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PROPOSAL

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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**

{SWD(2014) 65 final}
{SWD(2014) 66 final}

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 characterised by dynamic development driven by strong growth in demand. The global world market for organic food has expanded fourfold since 1999. The area under organic production in the European Union (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 take into account 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. Some of the exemptions that were needed for the development of the sector seem no longer to be justified.

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

- (1) removing obstacles to the sustainable development of organic production in the Union,
- (2) guaranteeing fair competition for farmers and operators and allowing the internal market to function more efficiently,
- (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's report² at its Agriculture and Fisheries meeting 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, aiming at further clarification and simplification, and addressing the current outstanding issues requiring further development.

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 L189, 20.7.2007, 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.

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

The review provides an 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 (TFEU).

1.3. Existing provisions in this area

The first piece of 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, and set out control and labelling requirements and rules for importing organic products. This provided a basis for protecting consumers and organic producers against false and misleading organic claims.

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

- 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 for in Regulation (EC) No 882/2004⁵ and made the accreditation of private control bodies obligatory,
- 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 more competitive economy.

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

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).

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 sustainable competitiveness to achieve an economically viable food production sector, together with 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, and products of the EU's outermost regions and mountain areas 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 policy and indicated in Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes⁸.

⁶ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608); Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671); Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487); Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

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, 14.12.2012, p. 1).

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 invited over 70 experts and academics to discuss fully 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 response to the questionnaire and almost 1 400 free contributions were received. The majority (96%) of responses were submitted by citizens of the European Union, while 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 respondents to the public consultation are concerned mainly with environmental and quality issues. They would like the European organic rules to be strengthened and wish to have uniformity of organic rules for farmers and other operators throughout the Union. Therefore the majority are 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 equal to national logos as a means of recognising organic products. The majority of citizens and stakeholders trust the organic control system while considering that it could be improved, mainly by introducing electronic certification. They are also 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 needed to respond dynamically to further market developments with more flexible rules. Long-standing exceptional rules would be integrated in the production rules.
- The principle-driven option aiming at re-focusing 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 lastly the improved status quo.

The principle-driven option is expected to produce the following results:

- A positive market outlook, thanks to greater consumer confidence, which is likely to support organic product prices and to attract newcomers,
- The removal of exceptions to the rules should contribute to the development of organic inputs, notably seeds,
- Clearer and simpler production rules will make the sector more attractive,
- Competition will become fairer as a result of 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 rise with an improved control system and harmonised production rules taking account of 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.

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' scope for granting exceptions to the rules,
- simplify the import regime,
- simplify requirements for small farmers, in particular 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

Organic production must continue to adhere to a set of principles that reflect closely the expectations of consumers.

Specific production rules are brought together in an Annex to 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 retroactive acknowledgement of the conversion period is in principle not possible any more. The agricultural ingredients used in the composition of organic processed products have to be exclusively organic. With the exceptions of micro-enterprises, organic operators other than farmers or operators producing seaweed or aquaculture animals are required to develop a system for improving their environmental performance.

The control system is improved by integrating all control-related provisions into 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 control bodies will no longer need to rely on two different legislative texts for the provisions related to controls.

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

The proposal seeks to do away with 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 more difficult.

The risk-based approach to official controls is reinforced by removing the requirement for 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, through delegated acts to be adopted in accordance with Regulation (EU) No XX/XXX (Official Controls Regulation), 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 more closely targeted. 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 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, and the provisions related to 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 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 are introduced for purposes of enhanced traceability and fraud prevention: operators may not be controlled by different control authorities or bodies for the same groups of products across different stages of the organic chain.

Specific provisions are also introduced to harmonise action to be taken when non-authorised products or substances are detected. In this context, there may be instances where farmers are prevented from marketing their products as organic due to the unintentional presence of non-authorised products or substances. Member States may be authorised by the Commission to grant national payments to compensate for the losses incurred in such instances. In addition, Member States may use the instruments of the Common Agricultural Policy to cover totally or partially such losses.

Lastly, the proposal sets out 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, a properly functioning internal market and maintenance of consumers' trust, while not prejudging the determination of sanctions that is within 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, the first paragraph of Article 42 and Article 43(2) thereof.

3.3. Subsidiarity and proportionality principles

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

As part of the overall CAP, to ensure smooth development of the single market, a Union-wide organic scheme 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, in particular by enhancing the bargaining power of the Union.

The proposal leads to further harmonisation in the following areas:

- The current scope offered to Member States for granting 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 in enforcing compliance), is reduced.
- The fact that the response to the same non-compliance with EU organic legislation can vary between 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 proven to provide an appropriate framework for Member States; no other type of measure would be appropriate. A directive would lay down more flexible rules, which could entail unfair competition among operators and lead to confusion and deception of consumers. 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 IMPLICATIONS

The proposal allocates a budget for technical assistance measures. Details of the budgetary 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. It involves the removal of 37 of the 135 existing obligations in the organic farming legislation. The proposal involves significant reduction of the administrative burden. Delegated acts stemming from the proposal will be drafted according to the same principles.

On production rules, the proposal greatly simplifies things for operators and national administrations with a limitation on the Member States' scope for granting exceptions. Several ineffective provisions are removed, particularly through reinforcement of the risk-based approach to 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 about by group certification, which entails 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 contained in an Annex to the Regulation.

6. ALIGNMENT

In 2010, the Commission adopted COM (2010)759 concerning the alignment to the Treaty of Lisbon of Council Regulation (EC) No 834/2007. A detailed discussion in trialogues in 2011 and 2012 lead in practice to a standstill on the alignment proposal. The current proposal incorporates the necessary elements of the alignment proposal, including architecture of legal provisions in basic act, delegated acts and implementing acts. . COM (2010) 759 will therefore be withdrawn as obsolete.

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 the first paragraph of Article 42 and Article 43(2) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social 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 and climate action practices, a high level of biodiversity, the preservation of natural resources, the application of high animal welfare standards and production standards in line with the demand of a growing number of consumers for products produced using natural substances and processes. Organic production thus plays a dual societal role, where it, on the one hand, provides for a specific market responding to consumer demand for organic products and, on the other hand, delivers publicly available goods contributing to the protection of the environment and animal welfare, as well as to rural development.
- (2) The observance of high health, environmental and animal welfare standards in the production of organic products is intrinsic to the high quality of those products. As underlined in the Communication from the Commission to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions on agricultural product quality 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

⁹ OJ C , , p. .

¹⁰ OJ C , , p. .

¹¹ COM (2009) 234 final.

and of the Council¹² and Regulation (EU) No 228/2013 of the European Parliament and of the Council¹³, respectively. In this sense, organic production pursues the same objectives within the common agricultural policy ('CAP') which are inherent to all the agricultural product quality schemes of the Union.

- (3) In particular, the objectives of the organic production policy are embedded in the objectives of the CAP by ensuring that farmers receive a fair return for complying with the organic production rules. In addition, the growing consumer demand for organic products creates conditions for further development and expansion of the market in those products and thus for an increase in the return of farmers engaged in organic production.
- (4) Furthermore, organic production is a system that contributes to the integration of environmental protection requirements into the CAP, and promotes sustainable agricultural production. That is why, measures financially supporting organic production have been introduced under the CAP, most recently under Regulation (EU) No 1307/2013 of the European Parliament and of the Council¹⁴, and in particular strengthened in the recent reform of the legal framework for rural development policy as established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council¹⁵.
- (5) Organic production also contributes to the achievements of the Union environmental policy objectives, in particular those of the 2020 Biodiversity Strategy¹⁶, the Green Infrastructure Communication¹⁷, the Soil Thematic Strategy¹⁸ and environmental legislation such as the Birds¹⁹ and Habitats²⁰ Directives, the Nitrates Directive²¹, the

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).

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

¹⁵ Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

¹⁶ COM(2011) 244 final, 'Our life insurance, our natural capital: an EU biodiversity strategy to 2020'.

¹⁷ SWD(2013) 155 final, 'Green Infrastructure (GI) – Enhancing Europe's Natural Capital'.

¹⁸ COM(2006) 231 final, 'Thematic Strategy for Soil Protection'.

¹⁹ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p.7).

²⁰ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7).

²¹ Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1).

Water Framework Directive²², the National Emissions Ceiling Directive²³ and the Directive on the sustainable use of pesticides²⁴.

- (6) In view of the objectives of the Union's organic production policy, the legal framework established for implementing that policy should aim at ensuring fair competition and a proper functioning of the internal market in organic products, and at maintaining and justifying consumer confidence in products labelled as organic. It should further aim at providing conditions under which the policy can progress in line with production and market developments.
- (7) The policy priorities of the Europe 2020 strategy as set out in the Commission Communication entitled 'Europe 2020: A strategy for smart, sustainable and inclusive growth'²⁵ include the aims of achieving a competitive economy based on knowledge and innovation, fostering a high-employment economy delivering social and territorial cohesion and supporting the shift towards a resource-efficient and low-carbon economy. The organic production policy should therefore provide operators with the right tools to better identify and promote their products while protecting them against unfair practices.
- (8) Given the dynamic evolution of the organic sector, Council Regulation (EC) No 834/2007²⁶ identified the need for a future review of the Union rules on organic production, taking into account the experience gained from the application of those rules. The results of that review carried out by the Commission show that the Union legal framework governing organic production should be improved to provide for rules that correspond to the high expectations of consumers and that guarantee sufficient clarity for those to whom they are addressed. Therefore, Regulation (EC) No 834/2007 should be repealed and replaced by a new Regulation.
- (9) Experience gained so far with the application of Regulation (EC) No 834/2007 shows a need to clarify the products to which this Regulation applies. Primarily, it should cover agricultural products, including aquaculture products, listed in Annex I to the Treaty on the Functioning of the European Union ('the Treaty'). Moreover, it should cover processed agricultural products for use as food or feed because the placing on the market of such products as organic provides a major outlet for agricultural products and ensures visibility to the consumer of the organic nature of the agricultural products from which they are processed. Likewise, this Regulation should cover certain other products which are linked to agricultural products in a similarly close way as processed agricultural products because those other products either constitute a major outlet for agricultural products or form an integral part of the production process. Finally, sea salt should be included in the scope of this Regulation because it is produced by applying natural production techniques and its production contributes to the development of rural areas, and thus falls within the objectives of this

²² Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p.1).

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

²⁴ Directive 2009/18/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)

²⁵ COM(2010)2020 final.

²⁶ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

Regulation. 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) In order to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (11) In order to take into account new production methods or material or international commitments, the power to adopt certain acts should be delegated to the Commission in 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 in that list.
- (12) Because of the local nature of mass catering operations, measures taken by Member States and private schemes in this area are considered adequate to ensure the functioning of the single market. Therefore, food prepared by mass caterers on their premises should not be subject to this Regulation. Equally, products of hunting and fishing of wild animals should not be covered by this Regulation since the production process cannot be fully controlled.
- (13) Research projects have demonstrated that consumer confidence is crucial in the market for organic food. In the long run, rules that are not trustworthy can jeopardise public confidence and lead to market failure. Therefore the sustainable development of organic production in the Union should be based on sound production rules which are harmonised at Union level. In addition, those production rules should meet operators' and consumers' expectations regarding the quality of organic products and the compliance with the principles and rules laid down in this Regulation.
- (14) This Regulation should apply without prejudice to related legislation, such as in the field of safety of the food chain, animal health and welfare, plant health, plant reproductive material, labelling and the environment. More specifically, as regards the authorisation of products and substances that may be used for the production of organic products, it is important to highlight that such products and substances have to be authorised at Union level first. Therefore this Regulation should apply without prejudice to other specific Union provisions relating to the authorisation and placing on the market of those products and substances.
- (15) As a matter of principle, the general production rules of this Regulation should include a prohibition on the use of ionising radiation 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. With the objective of minimising the regulatory burden of micro-enterprises as defined in [Commission Recommendation 2003/361/EC](#)²⁷ involved in

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[Commission Recommendation 2003/361/EC](#) of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, of 20.05.2003, p. 36).

organic production, it is appropriate to exempt them from this requirement. In order to ensure the correct application of the general production rules, the power to adopt certain acts should be delegated to the Commission in respect of establishing the criteria to which the environmental management system is to correspond.

- (16) The risk of non-compliance with the organic production rules is considered higher in agricultural holdings which include units not managed under organic production rules. Therefore, after an appropriate conversion period, all agricultural holdings in the Union which aim to become organic should be entirely managed in compliance with the requirements applicable to organic production. Organic agricultural holdings should undergo the same conversion period in all Member States, irrespective of whether they have previously adhered to agri-environmental measures supported by Union funds. However, no conversion period is necessary in the case of fallow land. In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules supplementing the general conversion rules or supplementing and amending the specific conversion rules.
- (17) 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 to ensure harmonisation and respect of the objectives and principles of organic production.
- (18) 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.
- (19) Concerning soil management and fertilisation, conditions should be laid down for the use of cultivation practices allowed in organic plant production and for the use of fertilisers and conditioners.
- (20) The use of pesticides, should be significantly restricted. Preference should be given to the application of measures that prevent any damage by pests and weeds through techniques which do not involve the use of plant protection products such as crop rotation. Presence of pests and weeds should be monitored to decide whether any intervention is economically and ecologically justified. The use of certain plant protection products should be allowed if such techniques do not provide adequate protection and only if those plant protection products have been authorised in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council²⁸, after having been assessed to be compatible with objectives and principles of organic production, including with restrictive conditions of use, and consequently authorised in accordance with this Regulation.
- (21) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or

²⁸ 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).

supplementing the specific plant production rules as regards cultivation practices, soil management and fertilisation, plant health and management of pests and weeds, management of mushroom production and other specific plants and plant production systems, the production origin of plant reproductive material and the collection of wild plants.

- (22) As livestock production naturally involves the management of agricultural land, where the manure is used to nourish crop production, landless livestock production should be prohibited. The choice of breeds should take account of their capacity to adapt to local conditions, their vitality and their resistance to disease, and a wide biological diversity should be encouraged.
- (23) Organic livestock and aquaculture production housing, including where relevant the aquatic medium, should satisfy the behavioural needs of the animals. Specific housing conditions and husbandry practices should 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.
- (24) In order to avoid environmental pollution of natural resources such as soil and water by nutrients, an upper limit for the use of manure per hectare and for keeping livestock per hectare should be set. That limit should be related to the nitrogen content of the manure.
- (25) Mutilations which lead to stress, harm, disease or suffering of animals should be prohibited.
- (26) Livestock should be fed on feed materials produced in accordance with the rules of organic production, and preferably coming from the own holding, taking their physiological needs into account. In addition, in order to provide for the basic nutritional requirements of livestock, certain minerals, trace elements and vitamins may need to be used under well-defined conditions.
- (27) Animal health management should mainly be based on prevention of disease. In addition, specific cleaning and disinfection measures should be applied. The preventive use of chemically-synthesised allopathic medicinal products should not be permitted in organic production, except in the event of sickness or injury of an animal requiring immediate treatment and limited to the minimum necessary to re-establish the well-being of the animal. In such cases, in order to guarantee the integrity of organic production for consumers, it should be possible to take restrictive measures such as doubling the official withdrawal period after use of such medicinal products as specified in the relevant Union legislation. Regarding beekeeping, it is necessary to lay down specific rules for disease prevention and veterinary treatment.
- (28) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or supplementing the specific 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, disease prevention and veterinary treatment.

- (29) This Regulation reflects the objectives of the new Common Fisheries Policy as regards aquaculture, which plays a key role in ensuring sustainable, long-term food security as well as growth and employment while reducing pressure on wild fish stocks, in a context of growing global aquatic food demand. The 2013 Communication from the Commission to the Council and the European Parliament on Strategic Guidelines for the sustainable development of European aquaculture²⁹ highlights the main challenges faced by the Union aquaculture and its potential for growth. It identifies organic aquaculture as a particularly promising sector, and highlights the competitive advantages deriving from organic certification.
- (30) Organic aquaculture is a relatively new field of organic production compared to organic agriculture where long experience exists at the farm level. Given consumers' growing interest in organic aquaculture products, further growth in the conversion of aquaculture units to organic production is likely. This is leading to increased experience, technical knowledge and development, with improvements in organic aquaculture that should be reflected in the production rules.
- (31) In order to ensure common understanding, avoid ambiguities and guarantee uniform application of the organic aquaculture animal and seaweed production rules, certain definitions relating to aquaculture should accompany those production rules.
- (32) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or supplementing the specific seaweed production rules as regards the suitability of the aquatic medium and the sustainable management plan, the harvesting of wild seaweed, seaweed cultivation, and 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 the suitability of the aquatic medium and the 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.
- (33) Operators producing organic food or feed should follow appropriate procedures based on systematic identification of critical processing steps in order to ensure that processed products comply with the organic production rules. Organic processed products should be produced by means of processing methods which guarantee that the organic integrity and vital qualities of the products are maintained through all stages of organic production.
- (34) Provisions concerning the composition of organic processed food should be laid down. In particular, such food should be produced mainly from agricultural ingredients that are organic with a limited possibility to use certain non-organic agricultural ingredients specified in this Regulation. In addition, only certain substances authorised

²⁹ COM(2013) 229 of 29.4.2013.

in accordance with this Regulation should be allowed for use in the production of organic processed food.

- (35) 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 is the case for products of hunting and fishing. Moreover, for the purposes of consumer information and transparency in the market, and to encourage the use of organic ingredients, it should also be made possible to refer to organic production in the ingredients list under certain conditions.
- (36) Provisions concerning the composition of organic processed feed and the use of certain substances and techniques in the production of that feed should be laid down.
- (37) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or supplementing the specific production rules for processed food and feed as regards the procedures to be followed, preventive measures to be taken, the 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 in the production of organic processed products, calculation of the percentage of agricultural ingredients, and the techniques used in food or feed processing.
- (38) Organic wine should be produced entirely from organic raw material and only certain substances authorised in accordance with this Regulation should be allowed to be added. Certain oenological practices, processes and treatments should be prohibited in the production of organic wine. Other practices, processes and treatments should be permitted under well-defined conditions.
- (39) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or supplementing the specific wine production rules as regards oenological practices and restrictions.
- (40) Initially yeast was not considered an agricultural ingredient under Regulation (EC) No 834/2007 and therefore it did not count for the agricultural composition of organic products. However, Commission Regulation (EC) No 889/2008³⁰ introduced the obligatory calculation of yeast and yeast products as agricultural ingredients for the purposes of organic production as of 31 December 2013, which gave the industry sufficient time to adjust to that rule. Accordingly, only organically produced substrates should be used in the production of organic yeast and only certain substances should be allowed for use in its production, confection and formulation. In addition, organic yeast should not be present in organic food or feed together with non-organic yeast.

³⁰ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

- (41) In order to ensure quality, traceability and compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or supplementing the specific production rules for organic yeast as regards the processing and the substrates used in its production.
- (42) In order to take account of any future need to have specific production rules for products whose production does not fall within any of the categories of specific production rules laid down in this Regulation, as well as in order to ensure quality, traceability and compliance with this Regulation and, subsequently, adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing specific production rules for such products, including amendments or supplements thereof.
- (43) 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 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, the existence of exceptions has created conditions for distortions in competition and has threatened to undermine consumer confidence. Accordingly, the scope for allowing exceptions from organic production rules should be further restricted and limited to cases of catastrophic circumstances.
- (44) 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 in respect of establishing 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.
- (45) 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.
- (46) In order to ensure the integrity of organic production and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of establishing rules amending or supplementing the specific rules on collection, packaging, transport and storage of organic products.
- (47) The use in organic production of products and substances such as plant protection products, fertilisers, soil conditioners, nutrients, components of animal nutrition, feed or food additives, processing aids and products for cleaning and disinfection should be limited to the minimum and under the specific conditions laid down in this Regulation. The same approach should be followed regarding the use of products and substances as food additives and processing aids in the production of organic processed food. Therefore, provisions should be laid down to define any possible use of such products and substances in organic production in general and in the production of organic

processed food in particular, subject to the principles laid down in this Regulation and to certain criteria.

- (48) In order to ensure quality, traceability and compliance with this Regulation as regards organic production in general and the production of organic processed food in particular, and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission to provide for additional criteria for the authorisation or withdrawal of the authorisation of products and substances for use in organic production in general and in the production of organic processed food in particular, and other requirements for the use of such authorised products and substances.
- (49) In the absence of specific Union rules on the measures to take when non-authorised substances or products are present in organic products, different approaches have been developed and implemented across the Union. This situation creates uncertainties for operators, control authorities and control bodies. It may also entail a different treatment of operators in the Union and affect consumers' confidence in organic products. It is therefore appropriate to lay down clear and uniform provisions to prohibit marketing as organic those products in which any non-authorised products or substances are present beyond given levels. Those levels should be established taking account in particular of Commission Directive 2006/125/EC³¹ on processed cereal-based foods and baby foods for infants and young children.
- (50) 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 specific criteria and conditions for the establishment and application of the levels of presence of non-authorised products and substances beyond which products shall not be marketed as organic and with respect to the establishment of those levels and their adaptation in the light of technical developments.
- (51) Organic production is based on the general principle of restriction of the use of external inputs. Farmers are required to take measures to prevent the risk of contamination by non-authorised products or substances. Despite such measures, there may be instances where farmers are prevented from marketing their agricultural products as organic due to the unintentional presence of non-authorised products or substances. It is therefore appropriate to provide for the possibility whereby Member States may, in accordance with Article 42 of the Treaty, be authorised by the Commission to grant national payments to compensate for the losses incurred in such instances. Member States may also use the instruments of the Common Agricultural Policy to cover totally or partially such losses.
- (52) The labelling of agricultural products and foodstuffs should be subject to the general rules laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council³², and in particular the provisions aimed at preventing labelling that may

³¹ Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

³² 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

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 in having their products correctly identified on the market and enjoying conditions of fair competition, and those of consumers in enabling them to make informed choices.

- (53) Accordingly, the terms used to indicate organic products should be protected from being used in the labelling of non-organic products throughout the Union and independently of the language used. The protection should also apply to the usual derivatives or diminutives of those terms, whether they are used alone or combined.
- (54) In order to create clarity for consumers throughout the Union market, the use of the organic production logo of the European Union should be made obligatory for all organic pre-packed food produced within the Union. It should otherwise be possible to use that logo on a voluntary basis in the case of non pre-packed organic products produced within the Union or any organic products imported from third countries. The model of the organic production logo of the European Union should be set out in this Regulation.
- (55) However, in order not to mislead consumers as to the organic nature of the entire product, it is considered appropriate to limit the use of that logo to products which contain only, or almost only, organic ingredients. It should therefore not be allowed to use it in the labelling of in-conversion products or processed products of which less than 95 % of their ingredients of agricultural origin are organic.
- (56) For the sake of avoiding any possible confusion amongst consumers about the Union or non-Union origin of a product, whenever the organic production logo of the European Union is used, consumers should be informed about the place where the agricultural raw materials of which the product is composed have been farmed. In this context, it should be allowed to refer to aquaculture in the label of products from organic aquaculture instead of referring to agriculture.
- (57) In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the power to adopt certain acts should be delegated to the Commission in respect of adapting the list of terms referring to organic production set out in this Regulation, establishing the specific labelling and composition requirements applicable to feed and ingredients thereof, laying 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 amending the organic production logo of the European Union and the rules relating thereto.
- (58) Organic production is only credible if accompanied by effective verification and controls at all stages of production, processing and distribution. Organic production should be subject to official controls or other official activities carried out in accordance with Regulation (EU) No (XXX/XXXX) of the European Parliament and of the Council³³ to verify compliance with the rules on organic production and labelling of organic products.

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).–

³³ Regulation (EU) No XX/XXX of the European Parliament and of the Council of [...] on official controls and other official activities performed to ensure the application of food and feed law, rules on

- (59) Specific requirements should be laid down to ensure compliance with the rules that are peculiar to organic production. In particular, provisions should be made for notification of the activities of the operators and for a certification system to identify the operators that comply with the rules governing organic production and labelling of organic products. Those provisions should also apply to any subcontractors of the operators concerned. The transparency of the certification system should be ensured by requiring Member States to make public the list of operators that have notified their activities and any fees that may be collected in relation to the controls for verifying compliance with the organic production rules.
- (60) 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. For that reason, the concept of ‘group of operators’ should be introduced and defined.
- (61) 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 of records by operators or groups of operators, the requirements for publication of the list of operators, the requirements and procedures to be applied for publication of the fees that may be collected in relation to the controls for verifying compliance with the organic production rules and for supervision by the competent authorities of the application of those fees, as well as the criteria for defining the groups of products in respect of which operators should be entitled to have only one organic certificate issued by the control authority or control body concerned.
- (62) In order to ensure that the certification of a group of operators is done effectively and efficiently, the power to adopt certain acts should be delegated to the Commission in respect of the responsibilities of the individual members of a group of operators, the composition and size of that group, the categories of 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.
- (63) The experience with the arrangements for import of organic products into the Union under Regulation (EC) No 834/2007 has shown that there is a need to revise those arrangements in order to respond to consumer expectations that imported organic products meet rules as high as those of the Union, as well as to better ensure the access of Union organic products to the international market. In addition, it is necessary to provide for clarity regarding the rules applicable to export of organic products, in particular by establishing a certificate of export and laying down provisions for export

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 ...).

to third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007.

- (64) The provisions governing the import of products that comply with the Union production and labelling rules and in respect of which operators have been subject to the control of control authorities and control bodies recognised by the Commission as competent to carry out controls and certification in the field of organic production in third countries, should be further reinforced. In particular, requirements concerning the accreditation bodies which accredit control bodies for the purposes of import of compliant organic products into the Union should be laid down, aiming at ensuring a level playing field for the supervision of the control bodies by the Commission. Furthermore, it is necessary to provide for the possibility for the Commission to contact directly the accreditation bodies and competent authorities in third countries to render the supervision of control authorities and control bodies respectively more efficient.
- (65) The possibility for organic products to get access to the Union market where such products do not comply with the Union rules on organic production but come from third countries whose organic production and control systems have been recognised as equivalent to those of the Union should be preserved. However, the recognition of equivalence of third countries, as laid down in Regulation (EC) No 834/2007, should only be granted through an international agreement between the Union and those third countries, where a reciprocal recognition of equivalence would be also pursued for the Union.
- (66) Third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 should continue to be recognised as such under this Regulation, for a limited period of time necessary to ensure a smooth transition to the scheme of recognition through an international agreement, provided that they continue to ensure the equivalence of their organic production and control rules to the relevant Union rules in force and that they fulfil all requirements relating to the supervision of their recognition by the Commission. That supervision should be based in particular on the annual reports the third countries send to the Commission.
- (67) The experience with the scheme of control authorities and control bodies recognised as competent to carry out controls and issue certificates in third countries for the purpose of import of products providing equivalent guarantees shows that the rules applied by those authorities and bodies are different and could be difficult to be considered as equivalent to the respective Union rules. Furthermore, multiplication of control authorities and control bodies standards hampers adequate supervision by the Commission. Therefore that scheme of recognition of equivalence should be abolished. However, sufficient time should be given to those control authorities and control bodies so that they can prepare themselves for obtaining recognition for the purposes of import of products complying with Union rules.
- (68) The placing on the market as organic of any organic product imported into the Union, under any of the import arrangements provided for in this Regulation, should be subject to the availability of the information necessary to ensure the traceability of the product on the food chain.

- (69) In order to ensure fair competition among operators, the traceability of the imported products intended to be placed on the market within the Union as organic or the transparency of the recognition and supervision procedure for 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, in electronic form wherever possible, the documents necessary for the purposes of import, also in electronic form wherever possible, 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 that Regulation necessary for the supervision of their recognition and the exercise of that supervision by the Commission, including on-the-spot examination.
- (70) Provision should be made to ensure that the movement of organic products that have been subject to a control in one Member State and which comply with this Regulation cannot be restricted in another Member State. In order to ensure the 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.
- (71) For the purpose of obtaining reliable information needed for the implementation of this Regulation, Member States should provide the Commission annually with the necessary information. For reasons of clarity and transparency, Member States should keep updated lists of competent authorities, control authorities and control bodies. The lists of control authorities and control bodies should be made public by the Member States and annually published by the Commission.
- (72) It is necessary to lay down measures to ensure a smooth transition to some modifications of the legal framework governing the import of organic products into the Union, as introduced by this Regulation. In particular, in order to ensure a smooth transition from the old to the new legal framework, the power to adopt certain acts should be delegated to the Commission in respect of the rules relating to conversion periods starting under Regulation (EC) No 834/2007, by way of derogation from the general rule that no previous periods may be recognised retroactively as being part of the conversion period.
- (73) Furthermore, a date for the expiration of the recognition of control authorities and control bodies for the purpose of equivalence should be set and provisions to address the situation until the expiration of their recognition should be laid down. Provisions should also be laid down regarding applications from third countries for the purpose of equivalence which have been submitted under Regulation (EC) No 834/2007 and which are pending at the time of entry into force of this Regulation.
- (74) In order to ensure the management of the list of control authorities and control bodies recognised for the purpose of equivalence under Regulation (EC) No 834/2007 and to facilitate the completion of the examination of applications from third countries for recognition for the purpose of equivalence that are pending at the date of entry into force of this Regulation, the power to adopt certain acts should be delegated to the

Commission in respect of the information to be sent by those control authorities and control bodies that is necessary for the supervision of their recognition and in respect of the exercise of that supervision by the Commission, as well as in respect of any procedural rules necessary for the examination of the pending applications from third countries.

- (75) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the technical details for the establishment of the database for the listing of the varieties for which plant reproductive material obtained by the organic production method is available, as regards the authorisation or the withdrawal of the authorisation of the products and substances that may be used in organic production in general and in the production of processed organic food in particular, including the procedures to be followed for the authorisation and the lists of those products and substances and, where appropriate, their description, compositional requirement and conditions for use, as regards the specific and practical modalities regarding 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 farmed, the assignment of code numbers to control authorities and control bodies and the indication of the place where the agricultural raw materials have been farmed, as regards the details and specifications regarding the content, form and way of notification of the notifications by operators and groups of operators of their activity to the competent authorities and the form of publication of the fees that may be collected for the controls, as regards the exchange of information between groups of operators and competent authorities, control authorities and control bodies and between Member States and the Commission, as regards the recognition or withdrawal of the recognition of control authorities and control bodies which are competent to carry out controls in third countries and the establishment of the list of those control authorities and control bodies and rules to ensure the application of measures in relation to cases of non-compliance, or suspicion thereof, affecting the integrity of imported organic products, as regards the establishment of a list of third countries recognised under Article 33(2) of Regulation (EC) No 834/2007 and the amendment of that list as well as rules to ensure the application of measures in relation to cases of non-compliance, or suspicion thereof, affecting the integrity of organic products imported from those countries, as regards the system to be used to transmit the information necessary for the implementation and monitoring of this Regulation, and as regards the establishment of the list of control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and the amendment of that list. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council³⁴.
- (76) The Commission should be empowered to adopt immediately applicable implementing acts where, in duly justified cases relating to the protection against unfair practices or practices which are incompatible with the principles and rules on organic production, the protection of consumers' confidence or the protection of fair competition between operators, imperative grounds of urgency so require to ensure the application of measures in relation to cases of non-compliance, or the suspicion thereof, affecting the

³⁴ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

integrity of imported organic products under the control of recognised control authorities or control bodies.

- (77) In order to ensure a smooth transition between on the one hand the rules on the organic origin of plant reproductive material and on animals for breeding purposes provided for in Regulation (EC) No 834/2007 and the exception to production rules adopted pursuant to Article 22 of that Regulation, and on the other hand the new production rules for plants and plant products and livestock provided for in this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of the granting of exceptions where exceptions are deemed necessary, in order to ensure access to plant reproductive material and live animals for breeding purposes that may be used in organic production. Since those acts are transitional in nature, they should apply for a limited period of time.
- (78) The Commission should consider the situation of the availability of organic plant reproductive material and animals for breeding purposes and present a report to this end to the European Parliament and the Council in 2021.
- (79) Provision should be made to allow the exhaustion of stocks of products which have been produced in accordance with Regulation (EC) No 834/2007 and placed on the market before this Regulation starts to apply.
- (80) The review of the legislative framework for organic production and labelling of organic products showed that the specific needs relating to the official controls and other official activities carried out in accordance with Regulation (EU) No XXX/XXX (Official controls Regulation) require provisions to better address instances of non-compliance. In addition, the provisions of Regulation (EU) No XXX/XXX [official controls Regulation] relating to the tasks and responsibilities of competent authorities, the approval and supervision of delegated bodies, official certification, reporting obligations and administrative assistance should be adapted to the specific needs of the organic production sector. Regulation (EU) No XXX/XXX [official controls Regulation] should therefore be amended accordingly.
- (81) Since the objectives of this Regulation, in particular fair competition and proper functioning of the internal market in organic products as well as ensuring consumer confidence in those products and in the organic production logo of the European Union, cannot be sufficiently achieved by the Member States themselves but can instead, because of the required harmonisation of the rules on organic production, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (82) It is appropriate to provide for a date of application of this Regulation that would give the possibility to operators to adapt to the new requirements introduced.

HAVE ADOPTED THIS REGULATION:

Chapter I

Subject matter, scope and definitions

Article 1

Subject matter

This Regulation establishes the principles of organic production and lays down the rules concerning organic production 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 on the Functioning of the European Union ('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 carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council³⁵ 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 related Union legislation in the fields of *inter alia* safety of the food chain, animal health and welfare, plant health, and plant reproductive material, and in particular to Regulation (EU) No XX/XXX of the European Parliament and of the Council³⁶ (plant reproductive material) and Regulation (EU) No XX/XXXX of the European Parliament and of the Council³⁷ (protective measures against pests of plants).
4. This Regulation shall apply without prejudice to other specific Union provisions relating to the placing of products on the market and, in particular, to Regulation (EU) No 1308/2013 of the European Parliament and of the Council³⁸, and to Regulation (EU) No 1169/2011.
5. In order to take into account new information on production methods or material or international commitments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending 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;

³⁵ 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).

³⁶ [full title] (OJ L,...).

³⁷ [full title] (OJ L,...).

³⁸ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

- (3) 'agricultural raw material' means an agricultural product that has not been subjected to any operation of preservation or processing;
- (4) 'preventive measures' means measures to be taken in order to ensure soil quality as well as prevention and control of pests and weeds, 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 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 a natural or legal person, or a group of natural or legal persons, regardless of the legal status granted to such group and its members by national law, who exercises an agricultural activity.
- (9) 'agricultural area' means agricultural area as defined in point (e) of Article 4(1) of Regulation (EU) No 1307/2013;
- (10) 'plants' means plants as defined in point 5 of Article 3 of Regulation (EC) No 1107/2009;
- (11) 'plant production' means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
- (12) 'plant products' means plant products as defined in point 6 of Article 3 of Regulation (EC) No 1107/2009;
- (13) 'pest' means a pest as defined in Article 1(1) of Regulation (EU) No XX/XXXX (protective measures against pests of plants);
- (14) 'plant protection products' means the products referred to in Article 2 of Regulation (EC) No 1107/2009;
- (15) 'livestock production' means the production of domestic or domesticated terrestrial animals, including insects;
- (16) 'veranda' means an additional, roofed, uninsulated, outdoor part of a livestock building, the longest side being usually equipped with wire fencing or netting with outdoor climate, natural and artificial illumination and a littered floor;
- (17) 'aquaculture' means aquaculture as defined in point (25) of Article 4(1) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council³⁹;

³⁹ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No

- (18) ‘veterinary treatment’ means all courses of a curative or preventive treatment against one occurrence of a specific disease;
- (19) ‘veterinary medicinal products’ means veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council⁴⁰;
- (20) ‘preparation’ means the operations of preserving or processing of organic products, including slaughter and cutting for livestock products, packaging, labelling or alterations made to the labelling relating to organic production;
- (21) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴¹;
- (22) ‘feed’ means feed as defined in point 4 of Article 3 of Regulation (EC) No 178/2002;
- (23) ‘feed material’ means feed material as defined in point (g) of Article 3(2) of Regulation (EC) No 767/2009 of the European Parliament and of the Council⁴²;
- (24) ‘in-conversion feed’ means feed produced during the conversion period, with the exclusion of those harvested in the 12 months following the beginning of the conversion;
- (25) ‘placing on the market’ means placing on the market as defined in point 8 of Article 3 of Regulation (EC) No 178/2002;
- (26) ‘traceability’ means traceability as defined in point 15 of Article 3 of Regulation (EC) No 178/2002;
- (27) ‘stages of production, preparation and distribution’ means any stage from and including the primary production of an organic product up to and including its storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;
- (28) ‘catastrophic circumstances’ means circumstances deriving from an ‘adverse climatic event’, an ‘environmental incident’, a ‘natural disaster’ or a ‘catastrophic event’ as defined respectively in points (h), (j), (k) and (l) of Article 2(1) of Regulation (EU) No 1305/2013;
- (29) ‘ingredient’ means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011;

1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

⁴⁰ 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).

⁴¹ 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).

⁴² Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

- (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 production and labelling of organic products as defined in point 39 of Article 2 of Regulation (EU) No XXX/XXXX [*Official controls Regulation*];
- (34) ‘control body’ means a delegated body as defined in point 38 of Article 2 of Regulation (EU) No XXX/XXXX [*Official controls Regulation*], as well as a body recognised by the Commission or by a third country recognised by the Commission to carry out controls in third countries for the import of organic products into the Union;
- (35) ‘non-compliance’ means non-compliance with this Regulation;
- (36) ‘genetically modified organism’ means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council⁴³ which is not obtained through the techniques of genetic modifications listed in Annex I.B to that Directive, hereinafter referred to as ‘GMO’;
- (37) ‘produced from GMOs’ means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (38) ‘produced by GMOs’ means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;
- (39) ‘food additive’ means a food additive as defined in point (a) of Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁴⁴;
- (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 Council⁴⁵;
- (41) ‘equivalence’ means meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity; ‘processing aid’ means processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008;

⁴³ 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).

⁴⁴ 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).

⁴⁵ 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).

- (42) ‘food enzyme’ means a food enzyme as defined in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council⁴⁶;
- (43) ‘ionising radiation’ means ionising radiation as defined in Article 1 of Council Directive 96/29/Euratom⁴⁷.

⁴⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7)

⁴⁷ 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) respect for nature's systems and cycles and sustainment and enhancement of the state of soil, water, air and biodiversity, of the health of plants and animals and of the balance between them;
- (b) contribution to a high level of biodiversity;
- (c) responsible use of energy and natural resources, such as water, soil, organic matter and air;
- (d) respect of high animal welfare standards and, in particular, fulfilment of animals' species-specific behavioural needs;
- (e) appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:
 - (i) use living organisms and mechanical production methods;
 - (ii) practice land-related crop cultivation and livestock production or practice aquaculture which complies with the principle of sustainable exploitation of 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) restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in point (e) do not exist, these shall be limited to:
 - (i) inputs from organic production;
 - (ii) natural or naturally-derived substances;
 - (iii) low solubility mineral fertilisers;

- (g) adaptation, where necessary, and within the framework of this Regulation, of the production process, taking account of the sanitary status, regional differences in ecological balance, climate and local conditions, stages of development and specific husbandry practices.

Article 5

Specific principles applicable to agricultural activities and aquaculture

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

- (a) maintenance and enhancement of soil life and natural soil fertility, soil stability, soil water retention and soil biodiversity preventing and combating loss of soil organic matter, soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem;
- (b) limitation of the use of non-renewable resources and external inputs to a minimum;
- (c) recycling of wastes and by-products of plant and animal origin as input in plant and livestock production;
- (d) maintenance of plant health by preventive measures, in particular the choice of appropriate species, varieties or heterogeneous material resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests;
- (e) choice of breeds having regard to the capacity of animals to adapt to local conditions, their vitality and their resistance to disease or health problems; the practice of site-adapted and land-related livestock production; the application of animal husbandry practices, which enhance the immune system and strengthen the natural defence against diseases, in particular including regular exercise and access to open air areas and pastureland, where appropriate;
- (f) observance of a high level of animal welfare respecting species-specific needs;
- (g) feeding of livestock with organic feed composed of agricultural ingredients from organic production and of natural non-agricultural substances;
- (h) exclusion of genetic engineering, animal cloning, artificially induced polyploidy and ionising radiation from the whole organic food chain;
- (i) continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems;
- (j) feeding of aquatic organisms with feed from sustainable exploitation of fisheries in accordance with Regulation (EU) No 1380/2013 or with organic feed composed of agricultural ingredients from organic production, including organic aquaculture, and of natural non-agricultural substances.

Article 6

Specific principles applicable to the processing of organic food and feed

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

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

Chapter III

Production rules

Article 7

General production rules

1. Operators shall comply with the following general production rules:
 - (a) the entire agricultural holding or aquaculture operation shall be managed in compliance with the requirements applicable to organic production;
 - (b) save as otherwise provided in point 2.2 of Part IV and point 1.3 of Part VI of Annex II, only products and substances authorised pursuant to Article 19 may be used in organic agriculture and aquaculture, provided that the product or substance in question has been authorised for use in agriculture and aquaculture, in accordance with the relevant provisions of Union law and, where necessary, in the Member States concerned, in accordance with national provisions based on Union law;
 - (c) the use of ionising radiation for the treatment of organic food or feed, or of raw materials used in organic food or feed shall be prohibited;
 - (d) organic operators other than micro-enterprises, farmers and operators producing seaweed or aquaculture animals, shall put in place an environmental management system with a view to improving their environmental performance.
2. In order to ensure the correct application of the general production rules, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 providing the criteria to which the environmental management system referred to in point (d) of paragraph 1 is to correspond. Those criteria shall take into account the specificities of small and medium size enterprises.

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 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.

(2a) By way of derogation from paragraph 2, in cases where the land has been left fallow before the notification referred to in Article 24(1) for at least the time period required for conversion and provided that other necessary requirements are fulfilled, no conversion period shall be necessary for this fallow land

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. By way of derogation from Article 7(1)(a), during the conversion period, the agricultural holding may be split into clearly separated units which are not all managed under organic production. As regards livestock, different species shall be involved in organic production during the conversion period. 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 easily be distinguished shall be involved in organic production during the conversion period.
6. In order to ensure quality, traceability and compliance with this Regulation as regards organic production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing the rules laid down in this Article or supplementing and amending 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 food or feed or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms and animals in organic production.
2. For the purposes of paragraph 1, with regard to GMOs or products produced from or by GMOs for food and feed, operators may rely on the labels of a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁴⁸ or Regulation (EC) No 1830/2003 of the European Parliament and of the Council⁴⁹.

⁴⁸ Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

⁴⁹ 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

3. Operators may assume that no GMOs or products produced from or by GMOs have been used in the manufacture of purchased food and feed when such products are not labelled, or accompanied by a document, pursuant to the Regulations referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those Regulations.

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 listing the varieties and heterogeneous material, according to Regulation (EU) No XX/XXX (PRM law) for which plant reproductive 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 developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the specific plant production rules as regards:
 - (a) cultivation practices;
 - (b) soil management and fertilisation;
 - (c) plant health and management of pests and weeds;
 - (d) management of mushroom production and other specific plant and plant production systems;
 - (e) the origin of plant reproductive material;
 - (f) the collection of wild plants.
4. The Commission shall adopt implementing acts laying down the technical details for establishing the database referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 11

Livestock production rules

1. Livestock operators shall in particular comply with the specific production rules set out in Part II of Annex II.

and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

2. In order to ensure quality, traceability and compliance with this Regulation as regards organic livestock production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 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 developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the specific seaweed production rules as regards:
 - (a) the suitability of the aquatic medium and the sustainable management plan;
 - (b) the 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 production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the specific production rules for aquaculture animals as regards:
 - (a) the suitability of the aquatic medium and the sustainable management plan;
 - (b) the origin of aquaculture animals;

- (c) aquaculture husbandry, including aquatic containment systems, production systems, maximum stocking density and, where appropriate, minimum 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 production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the specific production rules for processed food and feed as regards:
 - (a) procedures to be followed;
 - (b) preventive measures to be taken;
 - (c) the composition and conditions of use of processed food and feed, including products and substances allowed for use in 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) calculation of the percentage of agricultural ingredients referred to in Article 21(3)(a)(ii) and (b);
 - (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 wine production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 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 to be 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 developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 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 any future need to have specific production rules for products other than those referred to in Articles 10 to 15, and in order to ensure quality, traceability and compliance with this Regulation as regards organic production of those additional other products and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 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 event 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 36 providing for the criteria to qualify such situations as catastrophic and laying down specific rules on how to deal with them, on monitoring and on reporting requirements.

Article 18

Collection, packaging, transport and storage

1. Organic products shall be collected, packaged, transported and stored in accordance with the rules set out in Annex III.
2. In order to ensure the integrity of organic production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending or supplementing the rules set out in Annex III.

Article 19

Authorisation of products and substances used in organic production

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

In particular, the Commission may authorise certain products and substances for use in the production of organic processed food and include them in restricted lists, for the following purposes:

- (a) as food additives, food enzymes 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 pest for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available;
 - (ii) if products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be authorised only if their conditions for use preclude any direct contact with the edible parts of the crop;
- (d) in the case of products referred to in point (b) of the first subparagraph of paragraph 1, their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or for specific soil-conditioning purposes;
- (e) in the case of products referred to in points (c) and (d) of 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 behavioral needs of the species concerned or their use is necessary to produce or preserve feed because the production or preservation of feed is not possible without having recourse to such substances;
 - (ii) feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin, except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available.

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 shall be strictly limited to cases where the use of external inputs referred to in Article 4(f) would contribute to unacceptable environmental impacts.

3. In order to ensure quality, traceability and compliance with this Regulation as regards organic production in general and the production of processed organic food in particular, and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 providing for additional criteria for the authorisation or withdrawal of the authorisation of products and substances referred to in paragraph 1 for use in organic production in general and in the production of organic processed food in particular, 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 authorised 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 concerned shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the other Member States.

Requests for amendment or withdrawal shall be published by Member States.

5. The Commission shall adopt implementing acts authorising or withdrawing the authorisation of products and substances that may be used in organic production in general and products and substances that may be used in the production of processed organic food in particular, and establishing the procedures to be followed for the authorisation and the lists of those products and substances and, where appropriate, their description, compositional requirements and conditions for use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 20

Presence of non-authorised products or substances

1. Products in which the presence of products or substances that have not been authorised in accordance with Article 19 is detected beyond the levels established taking account in particular of Directive 2006/125/EC, shall not be marketed as organic.
2. 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 36 regarding the specific criteria and conditions for the application of the levels referred to in paragraph 1 and regarding the establishment of those levels and their adaptation in the light of technical developments.
3. By way of derogation from Article 211(1) of Regulation (EU) No 1308/2013, and subject to an authorization by the Commission adopted without applying the procedure referred to in Article 37(2) or (3) of this Regulation, Member States may

grant national payments to compensate farmers for the losses they have incurred due to the contamination of their agricultural products by non-authorized products or substances which prevents them from marketing those products as organic provided that the farmers have taken all appropriate measures to prevent the risk of such contamination. Member States may also use the instruments of the Common Agricultural Policy to cover totally or partially such losses.

Chapter IV

Labelling

Article 21

Use of terms referring to organic production

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

Furthermore, any terms, including terms used in trademarks, or 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. 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 point (b) of the first 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.

4. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning adaptation of the list of terms set out in Annex IV, taking into account linguistic developments within the Member States and concerning the establishment of specific labelling and compositional requirements applicable to feed and ingredients thereof.

Article 22

Compulsory indications

1. Where terms as referred to in Article 21(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 23 as regards pre-packed food as defined in point (e) of Article 2(2) of Regulation (EU) No 1169/2011 shall also appear on the packaging.
2. Where the organic production logo of the European Union is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed shall also appear in the same visual field as the logo and shall take one of the following forms, as appropriate:
 - (a) 'EU Agriculture', where the agricultural raw material has been farmed in the Union;
 - (b) 'non-EU Agriculture', where the agricultural raw material has been farmed in third countries;
 - (c) 'EU/non-EU Agriculture', where a part of the agricultural raw materials has been farmed in the Union and a part of it has been farmed in a third country.

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

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

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

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

3. The indications referred to in paragraphs 1 and 2 of this Article and in Article 23(3) shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
4. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 laying down further rules on labelling and the use of the indications referred to in point (a) of paragraph 1 and in paragraph 2 of this Article and in Article 23(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 paragraph 2 of this Article and in Article 23(3);
 - (b) the assignment of code numbers to control authorities and control bodies;
 - (c) the indication of the place where the agricultural raw materials have been farmed, in accordance with paragraph 2 of this Article and Article 232(3).

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

Article 23

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 in Article 22(2) shall also appear in the labelling.
4. The organic production logo of the European Union shall follow the model set out in Annex V and shall comply with the rules set out in that Annex.
5. National and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation.
6. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending the organic production logo of the European Union and the rules relating thereto set out in Annex V.

Chapter V

Organic certification

Article 24

Organic certification system

1. Operators or groups of operators that produce, prepare or store organic products, who import such products from a third country or export such products to a third country or who place such products on the market shall, prior to the placing on the market as organic or prior to conversion, notify their activity to the competent authorities of the Member State(s) where the activity is carried out.
2. Where operators or groups of operators subcontract any of their activities to a third party, both the operators and groups of operators and the third party to whom activities have been subcontracted shall comply with paragraph 1.
3. Operators and groups of operators shall keep records on the different activities they engage in, in accordance with this Regulation.
4. Competent authorities shall keep an updated list containing the names and addresses of operators and groups of operators that have notified their activities in accordance with paragraph 1 and shall make that list public, together with the information relating to their organic certificates as referred to in Article 25(1). 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 Council⁵⁰.
5. Member States shall ensure that the fees that may be collected by the competent authorities, control authorities or control bodies in accordance with Article 76 of Regulation (EU) No XX/XXXX (official controls Regulation) are made public.
6. 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 36 concerning the requirements for keeping records, the requirements for publication of the list referred to in paragraph 4 of this Article and the requirements and procedures to be applied for publication of the fees referred to in paragraph 5 of this Article and for supervision by the competent authorities of the application of those fees.
7. 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 publication of the fees referred to in paragraph 5. Those implementing acts

⁵⁰ 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).

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

Article 25

Organic certificate

1. Operators and groups of operators that have notified their activity in accordance with Article 24(1) and comply with this Regulation shall be entitled to be provided with an organic certificate. The organic certificate, issued in electronic form 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 and groups of operators shall not be entitled to be provided with an organic certificate by different control authorities or control bodies for the same group of products, including when those operators and groups of operators engage in different stages of production, preparation and distribution.
4. Members of a group of operators shall not be entitled to be provided with an individual organic certificate for any of the activities covered by the certification of the group.
5. Operators shall systematically verify the organic certificate of operators that are their suppliers.
6. 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 36 concerning the criteria for defining the groups of products referred to in paragraph 3.

Article 26

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 36 concerning the responsibilities of the individual members of a group of operators, the composition and dimension of a group of operators, the categories of 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 a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37 (2).

Chapter VI

Trade with third countries

Article 27

Export of organic products

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

However, a product intended to be exported as organic to a third country which is recognised in accordance with Article 31 may be exported to that third country if it complies with that third country's requirements to be placed on the market in that third country as organic.

2. In order to avoid creating unequal conditions for operators when exporting to third countries, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning specific rules for exports of organic products to a third country which is recognised in accordance with Article 31.
3. In order to ensure fair competition among operators, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning documents intended for customs authorities in third countries, in particular as regards an organic export certificate issued in electronic form wherever possible and providing assurance that exported organic products comply with this Regulation.

Article 28

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 29; or
 - (ii) comes from a third country which is recognised in accordance with:
 - Article 30; or

– Article 31;

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

Article 29

Recognition of control authorities and control bodies

1. The Commission may adopt implementing acts recognising, or withdrawing the recognition of control authorities and control bodies which fulfil the criteria set out in a delegated act adopted pursuant to paragraph 7 and which are competent to carry out controls in third countries, and establishing a list of those control authorities and control bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).
2. The control bodies shall be accredited to the relevant harmonised standard for ‘Conformity assessment – Requirements for bodies certifying products, processes and services’, the reference of which has been published in *the Official Journal of the European Union*.
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 Council⁵¹; 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.

⁵¹ 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 recognised control bodies or control authorities shall provide the certificate issued by the accreditation body or respectively the assessment report issued by the competent authority, and, as appropriate, reports on the regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities.

5. Based on the information referred to under paragraph 4, 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 from the accreditation bodies or, as appropriate, the competent authorities.
6. The nature of the supervision shall be determined on the basis of an assessment of the risk of non-compliance.
7. In order to ensure the transparency of the recognition and supervision procedures, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning 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, as well as concerning the exercise of the supervision by the Commission, including through on-the-spot examination.
8. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance affecting the integrity of organic products imported under the recognition provided for in this Article or suspicion of such cases. Such measures may consist in particular in the verification of the integrity of the organic products before placing the products on the market within the Union and, where appropriate, the suspension of the authorisation of placing on the market within the Union of such products as organic. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).
9. On duly justified imperative grounds of urgency relating to the protection against unfair practices or practices which are incompatible with the principles and rules on organic production, the protection of consumers' confidence or the protection of fair competition between operators, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 37(3) to take the measures referred to in paragraph 8 of this Article or to decide on the withdrawal of the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article.

Article 30

Equivalence under a trade agreement

A recognised third country referred to in the first indent of Article 28(1)(b)(ii) is a third country which the Union has recognised under a trade agreement as having a system of production meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity as those of the Union.

Equivalence under Regulation (EC) No 834/2007

1. A recognised third country referred to in the second indent of Article 28(1)(b)(ii) is a third country which has been recognised for the purpose of equivalence under Article 33(2) of Regulation (EC) No 834/2007, including those recognised under the transitional measure provided for in Article 40.

The recognition of the third countries referred to in the first subparagraph shall expire on [a date to be inserted which corresponds to 5 years following the date of application of the Regulation].

2. On the basis of annual reports to be sent to the Commission, by 31 March of each year, by the third countries referred to in paragraph 1 regarding the implementation and enforcement of the control measures established by them, 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 relevant harmonised standard for ‘Conformity assessment – Requirements for bodies certifying products, processes and services’, the reference of which has been published in the *Official Journal of the European Union*. If the accreditation is not granted by a national accreditation body in the Union in accordance with Regulation (EC) No 765/2008, it 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 37(2).
5. In order to ensure the management of the list of third countries referred to in paragraph 4, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the information to be sent by those third countries necessary for the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.
6. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance affecting the integrity of organic products imported from third countries referred to in this Article or suspicion of such cases. Such measures may consist in particular in the verification of the integrity of the organic products before placing the products on the market within the Union and, where appropriate, the suspension of the authorisation of placing on the market within the Union of such products as organic. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Chapter VII

General provisions

SECTION 1

FREE MOVEMENT OF ORGANIC PRODUCTS

Article 32

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

1. Competent authorities, control authorities and control bodies may not, on grounds relating to the production, to the labelling or to the presentation of the products, prohibit or restrict the marketing of organic products controlled by another competent authority, control authority or control body located in another Member State, if those products comply with this Regulation. In particular, no official controls and other official activities other than those under Regulation (EU) No XXX/XXX (Official controls Regulation) may be performed and no fees for official controls and other official activities other than those under Article 76 of that Regulation 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 36 laying down rules relating to the free movement of organic products for the purposes of paragraph 1 of this Article.

SECTION 2

INFORMATION AND REPORTING

Article 33

Information relating to the organic sector and trade

1. Each year Member States shall transmit to the Commission the information necessary for the implementation and monitoring of the application of this Regulation.
2. The Commission shall adopt implementing acts as regards the system to be used for transmitting the information referred to in paragraph 1, the details of information to be transmitted, and the date by which that information is to be transmitted. Those

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

Article 34

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

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

Member States shall 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 control authorities and control bodies referred to in point (b) of paragraph 1.

Article 35

Report

By 31 December 2021, the Commission shall present a report to the European Parliament and the Council on the availability of organic plant reproductive material and animals for breeding purposes.

Chapter VIII

Procedural, transitional and final provisions

SECTION 1

PROCEDURAL PROVISIONS

Article 36

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in [.....] may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
3. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
4. A delegated act adopted pursuant to [.....] shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 37

Committee procedure

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

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

SECTION 2

REPEAL, AMENDMENTS, TRANSITIONAL AND FINAL PROVISIONS

Article 38

Repeal

Regulation (EC) No 834/2007 is repealed.

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

Article 39

Transitional measures relating to conversion to organic farming

In order to ensure a smooth transition from the old to the new legal framework, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning rules providing for a derogation from Article 8(3) in relation to conversion periods for farmers initiating conversion before the entry into force of this Regulation.

Article 40

Transitional measures relating to the origin of plant reproductive material, animals for breeding purposes and young stock of aquaculture animals

In order to ensure a smooth transition between the rules on organic origin of plant reproductive material provided for in Article 12(1)(i) of Regulation (EC) No 834/2007 and on animals for breeding purposes provided for in Article 14(1)(a)(ii) of that Regulation and on young stock of aquaculture animals provided for in Article 15(1)(a)(ii) of that Regulation and the exception to production rules that the Commission adopted pursuant to Article 22 of Regulation (EC) No 834/2007, and the new production rules for plants and plant products and livestock and seaweed and aquaculture animals provided for in Articles 10(1) and 11(1), respectively, of this Regulation, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 providing for exceptions where granting exceptions is deemed necessary in order to ensure access to plant reproductive material and live animals for breeding purposes and young stock of aquaculture animals, that may be used in organic production. The delegated acts adopted under this Article shall cease to apply on 31 December 2021.

Article 41

Transitional measures relating to control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007

1. The recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007 shall expire on [31 December 2018] at the latest.
2. The Commission shall, by means of an implementing act, establish a list of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and may amend that list by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

3. In order to ensure the management of the list of control authorities and control bodies referred to in paragraph 2, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the information to be sent by those control authorities and control bodies necessary for the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.

Article 42

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

1. The Commission shall complete the examination of applications from third countries submitted under Article 33(2) of Regulation (EC) No 834/2007 which are pending at the date of entry into force of this Regulation. Regulation (EC) No 834/2007 shall apply to the examination of such applications.
2. In order to facilitate the completion of the examination of the applications referred to in paragraph 1, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the procedural rules necessary for the examination, including on the information to be submitted by the third countries.

Article 43

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

Products produced in accordance with Regulation (EC) No 834/2007 and placed on the market before 1 July 2017 may continue to be marketed after that date until stocks are exhausted.

Article 44

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

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

1. In Article 2, points 38 and 39 are 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;

39. 'control authority for organic production and labelling of organic products' means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to the application of the Union legislation in the area referred to in Article 1(2)(j),

including, where appropriate, the corresponding authority of a third country or operating in a third country;"

2. Article 3 is amended as follows:

(a) 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 production and labelling of organic products. In such cases, they shall allocate a code number to each of them.";

(b) In paragraph 4, point (c) is replaced by the following:

" (c) the control authorities for organic production and labelling of organic products referred to in paragraph 3;"

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) in the event 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-authorized 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 the event of repetitive or continued non-compliance, ensure that the operators or the group of operators concerned, as defined in points (6) and (7) of Article 3 of Regulation (EU) No [organic production] of the European Parliament and of the Council*, in addition to the measures referred to in point (a) of this paragraph, are prohibited from marketing products which refer to organic production, and that their organic certificate be suspended or withdrawn as appropriate.

2. 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 points (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.

3. In relation to the rules referred to in point (j) of Article 1(2), the delegated acts referred to in paragraph 2 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), and 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) requirements additional to those referred to in Article 8(1) for risk assessment and for establishing the frequency of official controls, and of sampling as appropriate, taking into account the risk of the occurrence of non-compliance;

(c) the frequency of official controls on operators, and the cases where and conditions under which certain such operators are to be exempted from certain official controls;

(d) methods and techniques for official controls additional to those referred to in Article 13 and Article 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 production, preparation and distribution, and at providing assurances as to compliance with the rules referred to in point (j) of Article 1(2);

(e) actions and measures additional to those provided for in Article 134(2) and (3) in case of suspicion of non-compliance, criteria additional to those referred to in the second subparagraph of Article 135(1), and criteria and measures additional to those provided for in Article 135(2) and in paragraph 1 of this Article in the event of non-compliance;

(f) requirements additional 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) reporting obligations additional to those referred to in Articles 12, 28 and 31 for the competent authorities, the control authorities 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, including the exchange of information concerning instances of non-compliance or the likelihood of non-compliance between competent authorities, control authorities and delegated bodies.

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

(b) methods and techniques additional to those referred to 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 criteria and content additional 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 activating 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 the event of non-compliance and of serious or recurrent non-compliance.

5. Where appropriate, the delegated acts referred to in paragraphs 3 and 4 shall derogate from the provisions of this Regulation referred to in those paragraphs.

* OJ L ..., p. ...”

4. In Article 128, paragraph 1 is replaced by the following:

"1. In the areas governed by the rules referred to in Article 1(2), with the exclusion of points (d), (e), (g), (h) and (j) of Article 1(2), the Commission may, by means of implementing acts, recognise that measures applied in a third country, or regions thereof, are equivalent to the requirements laid down in those rules, on the basis of:

(a) a thorough examination of information and data provided by the third country concerned pursuant to Article 124(1);

(b) where appropriate, the satisfactory outcome of a control performed in accordance with Article 119(1);

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2)."

5. In Article 141, paragraph 1 is replaced by the following:

"1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee shall be a Committee within the meaning of Regulation (EU) No 182/2011. For measures falling within the area referred to in Article 1(2)(j) of this Regulation, the Commission shall be assisted by the Organic production Committee established by Article 37(1) of Regulation (EU) No [organic production]."

Article 45

Entry into force and application

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

It shall apply from 1 July 2017⁵².

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
[...]

⁵² At least 6 months after enter into force.

Legislative financial statement

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

- 1.1. Title of the proposal/initiative
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LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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 Regulation (EC) No 834/2007

1.2. Policy area(s) concerned in the ABM/ABB structure⁵³

1.3. Nature of the proposal/initiative

- The proposal/initiative relates to **a new action**
- The proposal/initiative relates to **a new action following a pilot project/preparatory action**⁵⁴
- The proposal/initiative relates to **the extension of an existing action**
- The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

The proposal targets how rules concerning organic production contribute to the realisation of the policy priorities of the Europe 2020 strategy for smart, sustainable and inclusive growth, in particular 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. Specific objective(s) and ABM/ABB activity(ies) concerned

The specific objectives of the proposal are :

- to remove the obstacles to the development of organic production in the Union,
- to guarantee fair competition for farmers and operators and to improve the functioning of the internal market,
- to maintain or improve consumer confidence in organic products.

In accordance with the 2014-2020 Common Monitoring and Evaluation Framework (CMEF) for the Common Agricultural Policy (CAP)⁵⁵, the proposal contributes to the general objectives: "Sustainable management of natural resources and climate action" by providing public goods (mostly environmental) and by pursuing "climate change mitigation and adaptation" and "Viable food production" by "meeting consumers

⁵³ ABM: activity-based management – ABB: activity-based budgeting.

⁵⁴ As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

⁵⁵ Article 110 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council on the financing, management and monitoring of the common agricultural policy.

expectations" and by "improving the competitiveness of the agricultural sector and enhancing the share in food-chain", under the first Pillar of the CAP.

In addition, the proposal contributes to the general objective "sustainable management of natural resources and climate action" by restoring, preserving and enhancing ecosystems (priority 4) under Pillar II of the CAP.

The proposal is related to measures supported under both Pillar I (direct payments and markets) and Pillar II of the CAP.

ABB activity concerned: 05 04 Rural Development (and 05 02 Interventions in agricultural markets and 05 03 Direct aids).

1.4.2. *Expected result(s) and impact*

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

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 (animal welfare, environmental management system for processors and traders).

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

Specify the indicators for monitoring implementation of the proposal/initiative.

The main result indicators in the Common Monitoring and Evaluation Framework are:

- Share of organic area in total utilised agricultural area (UAA);
- Share of organic livestock in total livestock.

And the main output indicators are:

- Organic land area (in conversion and fully converted);
- Number of certified organic operators.

The following complementary indicators will also be monitored within the context of this Regulation:

- Livestock (number of organic animals and products of animal origin);
- Crop production and processing (number of operators and value/volume of production by type of economic activity);
- Number of exceptions used and number of exceptions removed,
- Knowledge of, and confidence in, the Union organic logo (Eurobarometer survey).

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The overall objective of the legislative framework, which is the sustainable development of organic production, is currently not fully met. It leads to lost opportunities for farmers and operators in the Union (the organic land area in the Union has only doubled in the last 10 years, while the market has increased fourfold), a risk of limitation to the organic market expansion and a risk of limitation to the environmental benefits associated with organic production.

The main drivers are: regulatory and non-regulatory obstacles to the development of organic production in the Union; a risk of erosion of consumer confidence, notably because of the many exceptions that are watering down organic production rules and because of the fraud cases that have developed in connection with shortcomings in the control system and in the import regime; unfair competition among operators in the Union and in Third Countries; and issues in the design and the enforcement of the legal provisions, notably issues with the functioning of the internal market, because of gaps in the legislation and different approaches in implementation.

1.5.2. Added value of EU involvement

The current proposal is an updating of an existing quality scheme set within the Common Agricultural Policy.

Production and trade of agricultural products and foodstuffs on the internal market and ensuring the functioning of the internal market are matters of Union competence. Both are competences shared with MS.

A Union wide scheme is more efficient than 28 different schemes and allows for a stronger and more consistent trade policy vis-à-vis global trading partners, most notably by enhancing the Union's bargaining power.

The organic logo of the European Union should cover products complying with a common set of rules that are applied across the whole Union.

Areas where further harmonisation is needed include: exceptions to the rules and action to preserve the integrity of organic production, including a common approach to address the presence of non-authorised substance residues in organic products.

1.5.3. Lessons learned from similar experiences in the past

An external evaluation of the Union legislation on organic farming was completed in 2013⁵⁶. In particular, it analysed the adequacy of the production rules and of the rules on controls, imports and labelling of organic products. The evaluation concluded that most of the rules laid down in the organic legislative framework are in general adequate for achieving its global objectives. Yet, it also identified a number of shortcomings and

⁵⁶ Sanders, J (ed.) 2013: Evaluation of the EU legislation on organic farming, Thünen Institute of Farm Economics http://ec.europa.eu/agriculture/evaluation/market-and-income-reports/organic-farming-2013_en.htm

proposed recommendations for improvement. These recommendations have been given due consideration in the present proposal.

The European Court of Auditors audited the effectiveness of the control system governing the production, processing, distribution and imports of organic products as provided in Council Regulation (EC) No 834/2007. The results, published in ECA Special Report No 9/2012, show a number of weaknesses and include recommendations for improvement that have been taken into account in the present proposal.

1.5.4. *Compatibility and possible synergy with other appropriate instruments*

The proposal is consistent with the new CAP, e.g. with the new Regulation on Direct Payments⁵⁷, under which organic farms benefit ipso facto from the new "green" payment, and with the new Regulation on Rural Development⁵⁸, providing for specific measures benefitting organic farming, and the new Common Fisheries Policy.

The proposal is also consistent with the proposal for a new Regulation on official controls in Food and Feed and with smart Regulation principles.

1.6. **Duration and financial impact**

Proposal/initiative of **limited duration**

– Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. **Management mode(s) planned**⁵⁹

Direct management by the Commission

– by its departments, including by its staff in the Union delegations;

– by the executive agencies;

Shared management with the Member States

Indirect management by delegating implementation tasks to:

⁵⁷ 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.

⁵⁸ 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 (EARFD) and repealing Council Regulation (EC) No 1698/2005.

⁵⁹ Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

- third countries or the bodies they have designated;
- international organisations and their agencies (to be specified);
- the EIB and the European Investment Fund;
- bodies referred to in Articles 208 and 209 of the Financial Regulation;
- public law bodies;
- bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
- bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;
- persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.
- *If more than one management mode is indicated, please provide details in the "Comments" section.*

Comments

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

Member States shall provide the Commission annually with the information necessary for implementation and monitoring of application of this Regulation. Member States shall also provide the Commission with annual information on the controls carried out to ensure compliance with the requirements on organic production, as part of their Multi-annual national control plans and Annual Reports referred to under the Official Controls Regulation.

Third Countries recognised as equivalent, and Control Bodies or Control Authorities recognised as compliant for the import of organic products into the Union shall submit to the Commission annual reports with the necessary information for implementation of the requirements under this Regulation.

2.2. Management and control system

2.2.1. Risk(s) identified

The general risks as regards to the rules in the proposal that can be identified relate to the effectiveness of the proposal, and not as regards to the EU expenditure given the relatively insignificant amounts which are involved:

Harmonised production rules that remove exceptions may, in an initial stage, create problems for some operators and discourage uptake of the organic scheme.

The transition period for the move from the equivalency to the compliance system, as concerns imports of organic products into the Union, may not fully ensure a level-playing field.

The replacement of the annual physical inspection of all operators, regardless of their risk profile, by a fully risk-based approach to controls may be considered as inappropriate by some stakeholders and/or control authorities or bodies in Member States.

Other risks may be linked to shortcomings in enforcement: namely, implementation by the competent authorities and control authorities or control bodies in Member States and Third Countries, and supervision by the Commission.

Experience gained with implementation of Regulation (EC) No 834/2007 - including through the results of audits, stakeholders' input in the framework of the impact assessment, and the recommendations from external studies and the external evaluation have been duly taken into account in the design of the proposal so as to mitigate these risks. Particular attention has also been paid to mitigate the risk linked to possible shortcomings in enforcement through efforts for clearer rules, simpler to manage and control

2.2.2. *Information concerning the internal control system set up*

Expenditure entailed by this proposal shall be implemented by the Commission under direct management, in accordance with the principles set out in article 32 of Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union – the Financial Regulation.

As required by the Financial Regulation, the Director General for Agriculture and Rural Development has put in place the organisational structure and the internal control processes suited to the achievement of the policy and control objectives, in accordance with the internal control standards adopted by the Commission and having regard to the risks associated with the environment in which the policy operates.

2.2.3. *Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error*

Expenditure entailed by this proposal will not lead to an increase in the error rate for the European Agricultural Rural Development Fund (EARDF), taking into account the relatively insignificant amounts involved.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal

activities, by the performance of effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid as well as, where appropriate, by effective, proportional and deterrent penalties, in accordance with Article 325 of the Treaty on the Functioning of the European Union, with Council Regulation (EC) No 2988/95 on the protection of the European Communities' financial interests, and with title IV of the Financial Regulation applicable to the general budget of the Union.

The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the spot checks and inspections on economic operators concerned directly or indirectly by such funding in accordance with the procedures laid down in Council Regulation No 2185/96 of 11 November 1996 with a view to establishing that there has been fraud. Decisions, agreements and contracts resulting from the implementation of the Regulation shall expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct such audits, on-the-spot checks and inspections.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [...]Heading.....]	Diff./non-diff. (60)	from EFTA countries 61	from candidate countries ⁶²	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
2	05 04 60 02 Assistance technique opérationnelle	Diff.	/NO	/NO	NO	NO

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

⁶⁰ Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations.

⁶¹ EFTA: European Free Trade Association.

⁶² Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

Heading of multiannual financial framework	2	Sustainable growth : natural resources
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DG: AGRI		2015	2016	2017	2018	2019	2020	TOTAL
• Operational appropriations								
	05 04 60 02 Assistance technique opérationnelle *	(1)	0,800	0,230	0,170	0,170	0,170	0,170
		(2)	0,800	0,230	0,170	0,170	0,170	0,170
Appropriations of an administrative nature financed from the envelope of specific programmes ⁶³								
	(3)							
TOTAL appropriations** for DG AGRI	=1+1a+3	0,800	0,230	0,170	0,170	0,170	0,170	1,710
	=2+2a+3	0,800	0,230	0,170	0,170	0,170	0,170	1,710

* Currently the control of imports of organic products takes place via TRACES which is partly financed from this line and the proposal is not expected to increase the needs for this measure. Furthermore to the already existing tool for the imports, the Regulation foresees that all organic production put in the market in the EU be subject to an e-certificate, it is therefore necessary to extend the e-certificate for import to cover products within the Union. An IT tool within Traces' architecture estimated at EUR 500 000 will have to be developed for the e-certificate for internal organic production foreseen in Article 23 of the Commission proposal in order to ensure it will be operational as from 01.01.2016. The maintenance is estimated at EUR 110 000 per year.

⁶³

Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

* Furthermore harmonisation of the database for organic seeds is foreseen in Article 10 of the proposal: To ensure the development of this separate seeds database, technical assistance from the Union estimated at EUR 300 000 is to be financed from this line outside TRACES. The maintenance is estimated to EUR 120 000 the first year after the development and to EUR 60 000 for the subsequent years.

		2015	2016	2017	2018	2019	2020	Total
• TOTAL operational appropriations	Commitments	(4) 0,800	0,230	0,170	0,170	0,170	0,170	1,710
	Payments	(5) 0,800	0,230	0,170	0,170	0,170	0,170	1,710
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes	(6)							
TOTAL appropriations for HEADING 2 of the multiannual financial framework	Commitments	=4+6 0,800	0,230	0,170	0,170	0,170	0,170	1,710
	Payments	=5+6 0,800	0,230	0,170	0,170	0,170	0,170	1,710

** The IT tools will be financed by the technical assistance for the Commission in accordance with Article 58(2) of the Regulation (EU) N° XXXX/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) N° 1698/2005. These amounts are already foreseen in the Multi-Annual Financial framework for 2014-2020.

Heading of multiannual financial framework	5	Administration
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EUR million

DG: AGRI		2015	2016	2017	2018	2019	2020	TOTAL
• Human resources		-	-	-	-	-	-	-
• Other administrative expenditure		0,127	0,127	0,055	0,055	0,055	0,055	0,474
TOTAL DG AGRI	Appropriations	0,127	0,127	0,055	0,055	0,055	0,055	0,474

TOTAL appropriations for HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,127	0,127	0,055	0,055	0,055	0,055	0,474
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TOTAL appropriations for HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,127	0,127	0,055	0,055	0,055	0,055	0,474
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EUR million

TOTAL appropriations under HEADINGS 1 to 5		2015	2016	2017	2018	2019	2020	TOTAL
Commitments		0,927	0,357	0,225	0,225	0,225	0,225	2,184
Payments		0,927	0,357	0,225	0,225	0,225	0,225	2,184

3.2.2. Estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million

Indicate objectives and outputs	Type ⁶⁴	Average cost	REALISATIONS (outputs)					2020	2019	2018	2017	2016	TOTAL
			Cost	Cost	Cost	Cost	Cost						
SPECIFIC OBJECTIVE⁶⁵													
To provide the conditions for the sustainable management of natural resources supporting the shift towards a resource efficient and low-carbon economy													
Output	Area under organic farming (Number of hectares)												
Output	Area under conversion (Number of hectares)												
Output	Number of certified organic operators ¹												
Output	Number of certified organic producers												
TOTAL COST													

⁶⁴

Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

⁶⁵

In line with the Common Monitoring and Evaluation framework of the CAP, a common monitoring and evaluation framework will be established as from 2014 onwards and indicators tables will therefore be duly completed at a later stage

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

- The proposal/initiative does not require the use of appropriations of an administrative nature
- The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	2015	2016	2017	2018	2019	2020	TOTAL
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HEADING 5 of the multiannual financial framework							
Human resources	-	-	-	-	-	-	-
Other administrative expenditure	0,127	0,127	0,055	0,055	0,055	0,055	0,474
Subtotal HEADING 5 of the multiannual financial framework	0,127	0,127	0,055	0,055	0,055	0,055	0,474

Outside HEADING 5⁶⁶ of the multiannual financial framework							
Human resources							
Other expenditure of an administrative nature							
Subtotal outside HEADING 5 of the multiannual financial framework	0,127	0,127	0,055	0,055	0,055	0,055	0,474

TOTAL	0,127	0,127	0,055	0,055	0,055	0,055	0,474
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The human resources appropriations required will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and taking account of budgetary constraints.

⁶⁶ Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources.
- The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

	2015	2016	2017	2018	2019	2020
XX 01 01 01 (headquarters and Commission's representatives)	18	18	18	18	18	18
XX 01 01 02 (Delegations)						
XX 01 05 01 (Indirect research)						
10 01 05 01 (Direct reserach)						
XX 01 02 01 (CA, SNE, INT from the "global envelope")	3	3	3	3	3	3
XX 01 02 02 (CA, LA,SNE, INT and JED in the delegations)						
XX 01 04 yy	- at headquarters					
	- delegations					
XX 01 05 02 (CA,SNE, INT – indirect research)						
10 01 05 02 (CA,SNE, INT – direct research)						
Other budget lignes (specify)						
TOTAL (*)	21	21	21	21	21	21

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	Policy development Policy implementation Planning, programming, monitoring and supervision Relations with Member States and stakeholders Negotiation, and representation of the Commission, with Third Countries Relations with other Union institutions and bodies
External staff	Assisting in policy implementation, monitoring and contacts with Member States and stakeholders

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible with the current multiannual financial framework.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.
- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties.
- The proposal/initiative provides for the co-financing estimated below

3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
 - on own resources
 - on miscellaneous revenue