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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 products<sup>1</sup>, 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 report<sup>2</sup> at its Agriculture and Fisheries meeting of 13-14 May 2013<sup>3</sup> 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.

The review of the organic production legislation is part of the Commission's Regulatory Fitness and Performance Programme<sup>4</sup>.

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).

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<sup>1</sup> Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L189, 20.7.2007, p. 1).

<sup>2</sup> 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.

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

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

### 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 882/2004<sup>5</sup> 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.

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 2014-2020<sup>6</sup>. The new provisions aim at sustainable competitiveness to achieve an economically viable food production

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<sup>5</sup> 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).

<sup>6</sup> Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608); 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).

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 controls<sup>7</sup>, 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 schemes<sup>8</sup>.

## **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

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<sup>7</sup> 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.

<sup>8</sup> Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

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 dialogues 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 Committee<sup>9</sup>,

Having regard to the opinion of the Committee of the Regions<sup>10</sup>,

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 policy<sup>11</sup>, organic production forms part of the Union's agricultural product quality schemes together with geographical indications, traditional specialties guaranteed and products of the outermost regions of the Union, as laid down in Regulation (EU) No 1151/2012 of the European Parliament and of the Council<sup>12</sup> and Regulation (EU) No 228/2013 of the European Parliament

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<sup>9</sup> OJ C , , p. .

<sup>10</sup> OJ C , , p. .

<sup>11</sup> COM (2009) 234 final.

<sup>12</sup> Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

and of the Council<sup>13</sup>, 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 Council<sup>14</sup>, 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 Council<sup>15</sup>.
- (5) Organic production also contributes to the achievements of the Union environmental policy objectives, in particular those of the 2020 Biodiversity Strategy<sup>16</sup>, the Green Infrastructure Communication<sup>17</sup>, the Soil Thematic Strategy<sup>18</sup> and environmental legislation such as the Birds<sup>19</sup> and Habitats<sup>20</sup> Directives, the Nitrates Directive<sup>21</sup>, the Water Framework Directive<sup>22</sup>, the National Emissions Ceiling Directive<sup>23</sup> and the Directive on the sustainable use of pesticides<sup>24</sup>.
- (6) In view of the objectives of the Union's organic production policy, the legal framework established for implementing that policy should aim at ensuring fair competition and a proper functioning of the internal market in organic products, and at

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

<sup>14</sup> Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

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

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

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

<sup>18</sup> COM(2006) 231 final, 'Thematic Strategy for Soil Protection'.

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

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

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

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

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

<sup>24</sup> 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)

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'<sup>25</sup> 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 834/2007<sup>26</sup> identified the need for a future review of the Union rules on organic production, taking into account the experience gained from the application of those rules. The results of that review carried out by the Commission show that the Union legal framework governing organic production should be improved to provide for rules that correspond to the high expectations of consumers and that guarantee sufficient clarity for those to whom they are addressed. 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 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

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<sup>25</sup> COM(2010)2020 final.

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

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<sup>27</sup> involved in 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

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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).

- 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 Council<sup>28</sup>, 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 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

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<sup>28</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

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 aquaculture<sup>29</sup> 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.

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<sup>29</sup> COM(2013) 229 of 29.4.2013.

- (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 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 889/2008<sup>30</sup> 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.
- (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

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<sup>30</sup> 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).

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/EC<sup>31</sup> 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

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<sup>31</sup> 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).

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 Council<sup>32</sup>, and in particular the provisions aimed at preventing labelling that may confuse or mislead consumers. In addition, specific provisions relating to the labelling of organic products should be laid down in this Regulation. They should protect both the interests of operators 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.

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<sup>32</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).–

- (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 Council<sup>33</sup> to verify compliance with the rules on organic production and labelling of organic products.
- (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.

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

- (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 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 Council<sup>34</sup>.

- (76) The Commission should be empowered to adopt immediately applicable implementing acts where, in duly justified cases relating to the protection against unfair practices or practices which are incompatible with the principles and rules on organic production, the protection of consumers' confidence or the protection of fair competition between operators, imperative grounds of urgency so require to ensure the application of measures in relation to cases of non-compliance, or the suspicion thereof, affecting the integrity of imported organic products 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

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

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 Council<sup>35</sup> 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 Council<sup>36</sup> (plant reproductive material) and Regulation (EU) No XX/XXXX of the European Parliament and of the Council<sup>37</sup> (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 Council<sup>38</sup>, 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;
- (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;

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<sup>35</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

<sup>36</sup> [full title] (OJ L,...).

<sup>37</sup> [full title] (OJ L,...).

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

- (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 Council<sup>39</sup>;
- (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 Council<sup>40</sup>;
- (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;

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<sup>39</sup> Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

<sup>40</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1).

- (21) 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>41</sup>;
- (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 Council<sup>42</sup>;
- (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;
- (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;

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<sup>41</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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

- (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 Council<sup>43</sup> 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 Council<sup>44</sup>;
- (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 Council<sup>45</sup>;
- (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;
- (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 Council<sup>46</sup>;
- (43) 'ionising radiation' means ionising radiation as defined in Article 1 of Council Directive 96/29/Euratom<sup>47</sup>.

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<sup>43</sup> 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).

<sup>44</sup> 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).

<sup>45</sup> 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).

<sup>46</sup> 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)

<sup>47</sup> 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 Council<sup>48</sup> or Regulation (EC) No 1830/2003 of the European Parliament and of the Council<sup>49</sup>.
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.

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<sup>48</sup> 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).

<sup>49</sup> Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

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.
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-authorised 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 Council<sup>50</sup>.
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 shall be adopted in accordance with the examination procedure referred to in Article 37(2).

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<sup>50</sup> 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).

## *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 Council<sup>51</sup>; or
  - (b) an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.
4. When examining requests for recognition, the Commission shall invite the control authority or control body to supply all the necessary information.

The 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

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<sup>51</sup> 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).

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.

#### *Article 31*

##### **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. Members 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-authorised substances and techniques or commingling with non-organic products, ensure that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned;

(b) in 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 2017<sup>52</sup>.

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*  
[...]

---

<sup>52</sup> At least 6 months after enter into force.

## **Legislative financial statement**

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

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- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
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### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
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  - 3.2.4. Compatibility with the current multiannual financial framework
  - 3.2.5. Third-party contributions
- 3.3. Estimated impact on revenue

## 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 structure<sup>53</sup>**

#### **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<sup>54</sup>**
- ☐ 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)<sup>55</sup>, 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 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.

<sup>53</sup> ABM: activity-based management – ABB: activity-based budgeting.

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

<sup>55</sup> 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.

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 2013<sup>56</sup>. 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 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 Payments<sup>57</sup>, under which organic farms benefit ipso facto from the new "green" payment,

<sup>56</sup> 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](http://ec.europa.eu/agriculture/evaluation/market-and-income-reports/organic-farming-2013_en.htm)

<sup>57</sup> 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.

and with the new Regulation on Rural Development<sup>58</sup>, 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<sup>59</sup>**

**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:

- ☐ 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

<sup>58</sup> Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005.

<sup>59</sup> 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](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

## **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 <sup>62</sup>	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation

<sup>60</sup> Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations.

<sup>61</sup> EFTA: European Free Trade Association.

<sup>62</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

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*

<b>Heading of multiannual financial framework</b>	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 *	Commitments	(1)	0,800	0,230	0,170	0,170	0,170	0,170	<b>1,710</b>
	Payments	(2)	0,800	0,230	0,170	0,170	0,170	0,170	<b>1,710</b>
Appropriations of an administrative nature financed from the envelope of specific programmes <sup>63</sup>									
		(3)							
<b>TOTAL appropriations ** for DG AGRI</b>	Commitments	=1+1a +3	0,800	0,230	0,170	0,170	0,170	0,170	<b>1,710</b>
	Payments	=2+2a +3	0,800	0,230	0,170	0,170	0,170	0,170	<b>1,710</b>

\* 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.

\* 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.

<sup>63</sup> 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.

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

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

<b>Heading of multiannual financial framework</b>	<b>5</b>	Administration
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EUR million

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

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

		2015	2016	2017	2018	2019	2020	TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework</b>	Commitments	0,927	0,357	0,225	0,225	0,225	0,225	<b>2.184</b>
	Payments	0,927	0,357	0,225	0,225	0,225	0,225	<b>2.184</b>

### 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			2016		2017		2018		2019		2020		TOTAL	
	REALISATIONS (outputs)													
	Type <sup>64</sup>	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost
SPECIFIC OBJECTIVE <sup>65</sup>			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 <sup>l</sup>													
Output	Number of certified organic producers													
TOTAL COST														

<sup>64</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>65</sup> 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
--	------	------	------	------	------	------	-------

<b>HEADING 5 of the multiannual financial framework</b>							
Human resources	-	-	-	-	-	-	-
Other administrative expenditure	<b>0,127</b>	<b>0,127</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,474</b>
<b>Subtotal HEADING 5 of the multiannual financial framework</b>	<b>0,127</b>	<b>0,127</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,474</b>

<b>Outside HEADING 5<sup>66</sup> of the multiannual financial framework</b>							
Human resources							
Other expenditure of an administrative nature							
<b>Subtotal outside HEADING 5 of the multiannual financial framework</b>	<b>0,127</b>	<b>0,127</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,474</b>

<b>TOTAL</b>	<b>0,127</b>	<b>0,127</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,055</b>	<b>0,474</b>
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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.

<sup>66</sup> 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)							
<b>XX 01 04 yy</b>	- at headquarters						
	- delegations						
<b>XX 01 05 02 (CA,SNE, INT – indirect research)</b>							
10 01 05 02 (CA,SNE, INT – direct research)							
Other budget lignes ( specify)							
<b>TOTAL (*)</b>		<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>

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



EUROPEAN  
COMMISSION

Brussels, 24.3.2014  
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ANNEXES 1 to 5

## **ANNEXES**

**to the**

**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}

## **ANNEX I**

### **OTHER PRODUCTS REFERRED TO IN ARTICLE 2(1)**

- yeasts used as food or feed,
- beer,
- maté,
- extracts, essences and concentrates of coffee, tea and maté and preparations with a basis of those products or with a basis of coffee, tea and maté; roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof,
- fruit nectars,
- cacao paste, butter, fat, oil and powder; chocolate, and other food preparations containing cocoa,
- sugar confectionery,
- preparations of cereals, flour, starch or milk; pastrycooks' products,
- soups,
- sauces,
- cooked meals,
- ice cream,
- flavoured yoghurts, yoghurts containing added fruits, nuts or cocoa,
- sea salt,
- natural gums and resins,
- pollen,
- beeswax,
- essential oils,
- spirit drinks, provided that the ethyl alcohol used for the production of the spirit drinks is exclusively of agricultural origin.

## **ANNEX II**

### **SPECIFIC PRODUCTION RULES REFERRED TO IN CHAPTER III**

#### **Part I: Plant production rules**

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

#### **1. General requirements**

- 1.1. Hydroponic production, which is a method of growing plants with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.
- 1.2. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.
- 1.3. Conversion
  - 1.3.1. For plants and plant products to be considered organic, the production rules laid down in this Regulation must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic production, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.
  - 1.3.2. The competent authority may decide, in the cases where the land has been contaminated with products not authorised for organic production, to extend the conversion period beyond the period referred to in point 1.3.1.
  - 1.3.3. In the case of treatment with a product not authorised for organic production, the competent authority shall require a new conversion period in accordance with point 1.3.1.

That period may be shortened in the following two cases:

- (a) treatment with a product not authorised for organic production as part of a compulsory control measure for pests or weeds, including quarantine organisms or invasive species, imposed by the competent authority of the Member State;
  - (b) treatment with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State.
- 1.3.4. In the cases referred to in points 1.3.2. and 1.3.3., the length of the conversion period shall be fixed taking into account the following factors:
  - (a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;
  - (b) the harvest following the treatment may not be sold with reference to organic production.
- 1.3.5. The specific conversion rules for land associated with organic livestock production should be as follows:
  - 1.3.5.1. The conversion rules shall apply to the whole area of the production unit on which animal feed is produced.

- 1.3.5.2. Notwithstanding point 1.3.5.1., the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.
- 1.4. Origin of plants including plant reproductive material
- 1.4.1. For the production of plants and plant products only organically produced plant reproductive material shall be used. To this end, the plant intended for plant reproductive material production and, where relevant, the mother plant shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.
- 1.4.2. Use of plant reproductive material not obtained from organic production
- Plant reproductive material not obtained from organic production may be used only when it comes from a production unit in conversion to organic production or where it is justified for use in research, test in small-scale field trials or for genetic resources conservation purposes agreed by the competent authority of the Member State.
- 1.5. Soil management and fertilisation
- 1.5.1. Organic plant production shall use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.
- 1.5.2. The fertility and biological activity of the soil shall be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production.
- 1.5.3. Where the nutritional needs of plants cannot be met by measures provided for in points 1.5.1. and 1.5.2. only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 19 may be used and only to the extent necessary.
- 1.5.4. The total amount of livestock manure, as defined in Council Directive 91/676/EEC<sup>1</sup>, applied on the agricultural holding, shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrements, including poultry manure, composted farmyard manure and liquid animal excrements.
- 1.5.5. Organic agricultural holdings may establish written cooperation agreements exclusively with other agricultural holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production. The maximum limit as referred to in point 1.5.4., shall be calculated on the basis of all of the organic production units involved in such cooperation.
- 1.5.6. Preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.
- 1.5.7. For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.

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

- 1.5.8. Mineral nitrogen fertilisers shall not be used.
- 1.6. Pest and weed management
- 1.6.1. The prevention of damage caused by pests and weeds shall rely primarily on the protection by:
- natural enemies,
  - the choice of species, varieties and heterogeneous material,
  - crop rotation,
  - cultivation techniques such as biofumigation, and
  - thermal processes such as solarisation and shallow steam treatment of the soil (to a maximum depth of 10 cm).
- 1.6.2. Where plants cannot be protected adequately from pests by measures provided for in point 1.6.1. or in the case of an established threat to a crop, only products authorised for use in organic production pursuant to Article 19 may be used and only to the extent necessary.
- 1.6.3. The traps or dispensers of products other than pheromones shall prevent the substances from being released into the environment and prevent contact between the substances and the crops being cultivated. The traps shall be collected after use and disposed of safely.
- 1.7. Products used for cleaning and disinfection
- With regard to cleaning and disinfection, only the products for cleaning and disinfection in plant production authorised for use in organic production pursuant to Article 19 shall be used.

## **2. Requirements for specific plants or plant products**

### **2.1. Rules on mushroom production**

For the production of mushrooms, substrates may be used, if they are composed only of the following components:

- (a) farmyard manure and animal excrements:
  - (i) either from agricultural holdings producing according to the organic production rules; or
  - (ii) referred to in point 1.5.3., only when the product referred to in point (i) is not available, provided that these farmyard manure and animal excrements do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;
- (b) products of agricultural origin, other than those referred to in point (a), from agricultural holdings producing according to the organic production rules;
- (c) peat not chemically treated;
- (d) wood, not treated with chemical products after felling;
- (e) mineral products referred to in point 1.5.3., water and soil.

### **2.2. Rules concerning the collection of wild plants**

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

- (a) those areas have not, for a period of at least three years before the collection, received treatment with products other than those authorised for use in organic production pursuant to Article 19;
- (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

## **Part II: Livestock production rules**

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

### **1. General requirements**

- 1.1. Where the farmer producing livestock does not manage agricultural land and has not established a written cooperation agreement with another farmer, landless livestock production shall be prohibited.
- 1.2. Conversion
  - 1.2.1. The conversion period shall start at the earliest when the farmer has notified his activity to the competent authorities and subjected his holding to the control system in accordance with this Regulation.
  - 1.2.2. Conversion periods specific to the type of animal production are set out in point 2.
  - 1.2.3. Animals and animal products produced during the conversion period shall not be marketed as organic.
  - 1.2.4. Animals and animal products may be considered organic at the end of the conversion period if there is simultaneous conversion of the complete production unit, including livestock, pasturage or any land used for animal feed.
- 1.3. Origin of animals
  - 1.3.1. Organic livestock shall be born and raised on organic agricultural holdings.
  - 1.3.2. Animals existing on the agricultural holding at the beginning of the conversion period and their products may be deemed organic after compliance with the applicable conversion period referred to in point 2.
  - 1.3.3. With regard to the breeding of organic animals:
    - (a) reproduction shall use natural methods; however, artificial insemination shall be allowed;
    - (b) reproduction shall not be induced by treatment with hormones or similar substances, unless as a form of veterinary therapeutic treatment in case of an individual animal;
    - (c) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;
    - (d) the choice of breeds shall be appropriate and shall contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals.
  - 1.3.4. In the choice of breeds or strains, account shall be taken of the capacity of animals to adapt to local conditions, without impairment of their welfare, their vitality and their

resistance to disease. In addition, breeds or strains of animals shall be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production, such as porcine stress syndrome, pale-soft-exudative (PSE) syndrome, sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference shall be given to indigenous breeds and strains.

- 1.3.5. For breeding purposes, non-organically raised animals may be brought onto an agricultural holding when breeds are in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006<sup>2</sup> and in that case animals of those breeds must not necessarily be nulliparous.

#### 1.4. Nutrition

##### 1.4.1. General nutrition requirements

With regard to nutrition the following rules shall apply:

- (a) feed for livestock shall be obtained primarily from the agricultural holding where the animals are kept or from other organic holdings in the same region;
- (b) livestock shall be fed with organic feed that meets the animal's nutritional requirements at the various stages of its development. Restricted feeding shall not be permitted in livestock production;
- (c) the keeping of livestock in conditions, or on a diet which may encourage anaemia, shall be prohibited;
- (d) fattening practices shall be reversible at any stage of the rearing process. Force-feeding is forbidden;
- (e) with the exception of bees, livestock shall have permanent access to pasture or roughage;
- (f) growth promoters and synthetic amino-acids shall not be used;
- (g) suckling animals shall be fed in preference on maternal milk for a minimum period;
- (h) feed materials of mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production pursuant to Article 19.

##### 1.4.2. Grazing of common land and transhumance

###### 1.4.2.1. Organic animals may be grazed on common land, provided that:

- (a) the common land is fully managed in accordance with this Regulation;
- (b) any non-organic animals which use the land concerned are derived from a production system equivalent to one of those provided for in Articles 28 and 30 of Regulation (EU) No 1305/2013<sup>3</sup>;

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<sup>2</sup> Commission Regulation (EC) No 1974/2006 of 15 December 2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 368, 23.12.2006, p. 15).

<sup>3</sup> Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

- (c) any livestock products from organic animals, whilst using this land, is not regarded as being from organic production, unless adequate segregation from non-organic animals can be proved.
- 1.4.2.2. During the period of transhumance animals may graze on non-organic land when they are being moved on foot from one grazing area to another. The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, shall be allowed for a maximum of 35 days covering both the outward and return journeys.
- 1.4.3. In-conversion feed
  - 1.4.3.1. For in-conversion agricultural holdings, up to 15 % of the total average amount of feed fed to livestock may originate from the grazing or harvesting of permanent pastures, perennial forage parcels or protein crops, sown under organic management on lands in their first year of conversion, provided that they are part of the holding itself. Feed in their first year of conversion may not be used for the production of organic processed feed. When both in-conversion feed and feed from parcels in their first year of conversion are being used, the total combined percentage of such feed shall not exceed the maximum percentages fixed in point 1.4.3.2.
  - 1.4.3.2. For organic agricultural holdings, up to 20 % on average of the feed formula of rations may comprise in-conversion feed, namely feed from the second year of conversion. For in-conversion agricultural holdings, when the in-conversion feed come from the holding itself, this percentage may be increased to 100.
  - 1.4.3.3. The figures in points 1.4.3.1. and 1.4.3.2. shall be calculated annually as a percentage of the dry matter of feed of plant origin.
- 1.4.4. Use of certain feed materials and substances in feed
 

Only organic feed materials of animal origin as well as feed materials and feed additives authorised for use in organic production pursuant to Article 19 may be used in the processing of organic feed and in the feeding of organic animals.
- 1.5. Health care
  - 1.5.1. Disease prevention
    - 1.5.1.1. Disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions.
    - 1.5.1.2. The use of immunological veterinary medicinal products shall be allowed.
    - 1.5.1.3. The use of chemically synthesised allopathic veterinary medicinal products or antibiotics for preventive treatment shall be prohibited.
    - 1.5.1.4. The use of substances to promote growth or production (including antibiotics, coccidiostats and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction or for other purposes (e.g. induction or synchronisation of oestrus), shall be prohibited.
    - 1.5.1.5. Where livestock is obtained from non-organic units, special measures such as screening tests or quarantine periods shall apply, depending on local circumstances.

- 1.5.1.6. With regard to cleaning and disinfection, only the products for cleaning and disinfection in livestock buildings and installations authorised for use in organic production pursuant to Article 19 shall be used.
- 1.5.1.7. Housing, pens, equipment and utensils shall be properly cleaned and disinfected to prevent cross-infection and the build-up of disease carrying organisms. Faeces, urine and uneaten or spilt feed shall be removed as often as necessary to minimise smell and to avoid attracting insects or rodents. Rodenticides (to be used only in traps), and the products authorised for use in organic production pursuant to Article 19 may be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.
- 1.5.2. Veterinary treatment
  - 1.5.2.1. Where despite preventive measures to ensure animal health animals become sick or injured they shall be treated immediately.
  - 1.5.2.2. Disease shall be treated immediately to avoid suffering of the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.
  - 1.5.2.3. Feed materials of mineral origin and nutritional additives authorised for use in organic production pursuant to Article 19 and phytotherapeutic and homeopathic products shall be used in preference to chemically-synthesised allopathic veterinary treatment including antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.
  - 1.5.2.4. With the exception of vaccinations, treatments for parasites and compulsory eradication schemes where an animal or group of animals receive more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products including antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year, the livestock concerned, or produce derived from them, shall not be sold as organic products, and the livestock shall undergo the conversion periods referred to in points 1.2 and 2.
  - 1.5.2.5. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to be twice the withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours.
  - 1.5.2.6. Treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed.
- 1.6. Housing conditions and husbandry practices
  - 1.6.1. Insulation, heating and ventilation of the building shall ensure that air circulation, dust level, temperature, relative air humidity and gas concentration, are kept within limits which ensure the well-being of the animals. The building shall permit plentiful natural ventilation and light to enter.
  - 1.6.2. Housing for livestock shall not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors. Livestock shall have permanent access

to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this, unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Union legislation. Animals shall have access to shelters or shady areas to protect them from adverse weather conditions.

- 1.6.3. The stocking density in buildings shall provide for the comfort, the well-being and the species-specific needs of the animals which, in particular, shall depend on the species, the breed and the age of the animals. It shall also take account of the behavioural needs of the animals, which depend in particular on the size of the group and the animals' sex. The density shall ensure the animals' welfare by providing them with sufficient space to stand naturally, move, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.
- 1.6.4. The minimum surface for indoor and outdoor areas, and other characteristics of housing for different species and categories of animals, shall be as set out in points 2.1.4., 2.2.4., 2.3.4. and 2.4.5.
- 1.6.5. Open air areas may be partially covered. Verandas shall not be considered as open air areas.
- 1.6.6. The total stocking density shall not exceed the limit of 170 kg of organic nitrogen per year and hectare of agricultural area.
- 1.6.7. To determine the appropriate density of livestock referred to in point 1.6.6, the competent authority shall set out the livestock units equivalent to the limit referred to in point 1.6.6., following the figures laid down in each of the specific requirement by animal production.
- 1.7. Animal welfare
  - 1.7.1. All persons involved in keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals.
  - 1.7.2. Husbandry practices, including stocking densities and housing conditions shall ensure that the developmental, physiological and ethological needs of animals are met.
  - 1.7.3. The livestock shall have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Union legislation.
  - 1.7.4. The number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure.
  - 1.7.5. Where Article 8(5) and point 1.4.2.2. of this Part apply, organic livestock shall be kept separate from other livestock.
  - 1.7.6. Tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time, and in so far as this is justified for veterinary reasons. Competent authorities may authorise cattle in micro-enterprises to be tethered if it is not possible to keep the cattle in groups appropriate to their behaviour requirements,

provided they have access to pastures during the grazing period, and at least twice a week access to open air areas when grazing is not possible.

- 1.7.7. Duration of transport of livestock shall be minimised.
- 1.7.8. Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.
- 1.7.9. Mutilation of animals shall be prohibited.
- 1.7.10. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out the operation only at the most appropriate age by qualified personnel.
- 1.7.11. Physical castration shall be allowed in order to maintain the quality of products and traditional production practices but only under adequate anaesthesia or analgesia and by carrying out the operation only at the most appropriate age by qualified personnel.
- 1.7.12. Loading and unloading of animals shall be carried out without the use of any type of electrical stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, shall be prohibited.

## **2. Requirements for specific livestock species**

### **2.1. Production of bovine, ovine and caprine animals**

#### **2.1.1. Conversion**

For bovine, ovine and caprine animals and their products to be considered organic, the production rules set out in this Regulation must have been applied for at least:

- (a) 12 months in the case of bovines animals for meat production, and in any case at least three quarters of their lifetime;
- (b) six months in the case of ovine and caprine animals and of animals for milk production.

#### **2.1.2. Nutrition**

With regard to nutrition the following rules shall apply:

- (a) bovine, ovine and caprine animals shall have access to pasturage for grazing whenever conditions allow;
- (b) notwithstanding point (a), male bovine animals over one year old shall have access to pasturage or an open air area;
- (c) in cases where bovine, ovine and caprine animals have access to pasturage during the grazing period and where the winter- housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived;
- (d) except during the period each year when the animals are under transhumance referred to in point 1.4.2.2., at least 90 % of the feed shall come from the farm itself or in case this is not feasible, be produced in cooperation with other organic farms in the same region;
- (e) rearing systems for bovine, ovine and caprine animals shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations

of bovine, ovine and caprine animals shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation shall be allowed;

- (f) all suckling bovine, ovine and caprine animals shall be fed in preference on maternal milk for a minimum period of three months for bovine animals and 45 days for ovine and caprine animals.

### 2.1.3. Specific housing conditions

With regard to the housing conditions the following rules shall apply:

- (a) housing of bovine, ovine and caprine animals shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in the table on minimum surface areas for bovine, ovine and caprine animals set out in point 2.1.4., shall be solid, that is, not of slatted or of grid construction;
- (b) the housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;
- (c) notwithstanding point (a) of the first subparagraph of Article 3(1) and the second subparagraph of Article 3(1) of Council Directive 2008/119/EC<sup>4</sup>, the housing of calves in individual boxes shall be forbidden after the age of one week, unless for individual animals for a limited period of time, and in so far as this is justified for veterinary reasons.

### 2.1.4. Stocking density

The number of bovine, ovine and caprine animals per hectare shall respect the following limits:

<b>Class or species</b>	<b>Maximum number of animals per ha equivalent to 170 kg N/ha/year</b>
Calves for fattening	5
Other bovine animals less than one year old	5
Male bovine animals from one to less than two years old	3,3
Female bovine animals from one to less than two years old	3,3
Male bovine animals two years old or over	2
Breeding heifers	2,5
Heifers for fattening	2,5

<sup>4</sup> Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).

Dairy cows	2
Cull dairy cows	2
Other cows	2,5
Goats	13,3
Ewes	13,3

The minimum surface areas indoors and outdoors and other characteristics of housing of bovine, ovine, and caprine animals shall be as follows:

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Breeding and fattening bovine animals	up to 100	1,5	1,1
	up to 200	2,5	1,9
	up to 350	4,0	3
	over 350	5 with a minimum of 1 m <sup>2</sup> /100 kg	3,7 with a minimum of 0,75 m <sup>2</sup> /100 kg
Dairy cows		6	4,5
Bulls for breeding		10	30
Ovine and caprine animals		1,5 sheep/goat	2,5
		0,35 lamb/kid	2,5 with 0,5 per lamb/kid

## 2.2. Production of equine animals

### 2.2.1. Conversion

For equine animals and their products to be considered organic, the production rules of this Regulation must have been applied for at least:

- (a) 12 months, for meat production, and in any case at least three quarters of their lifetime;
- (b) six months in the case of animals for milk production.

### 2.2.2. Nutrition

With regard to nutrition the following rules shall apply:

- (a) equine animals shall have access to pasturage for grazing whenever conditions allow;
- (b) in cases where equine animals have access to pasturage during the grazing period and where the winter-housing system gives freedom of movement to the

animals, the obligation to provide open air areas during the winter months may be waived;

- (c) except during the period each year when the animals are under transhumance as mentioned in point 1.4.2.2., at least 90 % of the feed shall come from the farm itself or in case this is not feasible, be produced in cooperation with other organic farms in the same region;
- (d) rearing systems for equine animals shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations of equine animals shall consist of roughage, fresh or dried fodder, or silage;
- (e) all suckling equine animals shall be fed in preference on maternal milk, for a minimum period of three months.

### 2.2.3. Specific housing conditions

With regard to the housing conditions the following rules shall apply:

- (a) housing of equine animals shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in the table on minimum surface areas for equine animals set out in point 2.2.4., shall be solid, that is, not of slatted or of grid construction;
- (b) the housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19.

### 2.2.4. Stocking density

The number of equine animals per hectare shall respect the following limit:

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Equine animals over six months old	2

The minimum surface areas indoors and outdoors and other characteristics of housing equine animals shall be as follows:

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Breeding and fattening equine animals	up to 100	1,5	1,1
	up to 200	2,5	1,9
	up to 350	4,0	3

	over 350	5 with a minimum of 1 m <sup>2</sup> /100 kg	3,7 with a minimum of 0,75 m <sup>2</sup> /100 kg
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## 2.3. Production of porcine animals

### 2.3.1. Conversion

For porcine animals and their products to be considered organic, the production rules of this Regulation must have been applied for at least six months.

### 2.3.2. Nutrition

With regard to nutrition the following rules shall apply:

- (a) at least 60 % of the feed shall come from the farm itself or in case this is not feasible, be produced in the same region in cooperation with other organic farms or feed operators;
- (b) all suckling porcine animals shall be fed in preference on maternal milk, for a minimum period of 40 days;
- (c) roughage, fresh or dried fodder, or silage shall be added to the daily ration for pigs.

### 2.3.3. Specific housing conditions

With regard to the housing conditions the following rules shall apply:

- (a) housing of porcine animals shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in the table on minimum surface areas for porcine animals set out in point 2.3.4., shall be solid, that is, not of slatted or of grid construction;
- (b) the housing of porcine animals shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;
- (c) sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period;
- (d) piglets shall not be kept on flat decks or in piglet cages;
- (e) exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

### 2.3.4. Stocking density

The number of porcine animals per hectare shall respect the following limits:

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Piglets	74
Breeding sows	6,5

Porcine animals for fattening	14
Other porcine animals	14

The minimum surface areas indoors and outdoors and other characteristics for housing porcine animals shall be as follows:

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Farrowing sows with piglets up to 40 days		7,5 sow	2,5
Fattening porcine animals	up to 50	0,8	0,6
	up to 85	1,1	0,8
	up to 110	1,3	1
Piglets	over 40 days and up to 30 kg	0,6	0,4
Brood porcine animals		2,5 female	1,9
		6 male  If pens are used for natural service: 10 m <sup>2</sup> /boar	8,0

## 2.4. Production of poultry

### 2.4.1. Conversion

For poultry and their products to be considered organic, the production rules of this Regulation must have been applied for at least:

- (a) 10 weeks for poultry for meat production, brought in before they are three days old;
- (b) six weeks in the case of poultry for egg production.

### 2.4.2. Origin of poultry

Poultry shall either be reared until they reach a minimum age or else shall come from slow-growing poultry strains as defined by the competent authority. Where slow-growing poultry strains are not used by the farmer the minimum age at slaughter shall be as follows:

- (a) 81 days for chickens;
- (b) 150 days for capons;
- (c) 49 days for Peking ducks;

- (d) 70 days for female Muscovy ducks;
- (e) 84 days for male Muscovy ducks;
- (f) 92 days for Mallard ducks;
- (g) 94 days for guinea fowl;
- (h) 140 days for male turkeys and roasting geese; and
- (i) 100 days for female turkeys.

#### 2.4.3. Nutrition

With regard to nutrition the following rules shall apply:

- (a) at least 60 % of the feed shall come from the farm itself or in case this is not feasible, be produced in the same region in cooperation with other organic farms or feed operators;
- (b) roughage, fresh or dried fodder, or silage shall be added to the daily ration.

#### 2.4.4. Specific housing conditions

With regard to the housing conditions the following rules shall apply:

- (a) poultry shall not be kept in cages;
- (b) water fowl shall have access to a stream, pond, lake or a pool whenever the weather and hygienic conditions permit in order to respect their species-specific needs and animal welfare requirements; when weather conditions do not permit, they shall have access to water which enables them to dip their head therein so as to clean plumage;
- (c) poultry shall have access to an open air area for at least one third of their life. Open air areas for poultry shall be mainly covered with vegetation and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking troughs;
- (d) where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs;
- (e) buildings for all poultry shall meet the following conditions:
  - (i) at least one third of the floor area shall be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;
  - (ii) in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens shall be available for the collection of bird droppings;
  - (iii) poultry shall have perches of a size and number commensurate with the size of the group and of the birds as laid down in the table on the minimum surface areas indoors and outdoors and other characteristics of housing for poultry production set out in point 2.4.5.;
  - (iv) the external boundary of the house, i.e. including a possible veranda, shall have exit/entry pop-holes of a size adequate for the birds, and those

pop-holes shall have a combined length of at least 4 m per 100 m<sup>2</sup> area of the house available to the birds. Where a veranda is present, the internal pop-holes between the house and the veranda shall have a combined length of 2 m per 100 m<sup>2</sup> area of the house. Twenty-four hour access to the veranda must be allowed;

- (v) poultry houses shall be constructed in a manner allowing all birds easy access to open air area, i.e. the maximum distance from any point within the house to the nearest external pop-hole shall not be more than 15 m;
- (vi) multi-layer systems shall have no more than three levels of usable area including the ground floor. There shall be no more than 1 m between levels or intermediate areas, such as nesting areas. Higher tiers shall be capable of having manure removed by an automated system;
- (f) natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours;
- (g) buildings shall be emptied of livestock between each batch of poultry reared. The buildings and fittings shall be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs shall be left empty during a period to be established by the Member States in order to allow vegetation to grow back. These requirements shall not apply where poultry are not reared in batches, are not kept in runs and are free to roam, throughout the day.

#### 2.4.5. Stocking density

The maximum number of animals per hectare shall respect the following limits:

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Broilers	580
Laying hens	230

The minimum surface area indoors and outdoors and other characteristics of housing for birds of the species *Gallus gallus* shall be as follows:

	<i>Breeders/ parents</i>	<i>Young stock</i>		<i>Fattening birds</i>		<i>Capons</i>	<i>Layers</i>
Age	Breeding birds	Pullets 0-8 weeks	Pullets 9-18 weeks	Starter 0-21 days	Finisher 22 to 81 days	22-150 days	Laying hens from 19 weeks
In house stocking rate (birds per m <sup>2</sup> of usable area) for fixed and	6 birds	24 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	15 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	20 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	10 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	10 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	6 birds

mobile houses							
Perch space (cm)							18
Multi-layer systems additional limits/m <sup>2</sup> of ground floor area (including veranda if 24h access)	9 birds	36 birds excluding veranda area	22 birds	Not normally applicable			9 birds
Flock size limits	3,000 including males	10,000*	3,300	10,000*	4,800	2,500	3,000
Open-air run stocking rates (m <sup>2</sup> /bird), provided that the limit of 170 kg of N/ha/year is not exceeded	4	1	4	1	4	4	4

\* sub-dividable to produce 3x3000 or 2x4800 batches

The minimum surface areas indoors and outdoors and other characteristics of housing for birds of species other than *Gallus gallus* shall be as follows:

	<i>Turkeys</i>		<i>Geese</i>	<i>Ducks</i>				<i>Guinea fowl</i>
Type	Male	Female	All	Peking	Male Muscovy	Female Muscovy	Mallard	All
In house stocking rate (birds per m <sup>2</sup> of usable area) for fixed and mobile houses	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>
Perch space (cm)	40	40	Not normally applicable	Not normally applicable	40	40	Not normally applicable	20

			e	e					
Flock limits	size	2,500	2,500	2,500	4,000 females 3,200 males	3,200	4,000	3,200	5,200
Open stocking provided that the limit of 170 kg of N/ha/year is not exceeded	air rate (m <sup>2</sup> /bird)	10	10	15	4.5	4.5	4.5	4.5	4

#### 2.4.6. Access to open air areas

With regard to access to open air areas the following rules shall apply:

- (a) poultry shall have access to an open air area for at least one third of their life. In particular, continuous daytime open air access shall be provided from as early an age as practically possible, whenever physiological and physical conditions allow, except in the case of temporary restrictions imposed on the basis of Union legislation;
- (b) open air areas for poultry shall be mainly covered with vegetation composed of a diverse range of plants and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking troughs. The vegetation on the open-air area must be harvested and removed at regular intervals to reduce the potential for nutrient surpluses. The open air areas shall not extend beyond a radius of 150 m from the nearest pop-hole of the poultry house. However an extension of up to 350 m from the nearest pop-hole of the poultry house is permissible provided that a sufficient number of shelters and drinking troughs are evenly distributed throughout the whole open-air area with at least four shelters per hectare;
- (c) under conditions where feed availability from the range area is limited, due for instance to long term snow cover or arid weather conditions, supplementary feeding of roughage must be included as part of poultry diets;
- (d) where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs.

#### 2.4.7. Animal welfare

Live plucking of poultry shall be prohibited.

### 2.5. Beekeeping

#### 2.5.1. Conversion

Beekeeping products may be sold with references to organic production only when the organic production rules set out in this Regulation have been complied with for at least one year.

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

2.5.2. Origin of bees

Preference shall be given to the use of *Apis mellifera* and their local ecotypes.

2.5.3. Nutrition

With regard to nutrition the following rules shall apply:

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

2.5.4. Specific rules on disease prevention and veterinary treatment in beekeeping

With regard to disease prevention and veterinary treatment the following rules shall apply:

- (a) for the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides (to be used only in traps), and appropriate products authorised for use in organic production pursuant to Article 19 shall be permitted;
- (b) physical treatments for disinfection of apiaries such as steam or direct flame shall be permitted;
- (c) the practice of destroying the male brood shall be permitted only to isolate the infestation of *Varroa destructor*;
- (d) if despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, the colonies may be placed in isolation apiaries;
- (e) formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with *Varroa destructor*;
- (f) if a treatment is applied with chemically synthesised allopathic products, during such a period, the colonies treated shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of one year laid down in point 2.5.1. shall apply to those colonies;
- (g) point (f) shall not apply to products authorised for use in organic production pursuant to Article 19.

2.5.5. Specific housing conditions in beekeeping

With regard to the housing conditions the following rules shall apply:

- (a) apiaries shall be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods;

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

#### 2.5.6. Specific rules on practices in beekeeping

With regard to beekeeping practices the following rules shall apply:

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

#### 2.5.7. Animal welfare

With regard to animal welfare the following rules shall apply:

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

### **Part III: Production rules for seaweed and aquaculture animals**

#### **1. Definitions**

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

- (1) ‘closed recirculation aquaculture facility’ means a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the recirculation of water, and depending on permanent external energy input to stabilise the environment for the aquaculture animals;
- (2) ‘energy from renewable sources’ means renewable non-fossil energy sources such as wind, solar, geothermal wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;
- (3) ‘hatchery’ means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;

- (4) 'nursery' means a place where an intermediate production system is applied between the hatchery and grow-out stages. The nursery stage is completed within the first third of the production cycle with the exception of species undergoing a smoltification process;
- (5) 'pollution' means the direct or indirect introduction into the aquatic environment of substances or energy as defined in Directive 2000/60/EC of the European Parliament and of the Council<sup>5</sup> and in Directive 2008/56/EC of the European Parliament and of the Council<sup>6</sup>, in the waters to which those Directives apply, respectively;
- (6) 'polyculture' means the rearing of two or more species usually from different trophic levels in the same culture unit;
- (7) 'production cycle' means the lifespan of an aquaculture animal or seaweed from the earliest life stage (fertilised eggs in the case of aquaculture animals) to harvesting;
- (8) 'locally grown species' means species which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007<sup>7</sup>, as well as the species listed in Annex IV to that Regulation;
- (9) 'stocking density' means the live weight of aquaculture animals per cubic metre of water at any time during the grow-out phase and in the case of flatfish and shrimp the weight per square metre of surface.

## 2. General requirements

- 2.1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for use in organic production, or pollutants that would compromise the organic nature of the products.
- 2.2. Organic and non-organic production units shall be separated adequately and in accordance with the minimum separation distances set by Member States, where such minimum separation distances have been set. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Seaweed production shall not be considered as organic when practiced at locations or in areas designated by Member State authorities as locations or areas which are unsuitable for organic aquaculture or seaweed harvesting.
- 2.3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control authority or control body. The content of the environmental assessment shall be based on Annex IV to

<sup>5</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

<sup>6</sup> Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

<sup>7</sup> Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture (OJ L 168, 28.6.2007, p. 1).

Directive 2011/92/EU of the European Parliament and of the Council<sup>8</sup>. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.

- 2.4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting.
- 2.5. The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.
- 2.6. Aquaculture and seaweed business operators shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

### **3. Requirements for seaweed**

In addition to the general production rules laid down in Articles 7, 8, 9 and 12, and where relevant in Section 2, the rules laid down in this Section 3 shall apply to the collection and production of seaweed. Those rules shall apply *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

- 3.1. Conversion
  - 3.1.1. The conversion period for a seaweed harvesting site shall be six months.
  - 3.1.2. The conversion period for a seaweed cultivation unit shall be a period of six months or one full production cycle, whichever is the longer.
  - 3.1.3. During the conversion period, the aquaculture holding may be split into clearly separated units which are not all managed under organic production. As regards seaweed production, the same species may be involved, provided that there is adequate separation between the units.
- 3.2. Production rules for seaweed
  - 3.2.1. The collection of wild seaweeds and parts thereof, growing naturally in the sea, is considered as organic production provided that:
    - (a) the growing areas are of high ecological status as defined by Directive 2000/60/EC<sup>9</sup>, and are not unsuitable from a health point of view.
    - (b) the collection does not affect significantly the stability of the natural ecosystem or the maintenance of the species in the collection area.

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<sup>8</sup> Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

<sup>9</sup> Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the quality required of shellfish waters (OJ L 376, 27.12.2006, p. 14).

- 3.2.2. The cultivation of seaweeds shall take place in coastal areas with environmental and health characteristics at least equivalent to those outlined in point 3.2.1(a) in order to be considered organic. In addition the following production rules shall apply:
- (a) sustainable practices shall be used in all stages of production, from collection of juvenile seaweed to harvesting;
  - (b) to ensure that a wide gene-pool is maintained, the collection of juvenile seaweed in the wild shall take place on a regular basis to supplement indoor culture stock;
  - (c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose.
- 3.3. Seaweed cultivation
- 3.3.1. Seaweed culture at sea shall only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal production, preferably located nearby as part of a polyculture system.
- 3.3.2. In facilities on land where external nutrient sources are used, the nutrient levels in the effluent water shall be verifiably the same, or lower, than the inflowing water. Only nutrients of plant or mineral origin authorised for use in organic production pursuant to Article 19 may be used.
- 3.3.3. Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.
- 3.3.4. Ropes and other equipment used for growing seaweed shall be re-used or recycled where possible.
- 3.4. Sustainable harvesting of wild seaweed
- 3.4.1. A once-off biomass estimate shall be undertaken at the outset of seaweed harvesting
- 3.4.2. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with this Regulation.
- 3.4.3. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate and by-catches are prevented, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.
- 3.4.4. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.

#### **4. Requirements for aquaculture animals**

In addition to the general production rules laid down in Article 7, 8, 9 and 12, the rules laid down in this Section 4 shall apply to species of fish, crustaceans, echinoderms and molluscs, as referred to in point 4.1.5.10. Those rules also shall apply *mutatis mutandis* to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

- 4.1. General requirements

#### 4.1.1. Conversion

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

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

4.1.1.2. During the conversion period, the aquaculture holding may be split into clearly separated units which are not all managed under organic production. As regards the production of aquaculture animals, the same species may be involved provided that there is adequate separation between the units.

#### 4.1.2. Origin of aquaculture animals

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

- (a) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and organic holdings;
- (b) locally grown species shall be used and breeding shall aim to give strains which are more adapted to production conditions, ensuring good animal health and welfare and good utilisation of feed resources. Documentary evidence of their origin and treatment shall be provided for the control authority or control body;
- (c) species shall be chosen which are robust and can be produced without causing significant damage to wild stocks;
- (d) wild caught or non-organic aquaculture animals may be brought into a holding with a view to improving genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding.

4.1.2.2. The following rules shall apply with regard to breeding:

- (a) the use of hormones and hormone derivatives shall be prohibited;
- (b) artificial production of monosex strains, except by hand sorting, induction of polyploidy, artificial hybridisation and cloning shall not be used;
- (c) the appropriate strains shall be chosen;
- (d) where appropriate, species-specific conditions for broodstock management, breeding and juvenile production shall be established.

#### 4.1.3. Nutrition

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

- (a) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
  - (b) feeding regimes shall be designed with the following priorities:
    - (i) animal health and welfare;
    - (ii) high product quality, including the nutritional composition which shall ensure high quality of the final edible product;
    - (iii) low environmental impact;
  - (c) the plant fraction of feed shall originate from organic production and the feed fraction derived from aquatic animals shall originate from organic aquaculture or sustainable exploitation of fisheries;
  - (d) in the case of non-organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under this Regulation;
  - (e) growth promoters and synthetic amino-acids shall not be used;
  - (f) only feed materials of mineral origin authorised for use in organic production pursuant to Article 19 may be used in organic aquaculture;
  - (g) only feed additives, certain products used in animal nutrition and processing aids as referred to in point 1.4.4. of Part II may be used in organic aquaculture.
- 4.1.3.2. The following rules shall apply with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:
- (a) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;
  - (b) the growing areas shall be of high ecological status as defined by Directive 2000/60/EC.
- 4.1.3.3. Specific rules on feed for carnivorous aquaculture animals
- Feed for carnivorous aquaculture animals shall be sourced with the following priorities:
- (a) organic feed of aquaculture origin;
  - (b) fish meal and fish oil from organic aquaculture trimmings sourced from fish, crustaceans or molluscs;
  - (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish, crustaceans or molluscs already caught for human consumption in sustainable fisheries;
  - (d) fish meal and fish oil and ingredients of fish origin derived from whole fish, crustaceans or molluscs caught in sustainable fisheries and not used for human consumption;
  - (e) organic feed materials of plant or animal origin; plant material shall not exceed 60% of total ingredients.
- 4.1.3.4. Specific rules on feed for certain aquaculture animals

Fish in inland waters, penaeid shrimps and freshwater prawns and tropical freshwater fish shall be fed as follows:

- (a) they shall be fed with feed naturally available in ponds and lakes;
- (b) where natural feed is not available in sufficient quantities as referred to in point (a), organic feed of plant origin, preferably grown on the farm itself or seaweed may be used. Operators shall keep documentary evidence of the need to use additional feed;
- (c) where natural feed is supplemented in accordance with point (b) the feed ration of species as referred to in point 4.1.5.10. (g) and of siamese catfish (*Pangasius* spp.) may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.

#### 4.1.4. Health care

##### 4.1.4.1. Disease prevention

With regard to disease prevention the following rules shall apply:

- (a) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, taking into account, *inter alia*, the species' requirements as to good water quality, flow and exchange rate, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;
- (b) the use of immunological veterinary medicines is allowed;
- (c) an animal health management plan shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal health services who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish;
- (d) holding systems, equipment and utensils shall be properly cleaned and disinfected;
- (e) bio-fouling organisms shall be removed only by physical means or by hand and where appropriate returned to the sea at a distance from the farm;
- (f) only substances for cleaning and disinfection of equipment and facilities authorised for use in organic production pursuant to Article 19 may be used.
- (g) with regard to fallowing the following rules shall apply:
  - (i) the competent authority shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea;
  - (ii) it shall not be mandatory for bivalve mollusc cultivation;
  - (iii) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again;
- (h) where appropriate, uneaten fish-feed, faeces and dead animals shall be removed promptly to avoid any risk of significant environmental damage as

regards water status quality, minimise disease risks, and to avoid attracting insects or rodents;

- (i) ultraviolet light and ozone may be used only in hatcheries and nurseries;
- (j) for biological control of ectoparasites preference shall be given to the use of cleaner fish.

#### 4.1.4.2. Veterinary treatments

The following rules shall apply with regard to veterinary treatments:

- (a) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. Where appropriate, restrictions with respect to courses of treatment and withdrawal periods shall be defined;
- (b) treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed;
- (c) when despite preventive measures to ensure animal health, according to point 4.1.4.1., a health problem arises, veterinary treatments may be used in the following order of preference:
  - (i) substances from plants, animals or minerals in a homoeopathic dilution;
  - (ii) plants and their extracts not having anaesthetic effects; and
  - (iii) substances such as trace elements, metals, natural immunostimulants or authorised probiotics;
- (d) the use of allopathic treatments shall be limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of a production cycle of less than a year a limit of one allopathic treatment applies. If the indicated limits for allopathic treatments are exceeded the aquaculture animals concerned shall not be sold as organic products;
- (e) the use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months;
- (f) the withdrawal period for allopathic veterinary treatments and parasite treatments in accordance with point (d), including treatments under compulsory control and eradication schemes, shall be twice the withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours;
- (g) whenever veterinary medicinal products are used, such use shall be declared to the control authority or the control body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

#### 4.1.5. Housing conditions and husbandry practices

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

- 4.1.5.2. Artificial heating or cooling of water shall only be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.
- 4.1.5.3. The husbandry environment of the aquaculture animals shall be designed in such a way that, in accordance with their species specific needs, the aquaculture animals shall:
- (a) have sufficient space for their wellbeing and, where appropriate, a minimum stocking density;
  - (b) be kept in water of good quality with, *inter alia*, an adequate flow and exchange rate, sufficient oxygen levels and keeping a low level of metabolites;
  - (c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location.
- In the case of freshwater fish, the bottom type shall be as close as possible to natural conditions.
- In the case of carp, the bottom shall be natural earth.
- 4.1.5.4. The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.
- 4.1.5.5. Rearing units on land shall meet the following conditions:
- (a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;
  - (b) at least five percent of the perimeter ("land-water interface") area shall have natural vegetation.
- 4.1.5.6. Containment systems at sea shall meet the following conditions:
- (a) they shall be located where water flow, depth and water-body exchange rates are adequate to minimise the impact on the seabed and the surrounding water body;
  - (b) they shall have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.
- 4.1.5.7. Containment systems shall be designed, located and operated to minimise the risk of escape incidents.
- 4.1.5.8. If fish or crustaceans escape, appropriate action shall be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained.
- 4.1.5.9. For aquaculture animal production in fishponds, tanks or raceways, farms shall be equipped with either natural-filter beds, settlement ponds, biological filters or mechanical filters to collect waste nutrients or use seaweeds or animals (bivalves and algae) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.
- 4.1.5.10. Stocking density

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

The stocking density shall be as set out by species or group of species:

(a) Organic production of salmonids in fresh water:

Species concerned: brown trout (*Salmo trutta*) – rainbow trout (*Oncorhynchus mykiss*) – American brook trout (*Salvelinus fontinalis*) – salmon (*Salmo salar*) – charr (*Salvelinus alpinus*) – grayling (*Thymallus thymallus*) – American lake trout (or grey trout) (*Salvelinus namaycush*) – huchen (*Huchohucho*)

Production system	Ongrowing farm systems must be fed from open systems. The flow rate must ensure a minimum of 60 % oxygen saturation for stock and must ensure their comfort and the elimination of production effluent.
Maximum stocking density	Salmonid species not listed below 15 kg/m <sup>3</sup> Salmon 20 kg/m <sup>3</sup> Brown trout and Rainbow trout 25 kg/m <sup>3</sup> Arctic charr 20 kg/m <sup>3</sup>

(b) Organic production of salmonids in sea water:

Species concerned: salmon (*Salmo salar*), brown trout (*Salmo trutta*) - rainbow trout (*Oncorhynchus mykiss*)

Maximum stocking density	10 kg/m <sup>3</sup> in net pens
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(c) Organic production of cod (*Gadus morhua*) and other Gadidae, sea bass (*Dicentrarchus labrax*), sea bream (*Sparus aurata*), meagre (*Argyrosomus regius*), turbot (*Psetta maxima* [= *Scophthalmus maximus*]), red porgy (*Pagrus pagrus* [= *Sparus pagrus*]), red drum (*Sciaenops ocellatus*) and other Sparidae, and spinefeet (*Siganus spp.*)

Production system	In open water containment systems (net pens/cages) with minimum sea current speed to provide optimum fish welfare or in open systems on land.
Maximum stocking density	For fish other than turbot: 15 kg/m <sup>3</sup> For turbot: 25 kg/m <sup>2</sup>

(d) Organic production of sea bass, sea bream, meagre, mullets (*Liza*, *Mugil*) and eel (*Anguilla spp.*) in earth ponds of tidal areas and costal lagoons

Containment system	Traditional salt pans transformed into aquaculture production units and similar earth ponds in tidal areas
Production system	There shall be adequate renewal of water to ensure the welfare of the species,  At least 50 % of the dikes must have plant cover

	Wetland based depuration ponds required
Maximum stocking density	4 kg/m <sup>3</sup>

(e) Organic production of sturgeon in fresh water:

Species concerned: Sturgeon family (*Acipenseridae*)

Production system	Water flow in each rearing unit shall be sufficient to ensure animal welfare  Effluent water to be of equivalent quality to incoming water
Maximum stocking density	30 kg/m <sup>3</sup>

(f) Organic production of fish in inland waters:

Species concerned: carp family (*Cyprinidae*) and other associated species in the context of polyculture, including perch, pike, catfish, coregonids, sturgeon

Production system	<p>In fishponds which shall periodically be fully drained and in lakes. Lakes must be devoted exclusively to organic production, including the growing of crops on dry areas.</p> <p>The fishery capture area must be equipped with a clean water inlet and of a size to provide optimal comfort for the fish. The fish must be stored in clean water after harvest.</p> <p>Organic and mineral fertilisation of the ponds and lakes shall be carried out with only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 19 with a maximum application of 20 kg nitrogen/ha.</p> <p>Treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters shall be prohibited.</p> <p>Areas of natural vegetation shall be maintained around inland water units as a buffer zone for external land areas not involved in the production operation in accordance with the rules of organic aquaculture.</p> <p>For grow-out 'polyculture' shall be used on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.</p>
Production yield	The total production of species is limited to 1500 kg of fish per hectare per year.

- (g) Organic production of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.):

Establishment of production unit/s	Location to be in sterile clay areas to minimise environmental impact of pond construction. Ponds to be built with the natural pre-existing clay. Mangrove destruction shall not be permitted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a produced shrimp.
Broodstock origin	A minimum of half the broodstock shall be domesticated after three years operating. The remainder is to be pathogen free wild broodstock originating from sustainable fisheries. A compulsory screening to be implemented on the first and second generation prior to introducing to the farm.
Eyestalk ablation	Is prohibited.
Maximum on farm stocking densities and production limits	Seeding: maximum 22 post larvae/m <sup>2</sup> Maximum instantaneous biomass: 240 g/m <sup>2</sup>

- (h) Molluscs and echinoderms:

Production systems	Long-lines, rafts, bottom culture, net bags, cages, trays, lantern nets, bouchot poles and other containment systems.  For mussel cultivation on rafts the number of drop-ropes shall not exceed one per square meter of surface area. The maximum drop-rope length shall not exceed 20 m. Thinning-out of drop-ropes shall not take place during the production cycle, however sub-division of drop ropes shall be permitted without increasing stocking density at the outset.
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- (i) Tropical fresh water fish: milkfish (*Chanos chanos*), tilapia (*Oreochromis* spp.), siamese catfish (*Pangasius* spp.):

Production systems	Ponds and net cages
Maximum stocking density	Pangasius: 10 kg/m <sup>3</sup> Oreochromis: 20 kg/m <sup>3</sup>

#### 4.1.6. Animal welfare

- 4.1.6.1. All persons involved in keeping aquaculture animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals
- 4.1.6.2. Handling of aquaculture animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in a manner to minimise physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.
- 4.1.6.3. The following restrictions shall apply to the use of artificial light:

- (a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of produced animals, this maximum shall not exceed 16 hours per day, except for reproductive purposes;
  - (b) abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.
- 4.1.6.4. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources.
- 4.1.6.5. The use of oxygen is only permitted for uses linked to animal health and welfare requirements and critical periods of production or transport, in the following cases:
  - (a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental pollution;
  - (b) occasional stock management procedures such as sampling and sorting;
  - (c) in order to assure the survival of the farm stock.
- 4.1.6.6. Appropriate measures shall be taken to keep the duration of transport of aquaculture animals to a minimum.
- 4.1.6.7. Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.
- 4.1.6.8. Slaughter techniques shall render fish immediately unconscious and insensible to pain. Handling prior to slaughter shall be performed in a way that avoids injuries while keeping suffering and stress at a minimum. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.
- 4.2. Specific rules for molluscs
  - 4.2.1. Origin of seed
 

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

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

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

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

#### 4.2.3. Cultivation

With regard to cultivation the following rules shall apply:

- (a) cultivation on mussel ropes and other methods listed in point 4.1.5.10 (h) may be eligible for organic production;
- (b) bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. The evidence of minimal environmental impact shall be supported by a survey and report on the exploited area to be provided by the operator to the control authority or control body. The report shall be added as a separate chapter to the sustainable management plan.

#### 4.2.4. Management

With regard to management the following rules shall apply:

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

#### 4.2.5. Specific cultivation rules for oysters

Cultivation in bags on trestles shall be permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the requirements set out in point 4.1.5.10. (h).

### **Part IV: Processed food and processed feed production rules**

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

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

- 1.1. Food and feed additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice<sup>10</sup>.
- 1.2. Operators producing processed food or feed shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
- 1.3. The application of the procedures referred to in point 1.2. shall guarantee at all times that the produced processed products comply with this Regulation.
- 1.4. Operators shall comply with and implement the procedures referred to in point 1.2., and in particular shall:
  - (a) take preventive measures to avoid the risk of contamination by unauthorised substances or products;
  - (b) implement suitable cleaning measures, monitor their effectiveness and record these operations;
  - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
- 1.5. The preparation of processed organic products shall be kept separate in time or space from non-organic products. When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:
  - (a) inform the control authority or control body accordingly;
  - (b) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;
  - (c) store organic products, before and after the operations, separate by place or time from non-organic products;
  - (d) keep available an updated register of all operations and quantities processed;
  - (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;
  - (f) carry out operations on organic products only after suitable cleaning of the production equipment.
- 1.6. Products, substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of organic food or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food shall not be used.

## **2. Requirements for the production of processed food**

- 2.1. The following conditions shall apply to the composition of organic processed food:
  - (a) the product shall be produced mainly from agricultural ingredients; in order to determine whether a product is produced mainly from agricultural ingredients, added water and salt shall not be taken into account;

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<sup>10</sup> Good manufacturing practices (GMPs) as defined in Article 3(a) of Commission Regulation (EC) N° 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (O.J. L 384, 29.12.2006, p. 75)

- (b) only those food additives, processing aids, flavourings, water, salt, preparations of micro-organisms and food enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses authorised for use in organic production pursuant to Article 19 may be used;
- (c) an organic ingredient shall not be present together with the same ingredient in conversion or in non-organic form;
- (d) food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.

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

2.2.1. Only the products and substances as referred to in point 2.1(b) as well as the products and substances referred to in points 2.2.2, 2.2.4. and 2.2.5., may be used in the processing of food, with the exception of products and substances of the wine sector, for which point 2 of Part V shall apply, and of yeast for which point 1.3 of Part VI shall apply.

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

- (a) preparations of micro-organisms and food enzymes normally used in food processing; however food enzymes to be used as food additives have to be authorised for use in organic production pursuant to Article 19;
- (b) substances, and products as defined in Article 3(2)(b) and (d) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council<sup>11</sup> labelled as natural flavouring substances or natural flavouring preparations, in accordance with Articles 15(1)(e) and Article 16 of that Regulation;
- (c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council<sup>12</sup>;
- (d) drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
- (e) minerals (trace elements included), vitamins, aminoacids, and micronutrients, only authorised as far their use is legally required in the foodstuffs in which they are incorporated.

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

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

<sup>11</sup> Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

<sup>12</sup> 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).

- (c) yeast and yeast products shall be calculated as agricultural ingredients.
- 2.2.4. The following non-organic agricultural ingredients may be used in the processing of organic food:
- (a) animal products:
    - (i) aquatic organisms, not originating from aquaculture, and permitted in non-organic foodstuffs preparation;
    - (ii) gelatin;
    - (iii) casings;
  - (b) unprocessed vegetable products as well as products derived therefrom by processing:
    - (i) edible fruits, nuts and seeds:
      - cola nuts *Cola acuminata*;
    - (ii) edible spices and herbs:
      - horseradish seeds *Armoracia rusticana*;
      - safflower flowers *Carthamus tinctorius*;
      - watercress herb *Nasturtium officinale*;
    - (iii) miscellaneous:
      - algae, including seaweed;
  - (c) processed vegetable products:
    - (i) sugars, starches and other products from cereals and tubers:
      - rice paper;
      - starch from rice and waxy maize, not chemically modified;
    - (ii) miscellaneous:
      - rum, only obtained from cane sugar juice.
- 2.2.5. Fats and oils whether or not refined, but not chemically modified, may be used in their non-organic form if they are derived from plants other than:
- cocoa *Theobroma cacao*;
  - coconut *Cocos nucífera*;
  - olive *Olea europaea*;
  - sunflower *Helianthus annuus*;
  - palm *Elaeis guineensis*;
  - rape *Brassica napus, rapa*;
  - safflower *Carthamus tinctorius*;
  - sesame *Sesamum indicum*;
  - soya *Glycine max*.

### 3. Requirements for the production of processed feed

- 3.1. Organic feed materials, or in-conversion feed materials, shall not enter simultaneously with the same feed materials produced by non-organic means into the composition of the organic feed product.
- 3.2. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.

## **Part V: Wine**

### **1. Scope**

- 1.1. In addition to the general production rules laid down in Articles 7, 8, 9 and 14, the rules laid down in this Part shall apply to the organic production of the products of the wine sector as referred to in point (l) of Article 1(2) of Regulation (EU) No 1308/2013.
- 1.2. Commission Regulations (EC) No 606/2009<sup>13</sup> and (EC) No 607/2009<sup>14</sup> shall apply, save as explicitly provided otherwise in this Part.

### **2. Use of certain products and substances**

- 2.1. Products of the wine sector shall be produced from organic raw material.
- 2.2. Only products and substances authorised for use in organic production pursuant to Article 19 may be used for the making of products of the wine sector, including during the processes and oenological practices, subject to the conditions and restrictions laid down in Regulation (EU) No 1308/2013 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.

### **3. Oenological practices and restrictions**

- 3.1. Without prejudice to Sections 1. and 2. and to specific prohibitions and restrictions provided for in points 3.2 to 3.5, only oenological practices, processes and treatments, including the restrictions provided for in Article 80 and 83(2) of Regulation (EU) No 1308/2013, and in Article 3, Articles 5 to 9 and Articles 11 to 14 of Regulation (EC) No 606/2009, and in the Annexes to those Regulations, used before 1 August 2010, shall be permitted.
- 3.2. The use of the following oenological practices, processes and treatments shall be prohibited:
  - (a) partial concentration through cooling according to point (c) of Section B.1 of Part I of Annex VIII to Regulation (EU) No 1308/2013;
  - (b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009;
  - (c) electrodialysis treatment to ensure the tartaric stabilisation of the wine according to point 36 of Annex I A to Regulation (EC) No 606/2009;

<sup>13</sup> Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).

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

- (d) partial dealcoholisation of wine according to point 40 of Annex I A to Regulation (EC) No 606/2009;
  - (e) treatment with cation exchangers to ensure the tartaric stabilisation of the wine according to point 43 of Annex I A to Regulation (EC) No 606/2009.
- 3.3. The use of the following oenological practices, processes and treatments is permitted under the following conditions:
  - (a) for heat treatments according to point 2 of Annex I A to Regulation (EC) No 606/2009, the temperature shall not exceed 70 °C;
  - (b) for centrifuging and filtration with or without an inert filtering agent according to point 3 of Annex I A to Regulation (EC) No 606/2009, the size of the pores shall be not smaller than 0,2 micrometer.
- 3.4. The use of the following oenological practices, processes and treatments shall be re-examined by the Commission before 1 August 2015 with a view to phase out or to further restrict those practices:
  - (a) heat treatments as referred to in point 2 of Annex I A to Regulation (EC) No 606/2009;
  - (b) use of ion exchange resins as referred to in point 20 of Annex I A to Regulation (EC) No 606/2009;
  - (c) reverse osmosis according to point (b) of Section B.1 of Part I of Annex VIII to Regulation (EU) No 1308/2013.
- 3.5. Any amendment introduced after 1 August 2010, as regards the oenological practice, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009, may be applicable in the organic production of wine only after the adoption of the measures necessary for the implementation of the production rules provided for in this Section 3 and, if required, an evaluation according to Article 19 of this Regulation.

## **Part VI: Yeast used as food or feed**

In addition to the general production rules laid down in Articles 7, 9 and 15, the rules laid down in this Part shall apply to organic yeast used as food or feed.

### **1. General requirements**

- 1.1. For the production of organic yeast only organically produced substrates shall be used.
- 1.2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.
- 1.3. The following substances may be used in the production, confection and formulation of organic yeast:
  - (a) processing aids authorised for use in organic production pursuant to Article 19;
  - (b) products and substances referred to in point 2. 2.2. (a) and (d) of Part IV.

## ANNEX III

### COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS

#### **1. Collection of products and transport to preparation units**

Operators may carry out simultaneous collection of organic and non-organic products only where appropriate measures are taken to prevent any possible mixture or exchange with non-organic products and to ensure the identification of the organic products. The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the control authority or control body.

#### **2. Packaging and transport of products to other operators or units**

2.1. Operators shall ensure that organic products are transported to other operators or units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by Union law:

- (a) the name and address of the operator and, where different, of the owner or seller of the product;
- (b) the name of the product or a description of the compound feedingstuff accompanied by a reference to organic production;
- (c) the name or the code number of the control authority or control body to which the operator is subject; and
- (d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the control authority or control body and which permits to link the lot with the records referred to in Article 24.

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

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

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

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

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

- (a) during transport, organically produced feed, in-conversion feed, and non-organic feed shall be effectively physically separated;
- (b) vehicles or containers which have transported non-organic products may only be used to transport organic products if:

- (i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic products and the operators record these operations;
- (ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with control arrangements and, where necessary, operators shall guarantee that non-organic products cannot be placed on the market with an indication referring to organic production;
- (iii) the operator keep documentary records of such transport operations available for the control authority or control body;
- (c) the transport of finished organic feed shall be separated physically or in time from the transport of other finished products;
- (d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round shall be recorded.

#### **4. Transport of live fish**

- 4.1. Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.
- 4.2. Before transport of organic fish and fish products, tanks shall be thoroughly cleaned, disinfected and rinsed.
- 4.3. Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.
- 4.4. Documentary evidence shall be maintained for operations referred to in points 4.1, 4.2 and 4.3.

#### **5. Reception of products from other operators of units**

On receipt of an organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications provided for in Section 2.

The operator shall crosscheck the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article 24.

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

Where organic products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot and with the certificate of control for import from third countries as appropriate.

On receipt of an organic product imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing, shall check the closing of the packaging or container and, in the case of products imported in accordance with Article 28(1)(b)(ii), shall check that the certificate of inspection referred to in that Article covers the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the records referred to in Article 24.

#### **7. Storage of products**

- 7.1. For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.
- 7.2. In case of organic plant and livestock production units, storage of input products other than those authorised for use in organic production pursuant to Article 19 is prohibited in the production unit.
- 7.3. The storage of allopathic veterinary medicinal products and antibiotics is permitted on agricultural and aquaculture holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in points 1.5.2.2 of Part II and 4.1.4.2(a) of Part III of Annex II, that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 24.
- 7.4. Where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:
  - (a) the organic products shall be kept separate from the other agricultural products or foodstuffs;
  - (b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;
  - (c) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products and the operators shall record these operations.

## ANNEX IV

### TERMS REFERRED TO IN ARTICLE 21

BG: биологичен.

ES: ecológico, biológico.

CS: ekologické, biologické.

DA: økologisk.

DE: ökologisch, biologisch.

ET: mahe, ökoloogiline.

EL: βιολογικό.

EN: organic.

FR: biologique.

GA: orgánach.

HR: ekološki.

IT: biologico.

LV: bioloģisks, ekoloģisks.

LT: ekologiškas.

LU: biologesch.

HU: ökológiai.

MT: organiku.

NL: biologisch.

PL: ekologiczne.

PT: biológico.

RO: ecologic.

SK: ekologické, biologické.

SL: ekološki.

FI: luonnonmukainen.

SV: ekologisk.

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**ANNEX V**  
**ORGANIC PRODUCTION LOGO OF THE EUROPEAN UNION AND CODE**  
**NUMBERS**

**1. Logo**

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

LOGO to be inserted

- 1.2. The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.
- 1.3. The organic production logo of the European Union may also be used in black and white as shown, only where it is not practicable to apply it in colour:

LOGO to be inserted

- 1.4. If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.
- 1.5. If a logo is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the logo can be used to improve contrast with the background colours.
- 1.6. In certain specific situations where there are indications in a single colour on the packaging, the organic production logo of the European Union may be used in the same colour.
- 1.7. The organic production logo of the European Union must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.
- 1.8. The organic production logo of the European Union may be associated with graphical or textual elements referring to organic production, under the condition that they do not modify or change the nature of the organic production logo of the European Union, nor any of the indications defined in accordance with Article 22. When associated to national or private logos using a green colour different from the reference colour provided for in point 2, the organic production logo of the European Union may be used in that non-reference colour.

**2. Code numbers**

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

AB-CDE-999

Where:

- (a) 'AB' is the ISO code for the country where the controls take place;
- (b) 'CDE' is a term, indicated in three letters to be decided by the Commission or each Member State, like "bio" or "öko" or "org" or "eko" establishing a link with organic production; and
- (c) '999' is the reference number, indicated in maximum three digits, to be assigned by:

- (i) each Member State's competent authority to the control authorities or control bodies to which they have delegated control tasks;
- (ii) the Commission, to:
  - the control authorities and control bodies recognised by the Commission pursuant to of Article 29;
  - to the competent authorities of third countries recognised by the Commission pursuant to of Article 31.