2b. Products from sustainable fisheries, may be used in the processing of organic feed and feeding organic animals provided that: (i) they are produced or prepared without chemical solvents; (ii) their use is restricted to non-herbivores; and (iii) the use of fish protein hydrolysate is restricted solely to young animals.
- 3.2c. Non-organic feed material of plant, animal and mineral origin may be used in the processing of organic feed and feeding organic animals provided that their use is authorized according to Article 19.

Part V: Wine

1. Scope

- 1.1. In addition to the general production rules laid down in Articles 7, 8, 9 and 14, 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 (l) of Article 1(2) of Regulation (EU) No 1308/2013.
- 1.2. Commission Regulations (EC) No 606/2009⁵⁰ and (EC) No 607/2009⁵¹ 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.

⁵⁰ 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).

⁵¹ 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).

Part VI: Yeast used as food or feed

In addition to the general production rules laid down in Articles 7, 9 and 15, the rules laid down in this Part shall apply to organic 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 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 19;
 - (b) products and substances referred to in point 2. 2.2. (a) and (d) of Part IV.

ANNEX III

COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS

1. Collection of products and transport to preparation units

Operators may carry out simultaneous collection of organic and non-organic products only where appropriate measures are taken to prevent any possible mixture or exchange with non-organic products and to ensure the identification of the organic 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 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 24.

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) transportation is direct between an operator and another operator who are both subject to the organic control system;
- (b) the products are accompanied by a document giving the information required under point 2.1; and
- (c) 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 shall be effectively physically separated;
- (b) vehicles or containers which have transported non-organic products may only be used to transport organic products if:
 - (i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic 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 shall guarantee that non-organic products cannot be placed on the market with an indication referring to organic production;
- (iii) the operator keep documentary records of such transport operations available for the control authority or control body;
- (c) the transport of finished organic feed shall be 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 shall be 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 product, the operator shall check the closing of the packaging or container 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 24.

6. Special rules for the reception of products from a third country

Where organic 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 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 28(1)(b)(ii), 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 24.

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 products shall be clearly identifiable at all times.

- 7.2. In case of organic plant and livestock production units, storage of input products other than those authorised for use in organic production pursuant to Article 19 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 4.1.4.2(a) of Part III of Annex II, that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 24.
- 7.4. Where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:
- (a) the organic 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, have been carried out before the storage of organic products and the operators shall record these operations.

ANNEX IV

TERMS REFERRED TO IN ARTICLE 21

BG: биологичен.

ES: ecológico, biológico.

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: biologesch, ökologesch.

HU: ökológiai.

MT: organiku.

NL: biologisch.

PL: ekologiczne.

PT: biológico.

RO: ecologic.

SK: ekologické, biologické.

SL: ekološki.

FI: luonnonmukainen.

SV: ekologisk.

ANNEX V

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. In certain specific situations 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 22. 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 they have delegated control tasks;
 - (ii) the Commission, to:
 - the control authorities and control bodies recognised by the Commission pursuant to of Article 29;
 - to the competent authorities of third countries recognised by the Commission pursuant to of Article 31.