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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**

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Grounds for and objectives of the proposal

Over the last 10 years the organic market has been characterized by a dynamic development driven by a strong growth in demand. The global world market for organic food has expanded fourfold since 1999. The area under organic production in the Union has doubled. Each year 500000 ha of land are converted to organic farming. However, neither internal supply nor the legislative framework has kept up with this market expansion. Production rules do not sufficiently integrate evolving consumer and citizen concerns and expectations; labelling rules are complicated; weaknesses in the control system and in the trade regime have been identified. The legislation is complex and entails a high level of administrative burden which is stopping small farmers from joining the Union's organic scheme.

The proposal aims at improving the legislation on organic production with the objectives of:

- (1) removing the obstacles to the sustainable development of organic production in the Union,
- (2) guaranteeing fair competition for farmers and operators and improving the functioning of the internal market,
- (3) maintaining or improving consumer confidence in organic products.

1.2. General context

When adopting Council Regulation (EC) No 834/2007 on organic production and labelling of organic products¹, the Council earmarked a series of issues on which the Commission was required to submit a report to the European Parliament and the Council, after having reviewed the experience gained from the application of Regulation (EC) No 834/2007.

The Council adopted conclusions on the Commission report² at its meeting on Agriculture and Fisheries of 13-14 May 2013³ and called on the Member States and on the Commission to develop the organic production sector at an ambitious level by reviewing the current legal framework, with a view to improving its usability while providing for a period of stability and certainty, and aiming at further clarification and simplification and addressing the current outstanding issues requiring further development.

The review of the Organic Production legislation is part of the Commission's Regulatory Fitness and Performance Programme⁴.

The review gives the opportunity to align the Commission implementing powers in Council Regulation (EC) No 834/2007 to the differentiation between delegated and implementing powers of the Commission introduced by Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFUE).

¹ 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, 20.6.2007, p. 1)

² COM (2012) 212 final of 11 May 2012 Report from the Commission to the European Parliament and to the Council on the application of Council regulation (EC) No 834/2007 on organic production and labelling of organic products

³ 8906/13 AGRILEG 56 – Organic Production: Application of the regulatory framework and development of the sector

⁴ Commission Communication on EU Regulatory Fitness of 12 December 2012 – COM(2012)746

1.3. Existing provisions on this area

The first Union legislation on organic production was adopted in 1991. Council Regulation (EEC) No 2092/91 provided a legal definition of organic production through production rules, defined control and labelling requirements and rules for importing organic products. This provided a basis to protect consumers and organic producers against false and misleading organic claims.

The legislation was revised with the adoption of Council Regulation (EC) No 834/2007 in June 2007, which notably:

- defined organic production further by describing its objectives and principles,
- improved the harmonisation of the organic production rules within the Union, by putting an end to national rules for animal products,
- introduced the possibility of exceptions to the rules under the responsibility of Member States (MS) but with strict limitations and for a limited period of time,
- linked the organic control system to the official food and feed controls system provided in Regulation (EC) No 882/2004⁵ and made obligatory the accreditation of private control bodies,
- restructured the import regime: in addition to the recognition of third countries for the purpose of equivalence, the European Union recognises control bodies (CBs) active in third countries for the purpose of equivalence or compliance. The previous system of individual authorisations granted by MS consignment by consignment was removed from the basic Regulation and is now being phased out.

1.4. Consistency with other policies

This initiative pursues the objectives of the Communication on Smart Regulation in the European Union. One of the aims of the review is to simplify legislative burdens.

It is in line with the general framework of the Europe 2020 Strategy in particular regarding the sustainable growth priority and the promotion of a more resource efficient, greener and a more competitive economy.

It is consistent with the reform of the Common Agricultural Policy (CAP), which shapes the overall framework for the development of agriculture in the Union for the period 2014-2020⁶. The new provisions aim at a sustainable competitiveness to achieve an economically viable food production

⁵ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1)

⁶ Regulation (EU) No 1307/2013 of the European Parliament and of the Council 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); Regulation (EU) No 1308/2013 of the European Parliament and of the Council 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); 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 repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487); Regulation (EU) No 1306/2013 of the European Parliament and of the Council on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

sector, together with the sustainable management of the Union's natural land-based resources, in which organic production has been identified as a key-element.

The proposal takes into account 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.

It is also consistent with the Commission's proposal for a new Council and Parliament regulation on official controls⁷, which aims at consolidating the integrated approach in all areas related to the food chain by rationalising and simplifying the overall legislative framework whilst simultaneously pursuing the objective of better regulation. In particular, definitions are aligned and/or clarified as appropriate, and the necessary specific control provisions are proposed to be integrated into the single legislative framework for official controls.

Finally, the organic production scheme forms part of the Union's agricultural product quality schemes together with geographical indications, traditional specialities guaranteed, products of the EU's outermost regions and mountain areas as is 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 policy and indicated in Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes⁸.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

2.1. Consultations

The current situation was analysed in depth on the basis of the information collected during a series of stakeholder hearings to which the Commission services invited over 70 experts and academics to discuss all the issues relating to the current and future challenges facing the organic sector.

The Commission launched an on-line consultation at the beginning of 2013. Around 45 000 replies were submitted in answer to the questionnaire and almost 1 400 free contributions were received. The majority (96%) of responses were submitted by citizens of the European Union, the remaining 4% were sent by stakeholders.

In addition, stakeholders of the sector were informed and consulted on the review in several meetings of the Advisory Group on Organic Farming.

Member States, as competent authorities in charge of implementing the legislation, were kept informed and were consulted on technical aspects of the review.

2.2. Main outcome of the consultations

The citizens and consumers who replied to the public consultation are concerned mainly with environmental and quality issues. They would like the European organic standard to be strengthened

⁷ Proposal for a Regulation of the European Parliament and of the Council 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), COM(2013)265 final of 6.5.2013.

⁸ 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, 14.12.2010, p. 1)

and wish to have uniformity of organic rules for farmers and other operators all over the Union. Therefore the majority is in favour of putting an end to the exceptions to the rules. High expectations were expressed as regards residues of products and substances that are not authorised for use in organic production. The organic logo of the European Union was ranked at the same level as national logos as a means to recognize organic products. The majority of citizens and stakeholders trust the organic control system while considering that it could be improved, notably by introducing electronic certification. Also the majority is in favour of group certification for small farmers.

The need to improve the legislation on organic production is widely acknowledged in the organic sector. There is also broad agreement that organic production should remain close to its principles and objectives and that exceptions to the rules should be ended.

2.3. Impact assessment

The impact assessment compared three alternative policy scenarios:

- The improved status quo, based on improvements and better enforcement of the current legislation,
- The market-driven option, which aims at providing the conditions to respond dynamically to further market developments with more flexible rules. Long lasting exceptional rules would be integrated in the production rules.
- The principle-driven option which aims at re-focussing organic production on its principles, which would be better reflected in the production rules. Exceptional rules would be ended.

The three policy options have been assessed against their potential to achieve the CAP 2020 objectives, specific policy objectives and operational objectives for the review, and in terms of effectiveness and efficiency. The principle-driven option performs better according to all criteria evaluated, followed by the market-driven option and then the improved status quo.

The expected results of the principle-driven option are the following:

- A positive market outlook, thanks to improved consumer confidence, is expected to support organic products prices and to attract newcomers,
- The removal of exceptions to the rules is expected to contribute to the development of organic inputs, notably seeds,
- Clearer and simpler production rules will make the sector more attractive,
- Fair competition will be improved notably by stronger harmonisation, simpler and clearer rules and the move from equivalence to compliance for the recognition of control bodies in third countries,
- Consumer confidence will be addressed with harmonised production rules taking into account evolving societal concerns (environmental management system for processors and traders, animal welfare),
- A risk-based approach is expected to improve the effectiveness and efficiency of controls and contribute, together with a more reliable import regime, to fraud prevention.
- Positive environmental impacts associated with organic production will be stressed by ending exceptional rules,
- Animal welfare conditions will be improved through the removal of exceptions such as tethering of animals.

The impact assessment concluded that the preferred option was the principle-driven option, together with the inclusion of the improvements proposed in the improved status quo, and with some sub-options.

Particular attention has been paid to simplification during the whole process. The preferred option will:

- clarify the provisions on scope, production rules, labelling and controls,
- remove ineffective provisions,
- limit the MS decision level to grant exceptions to the rules,
- simplify labelling rules,
- simplify the import regime,
- simplify requirements for small farmers, notably with the introduction of group certification.

As regards administrative costs, the current proposal will lead to the removal of 37 out of the 135 existing information obligations imposed on organic operators and administrations.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Summary of the proposed action

In order for organic production to remain close to consumers and citizens' expectations, the link of organic production with its principles is confirmed.

Specific production rules are gathered in an Annex of the proposed Regulation, thus addressing the issue of readability.

Production rules are strengthened and harmonised by removing exceptions, except where temporary measures are necessary in order to allow organic production to continue or recommence in the case of catastrophic circumstances. Organic agricultural holdings have to be entirely managed in compliance with the requirements applicable to organic production and the retrospective acknowledgement for the conversion period is not possible any more. The agricultural ingredients used in the composition of organic processed products have to be exclusively organic. Organic operators other than farmers or operators producing seaweed or aquaculture animals are required to develop a system to measure their environmental performance.

The control system is improved through the integration of all control related provisions in a single legislative text under the Commission proposal for a Regulation on official controls and other official activities in food and feed. Consequently, operators, competent authorities, control authorities and bodies will no longer need in the future to rely in two different legislative texts for the provisions related to controls.

Controllability is enhanced by the clarification, simplification and harmonisation of the production rules and the removal of a series of possible exceptions to such rules.

The proposal repeals the possibility to exempt certain types of retailers provided for in Regulation (EC) No 834/2007, which has led to different interpretations and practices across Member States and has made management, supervision and control system more difficult.

The risk-based approach to official controls is reinforced through the repeal of the requirement for a mandatory annual verification of compliance of all operators provided for in Regulation (EC) No 834/2007. This will make it possible to adapt the control frequency so that operators with a low risk profile may be physically inspected less than annually and/or subject to reduced annual physical inspections, while higher risk operators would be targeted by enhanced controls. There will thus be a

fairer balance of the control pressure on operators, with a reduced burden on those with a proven track record of compliance with the rules, and a more effective and efficient use of resources by the competent authorities, control authorities and control bodies.

Specific provisions are introduced in order to increase transparency with regard to fees that may be collected for the controls of the organic sector and the provisions related to the publication of operators together with information on their certification status are reinforced.

A system of group certification is introduced for small-scale farmers in the Union 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.

Specific provisions for the official controls on organic production and labelling are introduced for enhanced traceability and fraud prevention: operators may not be controlled by different control authorities or bodies for the same type or range of products; operators engaging in different stages of the organic chain should be controlled by the same control authority or body. Specific provisions are also introduced to harmonise action to be taken when non-authorised products or substances are detected.

The proposal, finally, defines action to be taken throughout the Union on the same broad categories of non-compliance so as to ensure a level playing field in the treatment of operators, the proper functioning of the internal market and consumers' trust, while not prejudging the definition of sanctions that is under Member States' competence.

The trade regime is adapted to improve the level playing for the organic operators of the European Union and in Third Countries and to better ensure consumer confidence. The possibility of equivalence agreements with Third Countries remains while the system of unilateral equivalency is phased out. The recognition of control bodies is proposed to be progressively shifted to a compliance regime.

3.2. Legal basis

Treaty on the Functioning of the European Union, Article 43(2) thereof.

3.3. Subsidiarity and proportionality principles

The proposal revises an existing quality scheme set within the CAP. Production and trade of agricultural products and foodstuffs on the market of the European Union and ensuring the proper functioning of the internal market in organic products are matters of Union competence. Both are competences shared with MS.

As part of the overall CAP, to ensure the smooth development of the single market, a Union-wide scheme on organics is more efficient than 28 different schemes. In addition, it allows for a stronger and more consistent trade policy vis-à-vis global trading partners, most notably by enhancing the bargaining power of the Union.

The proposal leads to further harmonisation in the following areas:

- The current possibility offered to Member States to grant exceptions to the rules, which leads to unfair competition among operators, risk of loss of consumer confidence, complexity in the legislation and trade issues (difficulties to implement compliance) is reduced.
- The fact that the response to the same non-compliance with EU organic legislation can vary according to Member States is an issue leading to unfair competition and ineffective functioning of the single market.

3.4. Choice of instruments

The proposed instrument is a regulation, since the existing provisions have been demonstrated to provide an appropriate framework for Member States; other types of measure would not be appropriate. A directive would provide more flexible rules, which could entail unfair competition among operators and lead to confusion and deception of consumer. A regulation provides a consistent approach for Member States to follow and reduces the administrative burden because operators are required to comply with a single set of rules. Soft law instruments such as guidelines are considered inadequate to tackle differences in the interpretation and implementation of the rules and in view of the international context.

4. BUDGETARY IMPLICATION

The proposal allocates a budget for technical assistance measures. Details of the financial implications can be found in the legislative financial statement.

5. OPTIONAL ELEMENTS: SIMPLIFICATION

The proposal provides for simplifications and clarifications and fills several gaps in the legislation.

On production rules, the proposal brings major simplifications for operators and national administrations with a limitation of the Member State decision level to grant exceptions. Several ineffective provisions are removed, notably with the reinforcement of the risk-based approach on controls. On the import side, the compliance regime for control bodies will be easier to manage for the producers, the control bodies and the Commission.

A significant simplification for small farmers is brought by group certification which allows more proportionate inspection and record-keeping requirements.

The proposal intends to make the legislation more user-friendly. In particular, while the general production rules remain in the text of the Regulation, the specific organic production rules are gathered in one Annex of the Regulation.

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee⁹,

Having regard to the opinion of the Committee of the Regions¹⁰,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Organic production is an overall system of farm management and food production that combines best environmental 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 public goods contributing to the protection of the environment and animal welfare, as well as to rural development.
- (2) The respect of high health, environmental and animal welfare standards in the production of organic products attributes 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 policy¹¹, 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 Council¹² and Regulation (EU) No 228/2013 of the European Parliament

⁹ OJ C , , p. .

¹⁰ OJ C , , p. .

¹¹ COM (2009) 234 final.

¹² 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).

and of the Council¹³, respectively. In this sense, organic production pursues the same objectives within the objectives of the Common Agricultural Policy ('CAP') which are inherent to all Union's agricultural product quality schemes.

- (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 the respect of the organic production standards. In addition, the growing consumer demand for organic products creates conditions for further development and expansion of the market of those products and thus for 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 and in particular strengthened in the recent reform of the legal framework of the rural development policy.
- (5) In view of the objectives of the Union organic production policy, the legal framework established for the realisation of that policy should aim at ensuring fair competition and a proper functioning of the internal market in organic products, and of 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.
- (6) 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'. 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.
- (7) Given the dynamic evolution of the organic sector, Council Regulation (EC) No 834/2007¹⁴ 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 of 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.
- (8) 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.

¹³ 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).

¹⁴ 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) Experience gained so far with the application of Regulation (EC) No 834/2007 shows a need to clarify to which products this Regulation applies. Primarily, it should cover agricultural products listed in Annex I to the Treaty. Moreover, it should cover processed agricultural products for use as food or feed in order to ensure that when those products are sold or consumed, the organic nature of the agricultural products from which they are processed remains fully visible to the consumer. Finally, 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 constitute a major outlet for agricultural products or form an integral part of the production process and, thus, contribute to the objectives pursued by this Regulation. For reasons of clarity, those other products, not listed in Annex I to the Treaty, should be listed in an Annex to this Regulation.
- (10) 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 in their premises should not be subject to this Regulation. Equally, products of hunting and fishing of wild animals should not be covered by this Regulation since the production process cannot be fully controlled.[
- (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 respect of the amendment of 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.
- (12) Research projects have highlighted that consumer confidence is crucial in the market for organic food. In the long run, standards that are not trustworthy can jeopardize 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 answer operators' and consumers' expectations regarding the compliance with the principles and rules laid down in this Regulation.
- (13) As a matter of principle, the general production rules of this Regulation should include the prohibition of the use of ionising radiation and genetically modified organisms (GMOs) and products produced from or by GMOs. Since consumers are more and more concerned about environmental impacts of food processing and transportation, organic operators other than farmers and operators producing seaweed or aquaculture animals should be required to manage their environmental performance according to a harmonised system. In order to implement the general production rules, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of the criteria to which the environmental management system is to correspond and of the rules for the application of the prohibition of the use of GMOs and products produced from or with GMOs in organic production.

The risk of non-compliance with the organic production rules is considered higher in agricultural holdings which include units not managed under organic production rules. Therefore, after an appropriate conversion period, all EU agricultural holdings should be entirely managed in compliance with the requirements applicable to organic production. Organic agricultural holdings should undergo the same conversion period in all Member States, irrespective of their previous adherence or not to agri-environmental measures supported by Union funds. In order to ensure quality,

traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules supplementing the general conversion rules or supplementing and amending the specific conversion rules.

- (14) Specific production rules should be established with regard to plant, livestock and aquaculture production, including rules for the collection of wild plants and seaweeds, and with regard to the production of processed food and feed, as well as of wine and yeast.
- (15) As organic plant production is based on nourishing the plants 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.
- (16) 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.
- (17) The use of pesticides, which may have detrimental effects on the environment or result in the presence of residues in agricultural products, should be significantly restricted. Preference should be given to the application of measures that prevent the damage caused by pests, diseases and weeds through techniques which do not involve the use of plant protection products. The use of certain plant protection products should be allowed if such techniques do not provide adequate protection and only if authorised, including with respective conditions of use, under this Regulation.
- (18) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules supplementing the specific plant production rules as regards cultivation practices, soil management and fertilisation, plant health and management of pests, diseases and weeds, management of mushroom production and other specific plants and plant production systems, origin of seed and vegetative propagating material, and collection of wild plants.
- (19) As livestock production naturally implies 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.
- (20) In organic livestock production housing should satisfy the behavioural needs of the animals. Specific housing conditions and husbandry practices should be laid down with regard to certain animals, including bees. Those conditions and practices should ensure a high level of animal welfare, which in certain aspects should go beyond the Union animal welfare standards applicable to livestock production in general. In most cases livestock should have permanent access to open air areas for grazing and such open air areas should in principle be organised under an appropriate system of rotation.
- (21) 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.

- (22) Mutilations which lead to stress, harm, disease or the suffering of animals should be prohibited. However, specific operations essential to certain types of production and for the sake of security of animals and human beings may be permitted under strict conditions.
- (23) Livestock should be fed on grass, fodder and feedingstuffs produced in accordance with the rules of organic production, preferably coming from the own holding, by taking into account their physiological needs. 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.
- (24) 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, unless in the event of sickness or injury of an animal requiring an immediate treatment and only limited to a strict minimum. 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 withdrawal period after use of such medicinal products. Regarding beekeeping, it is necessary to lay down specific rules for disease prevention and veterinary treatment.
- (25) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules supplementing the specific livestock production rules as regards the origin of animals, livestock housing, including minimum surface areas indoors and outdoors and the maximum number of animals per hectare, husbandry practices, breeding, feed and feeding, and disease prevention and veterinary treatment.
- (26) The Communication from the Commission to the Council and the European Parliament on a strategy for the sustainable development of European aquaculture of 2002¹⁵ set out a vision for the development of that sector over a ten year period to reach the status of a stable industry in rural and coastal areas providing alternatives to the fishing industry in terms of products and employment. The Communication pointed to the potential for organic aquaculture production and the requirement for norms and criteria to be developed.
- (27) 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.
- (28) To ensure common understanding, in order to avoid ambiguities and to guarantee the uniform application of the organic aquaculture animal and seaweed production rules, certain definitions relating to aquaculture should accompany these production rules.
- (29) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules supplementing the specific seaweed production rules as regards suitability of aquatic medium and sustainable management plan, harvesting of wild seaweed, seaweed cultivation, and

¹⁵ COM(2002) 511 of 19.9.2002.

antifouling measures and cleaning of production equipment and facilities, and in respect of the establishment of rules supplementing the specific production rules for aquaculture animals as regards suitability of aquatic medium and sustainable management plan, the origin of aquaculture animals, aquaculture husbandry, including aquatic containment systems, production systems and maximum stocking density, breeding, management of aquaculture animals, feed and feeding, and disease prevention and veterinary treatment.

- (30) Operators producing organic food or feed should follow appropriate procedures based on a 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 with the use of processing methods which guarantee that the organic integrity and vital qualities of the products are maintained through all stages of organic production.
- (31) 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 substances authorised in accordance with Article 18 should be allowed for use in the production of organic processed food.
- (32) Processed food should be labelled as organic only where all or almost all the ingredients of agricultural origin are organic. However, special labelling provisions should be laid down for processed foods which include agricultural ingredients that cannot be obtained organically, as it is the case for products of hunting and fishing. Moreover, for the purpose of consumer information, transparency in the market and to stimulate the use of organic ingredients, it should also be made possible to refer to organic production in the ingredients list under certain conditions.
- (33) 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.
- (34) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules supplementing the specific production rules for processed food and feed as regards the procedures to be followed, preventive measures to be taken, composition of processed food and feed, cleaning measures, the placing on the market of processed products including their labelling and identification, separation of organic products, agricultural ingredients and feed materials from non-organic products, agricultural ingredients and feed materials, the list of non-organic agricultural ingredients which may exceptionally be used for the production of organic processed products, the calculation of the percentage of agricultural ingredients in accordance with Article 18(4)(a)(ii), and the techniques used in food or feed processing.
- (35) Organic wine should be produced entirely from organic raw material and only substances authorised in accordance with Article 18 may 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.
- (36) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be

delegated to the Commission in respect of the establishment of rules supplementing the specific wine production rules as regards oenological practices and restrictions.

- (37) Initially yeast was not considered an agricultural ingredient under Regulation (EC) No 834/2007 and therefore it could not count for the agricultural composition of organic products. However, Commission Regulation (EC) 889/2008¹⁶ introduced the obligatory calculation of yeast and yeast products as agricultural ingredients for the purposes of organic production as from 1 January 2014, providing the industry with sufficient time to adjust to that rule. In view of that, 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.
- (38) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules supplementing the specific production rules for organic yeast as regards the processing and the substrates used in its production.
- (39) In order to take account of a possible future need to have specific production rules for products whose production does not fall within any of the categories of specific production rules laid down in this Regulation, as well as in order to ensure quality, traceability and compliance with this Regulation and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of specific production rules for such products.
- (40) Regulation (EC) No 834/2007 provided for different exceptions from organic production rules. The experience gained from the application of those provisions has shown that such exceptions have a negative impact on organic production. In particular, it has been found out that the very existence of such exceptions impedes the production of inputs in organic form and that the high level of animal welfare associated with organic production is not ensured. In addition, the management and control of exceptions entail considerable administrative burden, both for the national administrations and operators. Finally, this has created conditions for distortions in competition and has threatened to undermine consumer confidence. In view of that, the possibility to allow exceptions from organic production rules should be further restricted and limited to cases of catastrophic circumstances.
- (41) In order to allow organic production to continue or recommence in cases of catastrophic circumstances, the power to adopt certain acts should be delegated to the Commission to establish the criteria for qualifying cases of catastrophic circumstances and to lay down specific rules for addressing such cases and for the necessary monitoring and reporting requirements.
- (42) The use in organic production of products and substances 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. The same approach should be followed regarding the use of products and substances as food additives and processing aids in the production of organic

¹⁶ 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 337, 16.12. 2008, p. 1).

processed food. Therefore, provision should be made for the authorisation of such products and substances for use in organic production and in the production of organic processed food, subject to the principles laid down in this Regulation and to certain criteria.

- (43) In order to ensure quality, traceability and compliance with this Regulation as regards organic production and production of organic processed food and feed, and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission to provide for additional criteria for the authorisation or withdrawal of products and substances for use in organic production and in the production of organic processed food and feed, and other requirements for the use of such authorised products and substances.
- (44) Under certain conditions organic products and non-organic products can be collected and transported simultaneously. In order to duly separate organic from non-organic products during handling and to avoid any commingling specific provisions should be laid down.
- (45) In order to ensure the integrity of organic production and adaptation to technical development, the power to adopt certain acts should be delegated to the Commission in respect of the establishment of rules amending or supplementing the specific rules on collection, packaging, transport and storage of organic products.
- (46) 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 Council¹⁷, 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 should be laid down in this Regulation. They should protect both the interests of operators to have their products on the market correctly identified and to function in the conditions of fair competition, and those of consumers to enable them to make informed choices.
- (47) In view of that, the terms used to indicate organic products should be protected from being used on 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.
- (48) 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 EU. 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.
- (49) It is however considered appropriate to limit the use of that logo to products which contain only, or almost only, organic ingredients in order not to mislead consumers as to the organic nature of the entire product. 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 its ingredients of agricultural origin are organic.

¹⁷

Regulation (EU) No 1169/2011 of the European Parliament and of the Council ...[title to be inserted]

- (50) The use of national and private organic labels could be justified by standards that go beyond the requirements of the Union legislation. Therefore they should continue to be allowed.
- (51) For the sake of avoiding any possible confusion amongst consumers on the Union or non-Union origin of the 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 on the label of products from organic aquaculture instead of referring generally to agriculture.
- (52) In order to provide clarity for the consumer and to ensure that the appropriate information is communicated to the consumer, the power to adopt certain acts should be delegated to the Commission to adapt the list of terms referring to organic production set out in this Regulation, as well as to establish the specific labelling and composition requirements applicable to feed and ingredients thereof, to lay down further rules on labelling and the use of the indications, other than the organic production logo of the European Union, set out in this Regulation and to amend the organic production logo of the European Union.
- (53) 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 performed in accordance with Regulation (EU) No (XXX/XXXX) of the European Parliament and of the Council¹⁸ to verify compliance with the rules on organic production and labelling of organic products.
- (54) Specific requirements should be laid down to ensure compliance with the rules that are peculiar to the organic production. In particular, provisions should be made for the notification of the activities of the operators who are subject to official controls and for a certification system to identify the operators that comply with the rules governing organic production and labelling of organic products. The transparency of the certification system should be ensured by requiring from Member States to make public the list of operators having notified their activities and any fees that may be collected in relation to the controls for compliance with the organic production rules.
- (55) Small farmers 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.
- (56) In order to ensure the effectiveness, efficiency and transparency of the organic production and labelling system, the power to adopt certain acts should be delegated to the Commission in respect of the requirements for keeping records by operators, the

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Regulation (EU) No XX/XXX of the European Parliament and of the Council 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 ...).

requirements for the publication of the list of operators, as well as the requirements and procedures to be applied for the publication of the fees collected in relation to the controls for compliance with the organic production rules and for the supervision by the competent authorities of the application of those fees.

- (57) In order to ensure the effective and efficient functioning of the certification of a group of operators, the power to adopt certain acts should be delegated to the Commission in respect of the responsibilities of the individual members of a group of operators, the composition and dimension of that group, the scope of the products to be produced by a group of operators, the conditions for participation in the group, and 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.
- (58) 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 standards 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.
- (59) 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. This would ensure an even 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 bodies and control authorities respectively more efficient.
- (60) 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 scheme for recognition of equivalence of third countries, as laid down in Regulation (EC) No 834/2007, should be abolished and the equivalence of new third countries, which have not been recognised for that purpose under that Regulation, 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.
- (61) Third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 should continue to be recognised as such under this Regulation, 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.

- (62) 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 differences between the standards applied by those authorities and bodies could be substantial and difficult to adapt in practice to a level at which they can be considered equivalent to the respective Union rules. 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.
- (63) 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.
- (64) 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 procedure of control authorities and control bodies within the context of import of compliant organic products and in order to ensure the management of the list of third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007, the power to adopt certain acts should be delegated to the Commission in respect of the documents intended for customs authorities in third countries, in particular an organic export certificate, the documents necessary for the purposes of import, the criteria for recognition or withdrawal of the recognition of control authorities and control bodies in the context of import of compliant organic products, and in respect of the information to be sent by third countries recognised under Regulation (EC) No 834/2007 necessary for the supervision of their recognition and the exercise of that recognition by the Commission, including on-the-spot examination.
- (65) 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. In order to ensure proper functioning of the single market and trade between Member States, the power to adopt certain acts should be delegated to the Commission to lay down rules relating to the free movement of organic products.
- (66) It is necessary to lay down measures to ensure the smooth transition to some modifications of the legal framework governing the import of organic products into the Union, as introduced by this Regulation. In particular, a provision allowing recognition of conversion period starting under Regulation (EC) No 834/2007 should be set out. 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 be also 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
- (67) 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 complete the examination of applications from third countries for recognition for the purpose of equivalence that are pending at the moment 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.

- (68) Member States should provide the Commission annually with the necessary information for implementation of this Regulation concerning the organic sector and trade.
- (69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the measures and conditions necessary for the application of production rules; the specific and practical modalities as regards the 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 produced; the attribution of code numbers to control bodies and control authorities; the indication of the place where the agricultural raw materials have been produced; the laying down of form and modalities as regards presentation, composition, size and design of the use of the organic production logo of the European Union; the procedures for participation in group certification and for the exchange of information; the specific requirements for the operators' notification of their activity to the competent authorities and for their record keeping; the lists of recognised control authorities and control bodies recognised for their activities in third countries for the purpose of compliance; the withdrawal of the recognition of a control authority or a control body in cases of non-compliance with the provisions set out in this Regulation; precautionary measures in relation with cases of non-compliance affecting the integrity of organic products communicated or suspicions of such cases; the withdrawal of the recognition of third countries whose system of production no more complies with principles and production rules equivalent to those laid down in this Regulation or whose control measures are no more of equivalent effectiveness to those laid down in this Regulation; the measures to establish, publish, make available or diffuse the information concerning the details and specifications regarding the content, form and method of notification, submission and exchange of information required in the framework of this Regulation. Those powers should be exercised in accordance with 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.¹⁹
- (70) The Commission should be empowered to adopt immediately applicable implementing acts where, in duly justified cases relating to the protection against unfair practices in case of non-compliance, or the suspicion thereof, affecting the integrity of imported organic products under the control of recognised authorities or recognised bodies, imperative grounds of urgency so require.
- (71) Since the objectives of this Regulation in particular fair competition and a proper functioning of the internal market in organic products as well as ensuring consumer confidence in these products and in the organic production logo of the European Union, cannot be sufficiently achieved by the Member States but can rather, 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

¹⁹ OJ L 55, 28.2.2011, p. 13.

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,

Regulation (EU) No XXX/XXXX (Official controls) should be amended to take account of the results of the review of the political and legislative framework of organic production and the specific needs relating to the official controls and other official activities governing organic production and labelling of organic products, as identified in that review. In view of that, provisions are necessary to enhance the control of operators involved in organic production and action by the competent authorities, control authorities or control bodies in cases of detection of non-authorised products or substances and of non-compliance. In addition, the provisions relating to the tasks and responsibilities of the competent authorities, the approval and supervision of control bodies, the official certification, the reporting obligations and the administrative assistance should be also adapted to meet the specific needs of the organic production sector.

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 and the use of indications referring thereto in labelling and advertising.

Article 2

Scope

1. This Regulation shall apply to agricultural products listed in Annex I to the Treaty and to some other products listed in Annex I to this Regulation, insofar as those agricultural products and those other products are intended to be produced, prepared, distributed, placed on the market, imported or exported as organic.

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 shall not be subject to this Regulation.

Member States may apply national rules or, in the absence thereof, private standards on labelling and control of products originating from mass-catering operations.

3. 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 Council²⁰, and to Regulation (EU) No 1169/2011 of the European Parliament and of the Council²¹.

4. In order to take into account new production methods or material or international commitments, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 adapting 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;
- (2) 'organic' means coming from or related to organic production;
- (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, diseases and weeds, and to prevent contamination with products or substances that are not authorised under this Regulation;
- (5) 'conversion' means the transition from non-organic to organic production within a given period of time;
- (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 and export under their control;
- (7) 'group of operators' means a group in which each operator is a farmer who has a holding of up to 5 hectares of utilised agricultural area and who may, in addition to producing food or feed, be engaged in processing of food or feed.
- (8) 'farmer' means farmer as defined in point (a) of Article 4 of Regulation (EU) No 1307/2013 of the European Parliament and of the Council²²;
- (9) 'agricultural area' means agricultural area as defined in point (e) of Article 4 of Regulation (EU) No 1307/2013 of the European Parliament and of the Council;

²⁰ Regulation (EU) No 1308/2013 of the European Parliament and of the Council 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).

²¹ 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).

²² Regulation (EU) No 1307/2013 of the European Parliament and of the Council 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).

- (10) 'plants' means plants as defined in point 5 of Article 3 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council²³;
- (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) 'plant protection products' means the products referred to in Article 2 of Regulation (EC) No 1107/2009;
- (14) 'livestock production' means the production of domestic or domesticated terrestrial animals, including insects;
- (15) 'veranda' means an additional, roofed, uninsulated, outdoor part of a livestock building, the longest side usually equipped with wire fencing or netting with outdoor climate, natural and artificial illumination and a littered floor;
- (16) 'aquaculture' means aquaculture as defined in point (d) of Article 3 of Council Regulation (EC) No 1198/2006²⁴;
- (17) 'veterinary treatment' means all courses of a curative or preventive treatment against one occurrence of a specific disease;
- (18) 'veterinary medicinal products' means veterinary medicinal products as defined in point (2) of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council²⁵;
- (19) '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;
- (20) 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council²⁶;
- (21) 'feed' means feed as defined in point 4 of Article 3 of Regulation (EC) No 178/2002;
- (22) 'in-conversion feedingstuffs' means feedingstuffs produced during the conversion period, with the exclusion of those harvested in the 12 months following the beginning of the conversion;
- (23) 'placing on the market' means placing on the market as defined in point 8 of Article 3 of Regulation (EC) No 178/2002;
- (24) 'traceability' means traceability as defined in point 15 of Article 3 of Regulation (EC) No 178/2002;
- (25) 'stages of production, preparation and distribution' means any stage from and including the primary production of an organic product up to and including its

²³ 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).

²⁴ Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund (OJ L 223, 15.8.2006, p. 1).

²⁵ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1)

²⁶ 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).

storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;

- (26) 'catastrophic circumstances' means circumstances deriving from an 'adverse climatic event', an 'environmental incident', a 'natural disaster' or a 'catastrophic event' as defined in points (h), (j), (k) and (l) of Article 2(1) of Regulation (EU) No 1305/2013 of the European Parliament and of the Council²⁷ respectively;
- (27) 'mass-caterer' means mass-caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council;
- (28) 'pre-packed food' means pre-packed food as defined in point (e) of Article 2(2) of Regulation (EU) No 1169/2011;
- (29) 'ingredient' means ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011;
- (30) 'labelling' means labelling as defined in point (j) of Article 2(2) of Regulation (EU) No 1169/2011;
- (31) 'advertising' means any presentation of organic 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) 'control authority' means control authority for 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*]. The term control body also comprises the 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 (GMO)' means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council²⁸ which is not obtained through the techniques of genetic modifications listed in Annex I.B to that Directive;
- (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 in whole or in part from GMOs but not containing or consisting of GMOs;

²⁷ 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 repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

²⁸ 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)

- (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 Council²⁹;
- (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 Council³⁰;
- (41) 'processed food' means food that has undergone any treatment resulting in a substantial change in the original state of the food;
- (42) 'processing aid' means processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008;
- (43) 'ionising radiation' means ionising radiation as defined in Article 1 of Council Directive 96/29/Euratom³¹;
- (44) 'importer' means the natural or legal person within the Union who presents a consignment for release for free circulation into the Union, either in person, or through a representative.

²⁹ 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)

³⁰ 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)

³¹ 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 for agriculture that is based on the following general principles:

- (a) the respect of nature's systems and cycles and sustains and enhances the health of soil, water, plants and animals and the balance between them;
- (b) the contribution to a high level of biological diversity;
- (c) the responsible use of energy and the natural resources, such as water, soil, organic matter and air;
- (d) the respect of high animal welfare standards and in particular the fulfilment of animals' species-specific behavioural needs.
- (e) the 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 fisheries;
 - (iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products;
 - (iv) are based on the use of preventive measures, when appropriate;
- (f) the 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) the adaptation, where necessary, and within the framework of this Regulation, of the production taking account of the sanitary status, regional differences in ecological balance, climate and local conditions, stages of development and specific husbandry practices.

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) the maintenance and enhancement of soil life and natural soil fertility, soil stability and soil biodiversity preventing and combating soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem;
- (b) the limitation of the use of non-renewable resources and external inputs to a minimum;
- (c) the recycling of wastes and by-products of plant and animal origin as input in plant and livestock production;
- (d) the maintenance of plant health by preventive measures, in particular the choice of appropriate species and varieties resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and the protection of natural enemies of pests;
- (e) the 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) the observance of a high level of animal welfare respecting species-specific needs;
- (g) the feeding of livestock with organic feed composed of agricultural ingredients from organic production and of natural non-agricultural substances;
- (h) the exclusion of genetic engineering, cloning, artificially induced polyploidy and ionising radiation from the whole organic food chain;
- (i) the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems;
- (j) the feeding of aquatic organisms with feed from sustainable exploitation of fisheries as defined in point (e) of Article 3 of Council Regulation (EC) No 2371/2002³² or with organic feed composed of agricultural ingredients from organic production and of natural non-agricultural substances.

Article 6

Specific principles applicable to the processing of organic food and feed

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

- (a) the production of organic food from organic agricultural ingredients;
- (b) the production of organic feed from organic feed materials;
- (c) the limitation of the use of food additives and 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 case of essential technological need or for particular nutritional purposes;

³² Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (OJ L 358, 31.12.2002, p. 59).

- (d) the limitation of the use of feed additives and processing aids to a minimum extent and only in case of essential technological or zootechnical needs or for particular nutritional purposes;
- (e) the exclusion of substances and processing methods that might be misleading regarding the true nature of the product;
- (f) the processing of food or feed with care, preferably with 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 holding shall be managed in compliance with the requirements applicable to organic production.
 - (b) During the conversion period, the agricultural holding may be split into clearly separated units which are not all managed under organic production. As regards animals, different species shall be involved. As regards aquaculture, the same species may be involved, provided that there is adequate separation between the production sites. As regards plants, different varieties that can be easily differentiated shall be involved;
 - (c) only products and substances authorised pursuant to Article 18 may be used in organic agriculture and aquaculture, provided that the corresponding product or substance has been authorised in agriculture in the Member States concerned in accordance with the relevant provisions of Union law or the relevant national provisions based on Union law;
 - (d) 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;
 - (e) organic operators other than farmers and operators producing seaweed or aquaculture animals, shall put in place an environmental management system with a view to improving their environmental performance.
 - (f) organic products shall be collected, packaged, transported and stored in accordance with the rules set out in Annex III.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 33 to provide the criteria to which the environmental management system referred to in point (e) of paragraph 1 is to correspond and to amend or supplement the rules set out in Annex III. Those delegated acts shall take account of the rules set out in Regulation (EC) No 1221/2009 of the European Parliament and of the Council³³.

Article 8

Conversion

1. Farmers and operators producing seaweed or aquaculture animals shall respect a conversion period. During the whole conversion period they shall apply the rules on

³³ Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1).

organic production laid down in this Regulation and, in particular, the specific rules on conversion set out in Annex II.

2. The conversion period shall start at the earliest when the farmer or the operator producing seaweed or aquaculture animals has notified his activity to the competent authorities in accordance with this Regulation.
3. No previous period may be recognised retroactively as being part of the conversion period.
4. Products produced during the conversion period shall not be marketed as organic.
5. In order to ensure quality, traceability and compliance with this Regulation as regards organic production and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 to supplement the rules laid down in this Article or supplement and amend the rules set out in Annex II as regards conversion.

Article 9

Prohibition of the use of GMOs

1. GMOs and products produced from or by GMOs shall not be used in organic production as food or feed or in food or feed, as processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms or animals.
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 Council³⁴ or Regulation (EC) No 1830/2003 of the European Parliament and of the Council³⁵.
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 the paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those Regulations.
4. In order to ensure quality, traceability and compliance with this Regulation as regards organic production and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 laying down the rules for the application of the prohibition of the use of GMOs and products produced from or by GMOs in organic production.

³⁴ Regulation (EC) 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

³⁵ 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 (OJ L 268, 18.10.2003, p. 24).

Article 10

Plant production rules

1. Operators producing plants or plant products shall in particular comply with the specific production rules set out in Part I of Annex II.
2. Each Member State shall ensure that a computerised database is established for the listing of the varieties for which seed or vegetative propagating material obtained by the organic production method is available on its territory.
3. In order to ensure quality, traceability and compliance with this Regulation as regards organic plant production and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing the specific plant production rules as regards:
 - (a) cultivation practices;
 - (b) soil management and fertilization;
 - (c) plant health and management of pests, diseases and weeds;
 - (d) management of mushroom production and other specific plant and plant production systems;
 - (e) origin of seed and vegetative propagating material;
 - (f) collection of wild plants.
4. The Commission shall adopt implementing acts laying down the technical details for the establishment of the database referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).

Article 11

Livestock production rules

1. Livestock operators shall in particular comply with the specific production rules set out in Part II of Annex II.
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic livestock production and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing the specific livestock production rules as regards:
 - (a) the origin of animals;
 - (b) livestock housing, including minimum surface areas indoors and outdoors and the maximum number of animals per hectare;
 - (c) husbandry practices;
 - (d) breeding;
 - (e) feed and feeding;
 - (f) disease prevention and veterinary treatment;

Article 12

Production rules for seaweed and aquaculture animals

1. Operators producing seaweed and aquaculture animals shall in particular comply with the specific production rules set out in Part III of Annex II.
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic seaweed production and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing the specific seaweed production rules as regards:
 - (a) suitability of aquatic medium and sustainable management plan;
 - (b) harvesting of wild seaweed;
 - (c) seaweed cultivation;
 - (d) antifouling measures and cleaning of production equipment and facilities.
3. In order to ensure quality, traceability and compliance with this Regulation as regards organic aquaculture animals and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing the specific production rules for aquaculture animals as regards:
 - (a) suitability of aquatic medium and sustainable management plan;
 - (b) the origin of aquaculture animals;
 - (c) aquaculture husbandry, including aquatic containment systems, production systems and maximum stocking density;
 - (d) breeding;
 - (e) management of aquaculture animals;
 - (f) feed and feeding;
 - (g) disease prevention and veterinary treatment.

Article 13

Production rules for processed food and feed

1. Operators producing processed food and feed shall in particular comply with the specific 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 and feed and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 to amend or supplement the specific production rules for processed food and feed as regards:
 - (a) procedures to be followed;
 - (b) preventive measures to be taken;
 - (c) composition of processed food and feed;
 - (d) cleaning measures;

- (e) the placing on the market of processed products including their labelling and identification;
- (f) separation of organic products, agricultural ingredients and feed materials from non-organic products, agricultural ingredients and feed materials;
- (g) the list of non-organic agricultural ingredients which may exceptionally be used for the production of organic processed products;
- (h) the calculation of the percentage of agricultural ingredients in accordance with Article 19 (4) (ii);
- (i) techniques used in food or feed processing.

Article 14

Production rules for wine

1. Operators producing products of the wine sector shall in particular comply with the specific production rules set out in Part V of Annex II.
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic production of wine and adaptation to technical development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing the specific wine production rules as regards oenological practices and restrictions.

Article 15

Production rules for yeast used as food or feed

1. Operators producing yeast used as food or feed shall in particular comply with the specific 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 development, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing the specific yeast production rules as regards the processing and the substrates used.

Article 16

Production rules for other products

In order to take account of a possible future need to have specific production rules for additional other products, and in order to ensure quality, traceability and compliance with this Regulation as regards organic production of those additional other products, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending or supplementing Annex II with regard to specific production rules for those products.

Article 17

Adoption of exceptional production rules

In order to allow organic production to continue or recommence in the case of catastrophic circumstances and subject to the principles laid down in Chapter II, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 providing for the criteria to qualify such situations as catastrophic and laying down specific rules on how to address such situations, on monitoring and on reporting requirements.

Article 18

Authorisation of products and substances used in organic production

1. The Commission may authorise certain products and substances for use in organic production and inclusion in restricted lists, for the following purposes:
 - (a) as plant protection products;
 - (b) as fertilisers, soil conditioners and nutrients;
 - (c) as feed materials of mineral origin and other feed materials;
 - (d) as feed additives and processing aids;
 - (e) as products for cleaning and disinfection of ponds, cages, buildings and installations for animal production;
 - (f) as products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding.

The Commission may also authorise certain products and substances for use in the production of organic processed food and inclusion in restricted lists, for the following purposes:

- (a) as food additives and processing aids,
 - (b) as processing aids for the production of yeast and yeast products.
2. The authorisation of the products and substances referred to in the first subparagraph of 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 the first subparagraph of paragraph 1, the following shall apply:
 - (i) their use is essential for the control of a harmful organism or a particular disease 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 the first subparagraph paragraph 1, their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning purposes;
- (e) in the case of products referred to in points (c) and (d) of the first subparagraph 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 behavioural needs of the species concerned or their use is necessary to produce or preserve feed because the production or preservation of feed is not possible without having recourse to such substances;
 - (ii) feed of mineral origin, trace elements, vitamins or provitamins 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.

The authorisation of the products and substances referred to in the second subparagraph of paragraph 1 for use in the production of organic processed food 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.

The authorisation of the use of chemically synthesised products or substances is strictly limited to cases where the use of external inputs referred to in Article 5(b) of this Regulation would contribute to unacceptable environmental impacts.

3. In order to ensure specific quality, traceability and compliance with this Regulation as regards organic production and production of processed organic food and feed, and adaptation to technical development, the Commission shall be empowered to adopt delegated acts, in accordance with Article 33 providing for additional criteria for the authorization or withdrawal of products and substances referred to in paragraph 1 for use in organic production and in the production of organic processed food and feed, and other requirements and conditions for the use of such authorised products and substances.
4. Where a Member State considers that a product or substance should be added to, or withdrawn from the lists of authorized products and substances referred to in paragraph 1, or that the specifications of use mentioned in the production rules

should be amended, the Member State 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 Member States.

5. The Commission shall adopt implementing acts authorizing products and substances that may be used in organic production and products and substances that may be used in the production of processed organic food and feed, including the procedures to be followed for the authorization and the lists of those products and substances and, where appropriate, their description, compositional requirement and conditions for use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34 (2).

Chapter IV

Labelling

Article 19

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 which comply with this Regulation.
2. The terms referred to in paragraph 1 shall not be used anywhere in the Union and in any language listed in Annex IV for the labelling, advertising and commercial documents of a product which does not comply with this Regulation, unless it is clear that there is no link with organic agricultural production..

Furthermore, any terms, including terms used in trademarks, or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation shall not be used.
3. The terms referred to in paragraph 1 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 or with GMOs.
4. As regards processed food, the terms referred to in paragraph 1 may be used:
 - (a) in the sales description, provided that:
 - (i) the processed food complies with the production rules set out in Part IV of Annex II;
 - (ii) at least 95 % by weight of its agricultural ingredients are organic;
 - (b) only in the list of ingredients, where less than 95% of agricultural ingredients are organic and provided that those ingredients comply with the production rules set out in this Regulation.

The list of ingredients referred to in point (b) of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients. That list of ingredients 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 and the indication of the percentage referred to in the second subparagraph of this paragraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients.

5. In order to provide clarity for the consumer and to ensure that the appropriate information is communicated to the consumer, the Commission shall be empowered

to adopt delegated acts in accordance with Article 33 concerning the adaptation of the list of terms set out in Annex IV taking into account linguistic developments within the Member States and concerning the establishment of specific labelling and composition requirements applicable to feed and ingredients thereof.

Article 20

Compulsory indications

1. Where terms as referred to in Article 19(1) are used:
 - (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 21 as regards pre-packed food shall also appear on the packaging.
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 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" when appropriate.

The indication 'EU' or 'non-EU' may be replaced or supplemented by the name of a country in the case where all agricultural raw materials of which the product is composed have been farmed in that country.

For the indication 'EU' or 'non-EU' small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 5 % of the total quantity by weight of agricultural raw materials.

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

3. The indications referred to in paragraphs 1, 2 and Article 21(3) shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
4. In order to provide clarity for the consumer and to ensure that the appropriate information is communicated to the consumer, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 laying down further rules on labelling and the use of the indications referred to in point (a) of paragraph 1 and in paragraphs 2 and Article 21(3).
5. The Commission shall adopt implementing acts relating to the following:

- (a) specific and practical modalities as regards the presentation, composition and size of the indications referred to in point (a) of paragraph 1 and in paragraphs 2 and Article 21(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 paragraphs 2 and Article 21(3).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).

Article 21

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.
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 Article 20(2) shall also appear in the labelling.
4. The organic production logo of the European Union shall follow the model set out in Annex IV 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 the consumer and to ensure that the appropriate information is communicated to the consumer, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 amending the organic production logo of the European Union.

Chapter V

Organic certification

Article 22

Organic certification system

1. Any operator or group of operators who produces, prepares or stores organic products, who imports such products from a third country or exports such products to a third country or who places such products on the market shall, prior to the placing on the market as organic or prior to conversion, notify his activity to the competent authorities of the Member States where the activity is carried out.
2. Operators and groups of operators shall keep records on the different activities they engage in accordance with this Regulation.
3. Competent authorities shall keep an updated list containing the names and addresses of operators and groups of operators who 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 23(1). The competent authorities shall respect the requirements of the protection of personal data under Directive 95/46/EC of the European Parliament and of the Council³⁶.
4. Member States shall ensure that the fees that may be collected by the competent authorities, the control authorities or the control bodies in accordance with article 76 of Regulation (EU) No XX/XXXX (official controls Regulation) are made public.
5. In order to ensure the effectiveness, efficiency and transparency of the organic production and labelling system, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning the requirements for keeping records, the requirements for the publication of the list referred to in paragraph 3 and the requirements and procedures to be applied for the publication of the fees referred to in paragraph 4 and for the supervision by the competent authorities of the application of those fees.
6. The Commission may adopt implementing acts to provide details and specifications regarding the content, form and way of notification referred to in paragraph 1 and the form of the publication of the fees referred to in paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).

Article 23

Organic certificate

1. Operators and groups of operators that have notified their activity in accordance with Article 22(1) and comply with this Regulation shall be entitled to be provided with an organic certificate. The organic certificate, issued in the form of an electronic

³⁶ 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).

certificate wherever possible, shall at least allow the identification of the operator or group of operators, the type or range of products covered by the certificate and its period of validity.

2. The organic certificate is an official certification within the meaning of Articles 85 and 86 of Regulation (EU) No XXX/XXX (official controls regulation).
3. Operators shall systematically verify the organic certificate of their suppliers.

Article 24

Group of operators

1. Each group of operators shall establish a system for internal controls. That 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 in to 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 certification for the whole group.
3. In order to ensure the effective and efficient functioning of the certification of a group of operators, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning the responsibilities of the individual members of a group of operators, the composition and dimension of a group of operators, the scope of the products to be produced by a group of operators, the conditions for participation in a group of operators, 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.
4. The Commission may adopt implementing acts concerning the exchange of information between the 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 34(2).

Chapter VI

Trade with third countries

Article 25

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.
However, a product may be exported as organic to a third country which is recognized in accordance with Article 29 if it complies with the requirements of the third country to be placed as organic within its market.
2. In order to avoid creating unequal conditions to operators when exporting to third countries, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning specific rules for exports of organic products to a third country which is recognized in accordance with Article 29.
3. In order to ensure fair competition among operators, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning documents intended for customs authorities in third countries, in particular as regards an organic export certificate issued in the form of an electronic certificate wherever possible providing assurance that exported organic products comply with this Regulation.

Article 26

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 if the following conditions are met:
 - (a) the product is an organic product as referred to in Article 2(1);
 - (b) the product:
 - (i) complies with Chapters II, III and IV and all 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 27; or
 - (ii) comes from a third country which is recognised in accordance with:
 - Article 28; or
 - Article 29;
 - (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 with a view to ensuring the traceability of the organic product.
2. In order to ensure the traceability of the imported products intended to be placed on the market within the Union as organic, the Commission shall be empowered to

adopt delegated acts in accordance with Article 33 concerning documents necessary for the purposes of import which should be in electronic form wherever possible

Article 27

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 which fulfil the criteria set out in a delegated act adopted pursuant to paragraph 6 and which are competent to carry out controls in third countries. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).
2. The control bodies shall be accredited to the most recently notified version, by the publication in the C series of the Official Journal of the European Union, of the International Standard ISO/IEC for conformity assessment – requirements for bodies certifying products, processes and services. The control bodies shall undergo regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities by the accreditation body.
3. The accreditation referred to in paragraph 2 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 Council³⁷; or
 - (b) an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.
4. When examining requests for recognition, the Commission shall invite the control authority or control body to supply all the necessary information. The Commission may also entrust experts with the task of examining on the spot the application of the production rules and the control activities carried out in the third country by the control authority or control body concerned.

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

Based on the assessment reports, the Commission shall ensure appropriate supervision of the recognised control authorities and control bodies by regularly reviewing their recognition. For the purposes of that supervision, the Commission may request additional information to the accreditation bodies or, as appropriate, to the competent authorities.
5. The nature of the supervision shall be determined on the basis of an assessment of the risk of non-compliance.
6. In order to ensure the transparency of the recognition procedure, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning

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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).

the criteria to be applied to the recognition, or the withdrawal of the recognition, of the control authorities and control bodies referred to in paragraph 1.

7. 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 organics. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).
8. 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, protection of consumers' confidence or protection of fair competition between operators, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 34(3) to take the measures referred to in paragraph 7 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 28

Equivalence under a trade agreement

A recognised third country referred to in the first indent of Article 26(1)(b)(ii) is a third country which the Union has recognised under a trade agreement as having a system of production complying with principles and production rules equivalent to those of the Union and control measures of equivalent effectiveness to those of the Union.

Article 29

Equivalence under Regulation (EC) No 834/2007

1. A recognised third country referred to in the second indent of Article 26(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.
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, the Commission assisted by the Member States shall ensure appropriate supervision of the recognised third countries by regularly reviewing their recognition. The nature of the supervision shall be determined on the basis of an assessment of the risk of non-compliance.
3. The control bodies performing controls in the third countries referred to in paragraph 1 shall be accredited to the most recently notified version, by the publication in the C series of the Official Journal of the European Union, of the International Standard ISO/IEC for conformity assessment – requirements for bodies certifying products, processes and services. The control bodies shall undergo regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities by the accreditation body. The accreditation may only be granted by an accreditation body

outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.

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 34(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 33 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 34(2).

Chapter VII

General provisions

SECTION 1

FREE MOVEMENT OF ORGANIC PRODUCTS

Article 30

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 other controls than those under Regulation (EU) No XXX/XXX (official controls Regulation) may be performed or other fees than those under article 76 of Regulation (EU) No XXX/XXX may be collected.
2. In order to ensure the proper functioning of the single market and trade between Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 laying down rules relating to the free movement of organic products for the purposes of paragraph 1 of this Article.

SECTION 2

INFORMATION

Article 31

Information relating to the organic sector and trade

1. Member States shall transmit to the Commission the necessary information for the implementation and monitoring of the application of this Regulation.
2. The Commission shall adopt implementing acts as regards the system to be used to transmit 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 34(2).

Article 32

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

1. Member States shall keep a regularly updated list with
 - (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 make public the list referred to in point (b) of the first subparagraph..

2. The Commission shall publish annually on the internet the list of the control authorities and control bodies referred to in point (b) of the first paragraph.

Chapter VIII

Procedural and final provisions

SECTION 1

PROCEDURAL PROVISIONS

Article 33

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in [...] shall be conferred on the Commission for a [period of seven years] from ...^{*}. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in [...] 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 the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to [...] shall enter into force only if no objection has been expressed either by the European Parliament or 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.

*

OJ: Please insert the date of entry into force of this Regulation.

Article 34

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 of the European Parliament and the Council³⁸.
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.

SECTION 2

REPEAL, AMENDMENTS AND FINAL PROVISIONS

Article 35

Repeal

Regulation (EC) No 834/2007 is repealed.

Article 36

Transitional measures relating to conversion to organic farming

In order to ensure a smooth transition, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning the rules applicable to conversion periods for farmers initiating conversion before the entry into force of this Regulation.

Article 37

Transitional measures relating to control bodies and control authorities recognised under Article 33(3) of Regulation (EC) 834/2007

4.
 1. The recognition of control bodies and control authorities granted under Article 33(3) of Regulation (EC) 834/2007 shall expire on [31 December 2018] at the latest.
 2. The Commission shall, by means of an implementing act, establish a list of the control bodies and control authorities 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 34(2).

³⁸ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011 p. 13).

3. In order to ensure the management of the list of the control bodies and control authorities referred to in paragraph 1, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning the information to be sent by those control bodies and control authorities 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 38

Transitional measures relating to applications from third countries submitted under Article 33(2) of Regulation (EC) 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.
2. In order to complete the examination of the applications referred to in paragraph 1, the Commission shall be empowered to adopt delegated acts in accordance with Article 33 concerning the procedural rules necessary for the examination, including on the information to be submitted by the third countries.

Article 39

Amendments to Regulation (EU) No [...] on official controls and other official activities

Regulation (EU) No XXX/XXXX (Official controls Regulation) is amended as follows:

1. In article 2, point 38 is replaced by the following:
"38. 'delegated body' means a third party to which the competent authorities have delegated specific official control tasks or other official activities;"
2. In Article 3, paragraph 3 is replaced by the following:
"3. Competent authorities responsible for the verification of compliance with the rules referred to in point (j) of Article 1(2) may confer official control tasks or other official activities to one or more control authorities for organic products. In such cases, they shall attribute a code number to each of them."
3. Article 23 is replaced by the following:

"Article 23

Specific rules on official controls and on action to be taken by the competent authorities in relation to organic products and to protected designations of origin, protected geographical indications and traditional specialties guaranteed

1. In relation to the rules referred to in point (j) of Article 1(2), competent authorities shall:

(a) have procedures and arrangements in place to ensure that operators or groups of operators as defined in point (7) of Article 3 of Regulation (EU) No [...] of the European Parliament and of the Council* who engage in different stages of production, preparation and distribution and export for the same type or range of products are controlled by the same control authority for organic products or delegated body;

(b) have procedures and arrangements in place to ensure that, where operators or groups of operators contract out any of their activities to a third party, both the operator or group of operators and the third party to whom activities were subcontracted comply with the provisions on notification referred to in Article 22 of Regulation No XXX/XXXX (organic production and labelling of organic products);

(c) have procedures and arrangements in place to ensure that members of a group of operators are not entitled to be provided with an individual organic certificate for any of the activities covered by the certification of the group.

(d) have procedures and arrangements in place to ensure that, when the presence of products or substances that are not authorised pursuant to Article 18 of Regulation No XXX/XXX (organic production and labelling of organic products) is detected, the control authorities or control bodies shall carry out investigations in order to establish the causes for their presence, to guarantee the respect of the principles and rules set out in that Regulation and to allow taking appropriate action. Products in which such products or substances are present beyond a level established in accordance with paragraph 2(i) shall not be marketed as organic.

2. In relation to the rules referred to in point (j) of Article 1(2), when non-compliance is established, competent authorities shall:

(a) in case of non-compliance that affects the integrity of organic products throughout any of the stages of production, preparation and distribution and export in particular due to the use of prohibited or non-authorised substances and techniques or commingling with non-organic products, ensure that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned;

(b) in case of repetitive or prolonged non-compliance, ensure that the operator or the group of operators concerned, in addition to the measures referred to in point (a), is prohibited from marketing products which refer to organic production and that its organic certificate may be withdrawn for a period to be defined.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 139, concerning rules for the performance of official controls and other official activities to verify compliance with the rules referred to in point (j) and (k) of Article 1(2) and on action to be taken by the competent authorities following such official controls and other official activities.

4. In relation to the rules referred to in point (j) of Article 1(2), the delegated acts referred to in paragraph 3 of this Article shall lay down rules on:

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles 4, 8, 9, 10(1), 11 to 13, 34(1) and (2), 36, and in addition to Articles 25, 26, 28, 29, 30 and 32 for the approval and supervision of delegated bodies and to Articles 85 to 90 concerning official certification;

(b) additional requirements to those referred to in Article 8(1) for risk assessment, and for the establishment of the frequency of official controls, and of sampling as appropriate, taking into account the risk of the occurrence of non-compliance;

(c) the minimum frequency of official controls on operators as defined in point (d) of Article 2 of Regulation (EC) No 834/2007, and the cases where and the conditions under which certain such operators are to be exempted from certain official controls;

(d) additional methods and techniques for official controls to those referred to in Articles 13 and 33(1) to (5) and specific requirements for the performance of official controls aimed at ensuring the traceability of organic products at all stages of the production, preparation and distribution, and at providing assurances as to compliance with the rules referred to in point (j) of Article 1(2);

(e) additional measures to those provided for in Article 134(2) and (3) in case of suspicion of non-compliance, additional criteria to those referred to in the second subparagraph of Article 135(1), and additional measures to those provided for in Article 135(2) and in paragraph 2 of this Article in case of the occurrence of non-compliance; (f) additional requirements to those provided for in point (f) of Article 4(1) in relation to the facilities and equipment necessary to carry out official controls and specific and additional conditions and obligations to those referred to in Articles 25, 26, 28, 29, and 30 to 32 for the delegation of official control tasks and other official activities to delegated bodies;

(g) additional reporting obligations to those referred to in articles 12, 28 and 31 for the competent authorities, the control authorities [for organic products], and the delegated bodies in charge of official controls and other official activities;

(h) specific criteria and conditions for the activation and the functioning of the mechanisms of administrative assistance provided for in Title IV and for the exchange of information concerning non-compliances or the likelihood of non-compliances between competent authorities, control authorities [for organic products] and delegated bodies;

(i) the specific circumstances and reasons for the presence of non-authorised products or substances, and the specific criteria and conditions concerning the establishment of the level above which products in which such non-authorised products or substances are present, shall not be marketed as organic.

5. In relation to the rules referred to in point (k) of Article 1(2), the delegated acts referred to in paragraph 3 of this Article shall lay down rules on:

(a) additional requirements, methods and techniques to those referred to Articles 11 and 13 for official controls performed to verify compliance with product specifications and labelling requirements;

(b) additional methods and techniques to those referred in Article 13 for the performance of official controls aimed at ensuring the traceability of products falling within the scope of the rules referred to in point (k) of Article 1(2) at all stages of production, preparation and distribution, and at providing assurances as to compliance with those rules;

(c) specific additional criteria and specific additional content to those provided for in Article 108, for the preparation of the relevant parts of the multi-annual national control plan provided for in Article 107(1), and specific additional content of the report provided for in Article 112;

(d) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;

(e) specific measures to be taken, in addition to those referred to in Article 135(2) in case of non-compliance and of serious or recurrent non-compliance.

6. Where appropriate, the delegated acts referred to in paragraphs 4 and 5 shall derogate from the provisions of this Regulation referred to in those paragraphs.

* OJ L ..., p. ...”

Article 40

Entry into force

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

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
[...]