

- (88) Organic production is subject to official controls and to other official activities carried out in accordance with Regulation (EU) 2017/625 to verify compliance with the rules on organic production and the labelling of organic products. However, except as otherwise provided for in this Regulation, rules should apply to organic production in addition to those which are laid down in that Regulation as regards official controls and actions by competent authorities, and, where appropriate, by control authorities and control bodies, as regards actions to be taken by operators and groups of operators, as regards the delegation of certain official control tasks or certain tasks related to other official activities and their supervision, and as regards actions in cases of suspected or established non-compliance, including the prohibition against marketing products as organic or in-conversion products where the established non-compliance affects the integrity of those products.
- (89) In order to ensure a uniform approach on their territories, it should be solely up to the competent authorities to provide for a catalogue of measures to be taken in cases of suspected or established non-compliance.
- (90) Provisions on the exchange of certain relevant information among competent authorities, control authorities, control bodies and certain other bodies and on the action of such authorities and bodies, additional to the provisions of Regulation (EU) 2017/625, should be laid down in this Regulation.
- (91) In order to support the performance of official controls and other official activities to verify compliance with this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of specific criteria and conditions for the performance of official controls conducted to ensure the traceability at all stages of production, preparation and distribution, and compliance with this Regulation and in respect of additional elements to be taken into account in the determination, based on practical experience, of the likelihood of non-compliance.
- (92) In order to support the performance of official controls and other official activities to verify compliance with this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of the conditions for the delegation of official control tasks and tasks related to other official activities to control bodies, in addition to the conditions laid down in this Regulation.
- (93) The experience with the arrangements for the import of organic products into the Union under Regulation (EC) No 834/2007 has shown that there is a need to revise those arrangements in order to respond to consumer expectations that imported organic products meet standards as high as those of the Union, as well as in order to better ensure the access of Union organic products to the international market. In addition, it is necessary to provide clarity regarding the rules applicable to export of organic products, in particular by establishing organic export certificates.
- (94) The provisions governing the import of products that comply with the Union production and labelling rules, in respect of which operators have been subject to the control of control authorities and control bodies recognised by the Commission to carry out in third countries controls and certification in the field of organic production, 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 in order to ensure a level playing field for the supervision of the control bodies by the Commission. Furthermore, it is necessary to provide for the possibility for the Commission to contact directly the accreditation bodies and competent authorities in third countries to render the supervision of control authorities and control bodies respectively more efficient. In the case of products imported from third countries or the outermost regions of the Union with specific climatic and local conditions, it is appropriate to provide for the possibility for the Commission to grant specific authorisations for the use of products and substances in organic production.
- (95) It should remain possible for organic products to have 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. However, the recognition of equivalence of third countries, as laid down in Regulation (EC) No 834/2007, should only be granted through international agreements between the Union and those third countries, where a reciprocal recognition of equivalence would be also pursued for the Union.
- (96) Third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 should continue to be recognised as such under this Regulation, for a limited period necessary to ensure a smooth transition to the scheme of recognition through an international agreement, provided that they continue to ensure that their organic

production and control rules are equivalent 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 those recognised third countries send to the Commission.

- (97) The experience with the scheme of control authorities and control bodies recognised by the Commission to carry out controls and to issue certificates in third countries for the purpose of importing products, which provides equivalent guarantees, shows that the rules applied by those authorities and bodies differ, and it could be difficult to consider such rules as equivalent to the respective Union rules. Furthermore, the multiplication of standards for control authorities and control bodies hampers adequate supervision by the Commission. Therefore, that scheme of recognition of equivalence should be abolished. However, those control authorities and control bodies should be given sufficient time so that they can prepare themselves to obtain recognition for the purposes of import of products that comply with Union rules. Furthermore, the new rules for the recognition of control authorities and control bodies for the purpose of importing compliant products should already apply from the date of entry into force of this Regulation, in order to allow the Commission to prepare for the recognition of such control authorities and control bodies from the date of application of this Regulation.
- (98) The placing of any product on the market as an organic product, where that product has been imported into the Union under any of the import arrangements provided for in this Regulation, should be subject to the availability of the information necessary to ensure the traceability of the product on the food chain.
- (99) In order to ensure fair competition among operators, the power to adopt certain acts should be delegated to the Commission in respect of the documents intended for customs authorities in third countries, in particular organic export certificates.
- (100) In order to ensure the transparency of the recognition and supervision procedure for control authorities and control bodies within the context of import of compliant organic products and the effectiveness, efficiency and transparency of the controls of imported products, the power to adopt certain acts should be delegated to the Commission in respect of further criteria for recognition of control authorities and control bodies in the context of import of organic products that comply with this Regulation, as well as further criteria for the withdrawal of such recognition, in respect of the exercise of the supervision of the control authorities and control bodies recognised by the Commission and in respect of the controls and other actions to be performed by control authorities and control bodies for that purpose.
- (101) Where serious or repetitive infringements as regards the certification or the controls and actions under this Regulation have been detected, and where the control authority or control body concerned fails to take appropriate and timely remedial action in reaction to a request by the Commission, the recognition of that control authority or control body should be withdrawn without delay.
- (102) In order to ensure the management of the list of third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007, the power to adopt certain acts should be delegated to the Commission in respect of the information to be sent by those recognised third countries which is necessary for the supervision of their recognition and the exercise of that supervision by the Commission.
- (103) Provision should be made for ensuring that the movement of organic products that comply with this Regulation and have been subject to a control in one Member State cannot be restricted in another Member State.
- (104) For the purpose of obtaining reliable information for the implementation of this Regulation, Member States should regularly provide the Commission with the necessary information. For reasons of clarity and transparency, Member States should keep updated lists of competent authorities, control authorities and control bodies. The lists of control authorities and control bodies should be made public by the Member States and published by the Commission.
- (105) In view of the phasing out of the derogations concerning the use of non-organic plant reproductive material, non-organically reared poultry, and non-organic livestock for breeding purposes, the Commission should consider the availability of such material in organic form on the market in the Union. To that end, and on the basis of the data on the availability of organic material collected through the database and systems set up by Member States, five years after the date of application of this Regulation, the Commission should present a report to the European Parliament and the Council on the availability and reasons of a possible limited access of organic operators to such material.

- (106) In view of the phasing out of the derogations concerning the use of non-organic protein feed for poultry and porcine animals, and on the basis of the data provided every year by Member States on the availability of such protein feed in organic form on the market in the Union, five years after the date of application of this Regulation, the Commission should present a report to the European Parliament and to the Council on the availability of and reasons for a possible limited access of organic operators to such organic protein feed.
- (107) In order to take into account the evolution of availability on the market of organic plant reproductive material, organic animals and organic protein feed for poultry and porcine animals, the power to adopt certain acts should be delegated to the Commission in respect of ending or extending derogations and authorisations concerning the use of non-organic plant reproduction material, non-organic animals and non-organic protein feed for poultry and porcine animals.
- (108) It is necessary to lay down measures to ensure a smooth transition to the legal framework governing the import of organic and in-conversion products into the Union as modified by this Regulation.
- (109) Furthermore, a time limit for the expiry of the recognition of control authorities and control bodies for the purpose of equivalence granted under Regulation (EC) No 834/2007 should be set, and provisions to address the situation up to the expiry of their recognition should be laid down. Provisions should also be laid down regarding applications from third countries for recognition for the purpose of equivalence which have been submitted under Regulation (EC) No 834/2007 and which are pending on the date of entry into force of this Regulation.
- (110) In order to ensure the management of the list of control authorities and control bodies recognised for the purpose of equivalence under Regulation (EC) No 834/2007, the power to adopt certain acts should be delegated to the Commission in respect of the information that those control authorities and control bodies should send for the purpose of the supervision of their recognition and in respect of the exercise of that supervision by the Commission.
- (111) In order to facilitate the completion of the examination of applications from third countries for recognition for the purpose of equivalence that are pending on the date of entry into force of this Regulation, the power to adopt certain acts should be delegated to the Commission in respect of the procedural rules necessary for the examination of the pending applications from third countries.
- (112) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the documents that are to be supplied for the purpose of recognising a previous period as being part of the conversion period, as regards the minimum period for feeding of suckling animals with maternal milk and certain technical rules for livestock housing and husbandry practices, as regards detailed rules per species or per group of species of aquaculture animal on the stocking density and on the specific characteristics for production systems and containment systems, as regards techniques authorised in the processing of food and feed products, as regards the authorisation of the products and substances that may be used in organic production in general, and in the production of processed organic food in particular, as well as the withdrawal of such authorisations, and as regards the procedures for the authorisation and the lists of such products and substances and, where appropriate, the description, compositional requirement and conditions for the use of such products.
- (113) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the technical details for establishing and maintaining the databases that list the available organic or in-conversion plant reproductive material obtained by the organic production method, as regards the technical details for establishing and maintaining the systems for making available data on organic or in-conversion plant reproductive material or organic animals or organic aquaculture juveniles and the specifications for the collection of data for that purpose, as regards the arrangements for operators' participation in those systems, and as regards details concerning the information to be provided by Member State as regards derogations from the use of organic plant reproductive material, organic animals and organic feed and as regards the availability on the market of certain organic products.
- (114) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the measures to be adopted and reviewed by operators to identify and avoid risk of contamination of organic production and products with non-authorised products and substances, as regards the procedural steps to be taken in the case of a suspicion of non-compliance and the relevant documents, as regards the methodology on detection and evaluation of the presence of non-authorised products and substances, and as regards the details and format of the information to be transmitted by Member States to the Commission and other Member States concerning results of investigations on the presence of non-authorised products or substances.

- (115) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards detailed requirements for the labelling and advertising of certain in-conversion products, as regards the practical arrangements for the use, presentation, composition and size of the indications referring to the code numbers of control authorities and control bodies and the use, presentation, composition and size of the indication of the place where the agricultural raw materials have been farmed, as regards the assignment of code numbers to control authorities and control bodies and as regards the indication of the place where the agricultural raw materials have been farmed.
- (116) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the details and specifications regarding the format and technical means by which operators and groups of operators are to notify their activities to the competent authorities, as regards the arrangements for the publication of the lists of such operators and groups of operators, as regards the procedures and the arrangements for the publication of the fees that may be collected in relation to the controls, as regards details and specifications regarding the form of the certificate for operators and groups of operators and the technical means by which it is issued, as regards the composition and dimensions of groups of operators, as regards the relevant documents and record-keeping systems, as regards the system for internal traceability and the list of operators, and as regards the exchange of information between groups of operators and competent authorities, control authorities or control bodies and the exchange of information between the Member States and the Commission.
- (117) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the minimum percentage of all official controls to be carried out without prior notice and the minimum percentage of additional controls, as well as the minimum number of samples to be taken and of operators to be controlled within a group of operators, as regards the records for demonstrating compliance, as regards the declarations and other communications that are necessary for official controls, as regards the relevant practical measures for ensuring compliance, as regards uniform arrangements for the cases where competent authorities are to take measures in relation to suspected or established non-compliance, as regards the information to be provided in the case of suspected or established non-compliance, as regards the recipients of such information, and as regards the procedures for the provision of such information, including the functionalities of the computer system used.
- (118) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the content of certificates of inspection issued by third countries, as regards the procedure to be followed for the issuance and verification of such certificates, as regards the technical means by which such certificates are issued, as regards the recognition of control authorities and control bodies competent to carry out controls and to issue organic certificate in third countries, as well as the withdrawal of such recognition, as regards the establishment of the list of those control authorities and control bodies, as regards rules to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those cases that affect the integrity of imported organic or in-conversion products, as regards the establishment of a list of third countries recognised under Article 33(2) of Regulation (EC) No 834/2007 and the amendment of that list, and as regards rules to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those cases that affect the integrity of organic or in-conversion products imported from those countries.
- (119) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the system to be used for transmitting the information necessary for the implementation and monitoring of this Regulation, as regards the details of the information to be transmitted and the date by which that information is to be transmitted, and as regards the establishment of the list of control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and the amendment of that list.
- (120) The implementing powers conferred on the Commission should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(1)</sup>.
- (121) The Commission should be empowered to adopt immediately applicable implementing acts, where, in duly justified cases relating to 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 suspected or established non-compliance under the control of recognised control authorities or control bodies.

<sup>(1)</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 Member States of Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (122) Provision should be made to allow the exhaustion after the date of application of this Regulation of stocks of products which have been produced in accordance with Regulation (EC) No 834/2007 before that date.
- (123) Since the objectives of this Regulation, in particular fair competition and the 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 rather, by reason of the required harmonisation of the rules on organic production, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (124) It is appropriate to provide for a date of application of this Regulation that would give the possibility to operators to adapt to the new requirements,

HAVE ADOPTED THIS REGULATION:

#### CHAPTER I

### SUBJECT MATTER, SCOPE AND DEFINITIONS

#### *Article 1*

#### **Subject matter**

This Regulation establishes the principles of organic production and lays down the rules concerning organic production, related certification and the use of indications referring to organic production in labelling and advertising, as well as rules on controls additional to those laid down in Regulation (EU) 2017/625.

#### *Article 2*

#### **Scope**

1. This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:

- (a) live or unprocessed agricultural products, including seeds and other plant reproductive material;
- (b) processed agricultural products for use as food;
- (c) feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

2. This Regulation applies to any operator involved, at any stage of production, preparation and distribution, in activities relating to the products referred to in paragraph 1.

3. Mass catering operations carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 are not subject to this Regulation except as set out in this paragraph.

Member States may apply national rules or, in the absence thereof, private standards, on the production, labelling and control of products originating from mass catering operations. The organic production logo of the European Union shall not be used in the labelling, the presentation or the advertising of such products, and shall not be used to advertise the mass caterer.

4. Except where otherwise provided, this Regulation applies without prejudice to related Union legislation, in particular, legislation in the fields of safety of the food chain, animal health and welfare, plant health and plant reproductive material.

5. This Regulation applies without prejudice to other specific Union law 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>(1)</sup> and to Regulation (EU) No 1169/2011.

<sup>(1)</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).



6. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending the list of products set out in Annex I by adding further products to the list, or by amending those added entries. 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 apply:

- (1) 'organic production' means the use, including during the conversion period referred to in Article 10, of production methods that comply with this Regulation at all stages of production, preparation and distribution;
- (2) 'organic product' means a product resulting from organic production, other than a product produced during the conversion period referred to in Article 10. The products of hunting or fishing of wild animals are not considered as organic products;
- (3) 'agricultural raw material' means an agricultural product that has not been subjected to any operation of preservation or processing;
- (4) 'preventive measures' means measures that are to be taken by operators at every stage of production, preparation and distribution in order to ensure the preservation of biodiversity and soil quality, measures for the prevention and control of pests and diseases and measures that are to be taken to avoid negative effects on the environment, animal health and plant health;
- (5) 'precautionary measures' means measures that are to be taken by operators at every stage of production, preparation, and distribution to avoid contamination with products or substances that are not authorised for use in organic production in accordance with this Regulation, and to avoid the commingling of organic products with non-organic products;
- (6) 'conversion' means the transition from non-organic to organic production within a given period, during which the provisions of this Regulation concerning organic production apply;
- (7) 'in-conversion product' means a product that is produced during the conversion period referred to in Article 10;
- (8) 'holding' means all the production units operated under single management for the purpose of producing live or unprocessed agricultural products, including products originating from aquaculture and beekeeping, referred to in point (a) of Article 2(1) or products listed in Annex I other than essential oils and yeast;
- (9) 'production unit' means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs managed as described in point (10), point (11) or point (12);
- (10) 'organic production unit' means a production unit, excluding during the conversion period referred to in Article 10, which is managed in compliance with the requirements applicable to organic production;
- (11) 'in-conversion production unit' means a production unit, during the conversion period referred to in Article 10, which is managed in compliance with the requirements applicable to organic production; it may be constituted of land parcels or other assets for which the conversion period referred to in Article 10 starts at different moments in time;
- (12) 'non-organic production unit' means a production unit which is not managed in compliance with the requirements applicable to organic production;
- (13) 'operator' means the natural or legal person responsible for ensuring that this Regulation is complied with at every stage of production, preparation and distribution that are under that person's control;
- (14) 'farmer' means a natural or legal person, or a group of natural or legal persons, regardless of the legal status of that group and its members under national law, who exercises an agricultural activity;
- (15) 'agricultural area' means agricultural area as defined in point (e) of Article 4(1) of Regulation (EU) No 1307/2013;
- (16) 'plants' means plants as defined in point (5) of Article 3 of Regulation (EC) No 1107/2009;