

*Article 45***Import of organic and in-conversion products**

1. A product may be imported from a third country for the purpose of placing that product on the market within the Union as an organic product or as an in-conversion product, provided that the following three conditions are met:

- (a) the product is a product as referred to in Article 2(1);
- (b) one of the following applies:
  - (i) the product complies with Chapters II, III and IV of this Regulation, and all operators and groups of operators referred to in Article 36, including exporters in the third country concerned, have been subject to controls by control authorities or control bodies recognised in accordance with Article 46, and those authorities or bodies have provided all such operators, groups of operators and exporters with a certificate confirming that they comply with this Regulation;
  - (ii) in cases where the product comes from a third country which is recognised in accordance with Article 47, that product complies with the conditions laid down in the relevant trade agreement; or
  - (iii) in cases where the product comes from a third country which is recognised in accordance with Article 48, that product complies with the equivalent production and control rules of that third country and is imported with a certificate of inspection confirming this compliance that was issued by the competent authorities, control authorities or control bodies of that third country; and
- (c) the operators in third countries are able at any time to provide the importers and the national authorities in the Union and in those third countries with information allowing the identification of the operators that are their suppliers and the control authorities or control bodies of those suppliers, with a view to ensuring the traceability of the organic or in-conversion product concerned. That information shall also be made available to the control authorities or control bodies of the importers.

2. The Commission may, in accordance with the procedure set out in Article 24(9), grant specific authorisations for the use of products and substances in third countries and in the outermost regions of the Union, taking into account differences in the ecological balance in plant or animal production, specific climatic conditions, traditions and local conditions in those areas. Such specific authorisations may be granted for a renewable period of two years and shall be subject to the principles laid down in Chapter II and to the criteria set out in Article 24(3) and (6).

3. When providing for the criteria for determining whether a situation qualifies as catastrophic circumstances, and when laying down specific rules on how to deal with such circumstances in accordance with Article 22, the Commission shall take into account differences in the ecological balance, climate and local conditions in third countries and in the outermost regions of the Union.

4. The Commission shall adopt implementing acts to lay down specific rules concerning the content of the certificates referred to in point (b) of paragraph 1, the procedure to be followed for their issuance, their verification and the technical means by which the certificate is issued, in particular as regards the role of competent authorities, control authorities and control bodies, ensuring the traceability and compliance of imported products intended to be placed on the Union market as organic products or as in-conversion products as referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

5. Compliance with the conditions and measures for the import of organic products and in-conversion products referred to in paragraph 1 into the Union shall be ascertained at border control posts, in accordance with Article 47(1) of Regulation (EU) 2017/625. The frequency of the physical checks referred to in Article 49(2) of that Regulation shall depend on the likelihood of non-compliance as defined in point (57) of Article 3 of this Regulation.

*Article 46***Recognition of control authorities and control bodies**

1. The Commission may adopt implementing acts to recognise control authorities and control bodies that are competent to carry out controls and to issue organic certificates in third countries, to withdraw the recognition of such control authorities and control bodies, and to establish a list of recognised control authorities and control bodies.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

2. Control authorities or control bodies shall be recognised in accordance with paragraph 1 of this Article for the control of import of the categories of products listed in Article 35(7) if they fulfil the following criteria:

- (a) they are legally established in one Member State or third country;
- (b) they have the capacity to carry out controls to ensure that the conditions set out in points (a), (b)(i) and (c) of Article 45(1) and in this Article are met in relation to organic products and in-conversion products intended for import into the Union;
- (c) they offer adequate guarantees of objectivity and impartiality and are free from any conflict of interest as regards the exercise of their control tasks;
- (d) in the case of control bodies, they are accredited under the relevant harmonised standard for 'Conformity assessment – Requirements for bodies certifying products, processes and services', the reference of which has been published in the *Official Journal of the European Union*;
- (e) they have the expertise, equipment and infrastructure required to carry out control tasks, and have a sufficient number of suitable qualified and experienced staff; and
- (f) they meet any additional criteria that may be laid down in a delegated act adopted pursuant to paragraph 7.

3. The accreditation referred to in point (d) of paragraph 2 may only be granted by:

- (a) a national accreditation body in the Union in accordance with Regulation (EC) No 765/2008; 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. Control authorities and control bodies shall submit a request for recognition to the Commission. Such request shall consist of a technical dossier containing all information that is necessary to ensure that the criteria set out in paragraph 2 are met.

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

5. Based on the information referred to under paragraph 4 and on any other relevant information relating to the control authority or control body, the Commission shall ensure appropriate supervision of the recognised control authorities and control bodies by regularly reviewing their performance and recognition. For the purposes of that supervision, the Commission may request additional information from the accreditation bodies or the competent authorities, as appropriate.

6. The nature of the supervision referred to in paragraph 5 shall be determined on the basis of an assessment of the likelihood of non-compliance, taking into account, in particular, the activity of the control authority or control body, the type of products and operators under its control and the changes in the production rules and control measures.

The recognition of control authorities or of control bodies referred to in paragraph 1 shall in particular be withdrawn without delay, in accordance with the procedure referred to in that paragraph, where serious or repetitive infringements as regards the certification or the controls and actions laid down in accordance with paragraph 8 have been detected and where the control authority or control body concerned has failed to take appropriate and timely remedial action in reaction to a request by the Commission within a period determined by the Commission. Such period shall be determined in accordance with the severity of the problem and in general shall not be less than 30 days.

7. The Commission is empowered to adopt delegated acts in accordance with Article 54:

- (a) amending paragraph 2 of this Article by adding further criteria to those laid down therein for the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article and for the withdrawal of such recognition, or by amending those added criteria;
- (b) supplementing this Regulation as regards:
  - (i) the exercise of the supervision of the control authorities and control bodies recognised by the Commission in accordance with paragraph 1, including on-the-spot examinations; and
  - (ii) the controls and other actions to be performed by those control authorities and control bodies.

8. The Commission may adopt implementing acts to ensure the application of the measures to be taken in relation to cases of suspected or established non-compliance, in particular those affecting the integrity of organic or in-conversion products imported under the recognition provided for in this Article. Such measures may consist in particular in the verification of the integrity of organic or in-conversion products before placing the products on the market within the Union and, where appropriate, in the suspension of the authorisation for the placing on the market of such products within the Union as organic products or in-conversion products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

9. On duly justified imperative grounds of urgency 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, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 55(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 47

##### **Equivalence under a trade agreement**

A recognised third country referred to in point (b)(ii) of Article 45(1) 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 48

##### **Equivalence under Regulation (EC) No 834/2007**

1. A recognised third country referred to in point (b)(iii) of Article 45(1) is a third country which has been recognised for the purposes of equivalence under Article 33(2) of Regulation (EC) No 834/2007, including those recognised under the transitional measure provided for in Article 58 of this Regulation.

That recognition shall expire on 31 December 2025.

2. On the basis of annual reports to be sent to the Commission, by 31 March of each year, by the third countries referred to in paragraph 1 regarding the implementation and enforcement of the control measures established by them, and in the light of any other information received, the Commission shall ensure appropriate supervision of the recognised third countries by regularly reviewing their recognition. For this purpose, the Commission may request the assistance of Member States. The nature of the supervision shall be determined on the basis of an assessment of the likelihood of non-compliance, taking into account in particular the volume of exports to the Union from the third country concerned, the results of the monitoring and supervisory activities carried out by the competent authority and the results of previous controls. The Commission shall regularly report to the European Parliament and the Council on the outcome of its review.

3. 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 55(2).

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation as regards the information to be sent by the third countries listed in accordance with paragraph 3 of this Article which is 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.

5. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of suspected or established non-compliance, in particular those affecting the integrity of organic or in-conversion products imported from third countries referred to in this Article. Such measures may consist in particular in the verification of the integrity of organic or in-conversion products before placing the products on the market within the Union and, where appropriate, in the suspension of the authorisation for the placing on the market of such products within the Union as organic products or in-conversion products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).

*Article 49***Report from the Commission on the application of Articles 47 and 48**

By 31 December 2021, the Commission shall present a report to the European Parliament and the Council on the state of application of Articles 47 and 48, in particular as regards the recognition of third countries for the purpose of equivalence.

## CHAPTER VIII

## GENERAL PROVISIONS

## SECTION 1

***Free movement of organic and in-conversion products****Article 50***Non-prohibition and non-restriction of the marketing of organic and in-conversion products**

Competent authorities, control authorities and control bodies shall not, on grounds that relate to the production, labelling or presentation of the products, prohibit or restrict the marketing of organic or in-conversion products subject to control by another competent authority, control authority or control body located in another Member State where those products comply with this Regulation. In particular, no official controls and other official activities other than those under Regulation (EU) 2017/625 shall be performed and no fees for official controls and other official activities other than those provided for in Chapter VI of that Regulation shall be collected.

## SECTION 2

***Information, reporting and related derogations****Article 51***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. As far as possible, such information shall be based on established sources of data. The Commission shall take into account the data needs and synergies between potential data sources, in particular their use for statistical purposes where appropriate.

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 55(2).

*Article 52***Information relating to the competent authorities, control authorities and control bodies**

1. Member States shall keep a regularly updated list of:

- (a) the names and addresses of the competent authorities; and
- (b) the names, addresses and code numbers of the control authorities and control bodies.

Member States shall transmit those lists, and any change thereof, to the Commission and make them public, except where such transmission and publication has already taken place in accordance with Article 4(4) of Regulation (EU) 2017/625.

2. Based on the information provided for under paragraph 1, the Commission shall regularly publish on the internet an updated list of control authorities and control bodies referred to in point (b) of paragraph 1.

*Article 53***Derogations, authorisations and report**

1. The derogations from the use of organic plant reproductive material and from the use of organic animals provided in points 1.8.5 of Part I of Annex II and points 1.3.4.3 and 1.3.4.4 of Part II of Annex II, with the exception of point 1.3.4.4.2 of Part II of Annex II, shall expire on 31 December 2035.

2. From 1 January 2028, based on the conclusions as regards availability of organic plant reproductive material and animals presented in the report provided for in paragraph 7 of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 54 amending this Regulation by:

- (a) ending the derogations referred to in point 1.8.5 of Part I of Annex II and in points 1.3.4.3 and 1.3.4.4 of Part II of Annex II, with the exception of point 1.3.4.4.2 of Part II of Annex II, at an earlier date than 31 December 2035 or extending them beyond that date; or
- (b) ending the derogation referred to in point 1.3.4.4.2 of Part II of Annex II.

3. From 1 January 2026, the Commission shall be empowered to adopt delegated acts in accordance with Article 54 amending point (b) of Article 26(2) to extend the scope of the information system referred to in Article 26(2) to pullets and point 1.3.4.3 of Part II of Annex II to base the derogations concerning pullets on the data collected in accordance with this system.

4. From 1 January 2025, the Commission shall be empowered to adopt delegated acts in accordance with Article 54, based on the information as regards availability of organic protein feed for poultry and porcine animals made available by Member States in accordance with paragraph 6 of this Article or presented in the report referred to in paragraph 7 of this Article, ending the authorisations to use non-organic protein feed in the nutrition of poultry and porcine animals referred to in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II at an earlier date than 31 December 2025 or extending them beyond that date.

5. When extending the derogations or authorisations referred to in paragraphs 2, 3 and 4, the Commission shall do so only for as long as it has information, in particular information provided by Member States in accordance with paragraph 6, that confirms the unavailability on the Union market of the plant reproductive material, animal or feed concerned.

6. By 30 June of each year, Member States shall make available to the Commission and to the other Member States:

- (a) information provided in the database referred to in Article 26(1) and in the systems referred to in Article 26(2) and, if relevant, in the systems referred to in Article 26(3);
- (b) information on the derogations granted in accordance with point 1.8.5 of Part I of Annex II and points 1.3.4.3 and 1.3.4.4 of Part II of Annex II; and
- (c) information on the availability on the Union market of organic protein feed for poultry and porcine animals and on the authorisations granted in accordance with points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II.

7. By 31 December 2025, the Commission shall present a report to the European Parliament and the Council on the availability on the Union market of and, if relevant, on the causes of limited access to:

- (a) organic plant reproductive material;
- (b) organic animals covered by the derogations referred to in points 1.3.4.3 and 1.3.4.4 of Part II of Annex II;
- (c) organic protein feed intended for the nutrition of poultry and porcine animals subject to the authorisations referred to in points 1.9.3.1(c) and 1.9.4.2(c) of Part II of Annex II.

In drawing up that report, the Commission shall take into account, in particular, the data collected in accordance with Article 26 and the information relating to the derogations and the authorisations referred to in paragraph 6 of this Article.

## CHAPTER IX

### PROCEDURAL, TRANSITIONAL AND FINAL PROVISIONS

#### SECTION 1

#### *Procedural provisions*

#### *Article 54*

#### **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 power to adopt delegated acts referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) shall be conferred on the Commission for a period of five years from 1 January 2021. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) 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.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) 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 55

##### **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.

4. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

#### SECTION 2

##### **Repeal and transitional and final provisions**

#### Article 56

##### **Repeal**

Regulation (EC) No 834/2007 is repealed.

However, that Regulation shall continue to apply for the purpose of completing the examination of pending applications from third countries, as provided for in Article 58 of this Regulation.

References to the repealed Regulation shall be construed as references to this Regulation.