

REGULATION (EU) .../...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of ...
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

Final provisions on Seeds and Biodiversity

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.
- (...)
- (36) Research in the Union on plant reproductive material that does not fulfil the variety definition as regards uniformity shows that there could be benefits of using this diverse material, in particular with regards to organic production, for example to reduce the spread of diseases and improve resilience and increasing biodiversity.
- (37) Therefore, plant reproductive material not belonging to a variety, but belonging to a plant grouping within a single botanical taxon with a high level of genetic and phenotypic diversity between individual reproductive units, should be available to be used for organic production. For this reason, operators should be allowed to market plant reproductive material of **organic heterogeneous material** without complying with the requirements for registration and the certification categories of pre-basic, basic and certified material, or the requirements for other categories, as set out in Council Directives 66/401/EEC²², 66/402/EEC²³, 68/193/EEC²⁴, 98/56/EC²⁵, 2002/53/EC²⁶, 2002/54/EC²⁷, 2002/55/EC²⁸, 2002/56/EC²⁹, 2002/57/EC³⁰, 2008/72/EC³¹ and 2008/90/EC³², or acts adopted pursuant to those Directives, following a **notification** to the responsible bodies referred to in those Directives and, once the Commission has adopted harmonised requirements, provided that such material complies with those requirements.

- (38) 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 setting out certain rules for the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species.
- (39) In order to meet the needs of organic producers, to foster research and to develop **organic varieties suitable for organic production** taking into account the specific needs and objectives of organic agriculture such as enhanced genetic diversity, disease resistance or tolerance and adaptation to soil and climate specific conditions, a **temporary experiment** should be organised in accordance with Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC. This temporary experiment, carried out for a term of seven years, with sufficient quantities of the material concerned and being subject to yearly reporting, should serve to establish the criteria for the description of the characteristics, as well as the definition of the production and marketing conditions for that material.

Article 3

Definitions

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

- (17) ‘**plant reproductive material**’ means plants as well as all parts of plants at any growth stage including seeds, capable of, and intended for, producing entire plants;
- (18) ‘**organic heterogeneous material**’ means plant grouping within a single botanical taxon of the lowest known rank which:
- (a) presents common phenotypic characteristics;
 - (b) is, however, characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that this plant grouping is represented by the material as a whole, and not by a small number of units;
 - (c) is not a variety within the meaning of Article 5(2) of Council Regulation (EC) No 2100/94 (*Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1)*);
 - (d) is not a mixture of varieties;
 - (e) has been produced in accordance with the requirements of this Regulation;
- (19) ‘**organic variety suitable for organic production**’ means a variety within the meaning of Article 5(2) of Regulation (EC) No 2100/94 which:
- (a) is characterised by a high level of genetic and phenotypical diversity between individual reproductive units;

- (b) results from organic breeding activities referred to in Annex II, Part I, point 1.8.4;
- (20) ‘**mother plant**’ means an identified plant from which plant reproductive material is taken for reproduction of new plants;
- (21) ‘**generation**’ means a group of plants constituting a single step in the line of descent of plants;

Chapter II

Objectives of, and principles for, organic production

Article 4

Objectives

The organic production shall pursue the following general objectives:

- (...)
- contribution to a high level of biodiversity,
- (...)
- encouragement of the preservation of rare and/or native breeds in danger of extinction,
- contribution to the development of the offer of plant genetic material adapted to the specific needs and objectives of organic agriculture,
- contribution to a high level of biodiversity, notably by using diverse plant genetic material, such as organic heterogeneous material and organic varieties suitable for organic production,
- foster the development of organic plant breeding activities in order to contribute to favourable economic perspectives of the organic production sector.

Article 5

General principles

Organic production is a sustainable management system that is based on the following general principles:

- (...)
- (d) production of a wide variety of high quality food and other agricultural and aquaculture products that respond to consumers’ demand for goods produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare;
- (...)

- (g) restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, these external inputs shall be limited to:
 - (i) inputs from organic production, in the case of plant reproductive material, priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic farming;
 - (...)

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:

- (...)
- (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) use of seeds and animals with a high degree of genetic diversity, resistance against diseases and longevity;
- (f) choice of plant varieties having regard to the particularities of the organic production systems, focussing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect of the natural crossing barriers;
- (g) use of organic plant reproductive material such as organic heterogeneous material, and organic varieties suitable for organic production;
- (h) production of organic varieties through natural reproductive ability and focussing on containment within natural crossing barriers;
- (i) without prejudice to Article 14 of Regulation (EC) No 2100/94 and to the national plant variety rights granted under Member States' national law, possibility for farmers to use plant reproductive material obtained from their own farm in order to foster genetic resources adapted to the special conditions of organic production;
- (j) choice of animal breeds having regard to a high degree of genetic diversity, the capacity of animals to adapt to local conditions, their breeding value, their longevity, their vitality and their resistance to disease or health problems;
- (...)

Article 13

Specific provisions for the marketing of plant reproductive material of organic heterogeneous material

1. Plant reproductive material of organic heterogeneous material may be marketed without complying with the requirements for registration and the certification categories of pre-basic, basic and certified material, or the requirements for other categories, as set out in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, or acts adopted pursuant to those Directives.
2. Plant reproductive material of organic heterogeneous material as referred to in paragraph 1 may be marketed following a notification of the organic heterogeneous material by the supplier to the responsible official bodies referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC of a dossier containing:
 - (a) the contact details of the applicant;
 - (b) the species and denomination of the organic heterogeneous material;
 - (c) the description of the main agronomic and phenotypic characteristics that are common to that plant grouping, including breeding methods, results from tests, if available, the country of production and the parental material used;
 - (d) a declaration by the applicant concerning the trueness of the elements in points (a) to (c);
 - (e) a representative sample.

That notification shall be sent by registered letter, or any other means of communication accepted by the official bodies, with confirmation of receipt.

Within three months after the date shown on the return receipt, and provided that no additional information was requested or no formal refusal for reasons of incompleteness of the dossier or non-compliance as defined in Article 3(57) was communicated to the supplier, the competent authority shall be deemed to have acknowledged the notification and its content.

After express or implied acknowledgment of the notification, the competent authority may proceed to the listing of the notified organic heterogeneous material. This listing shall be free of charge for the supplier.

The listing of an organic heterogeneous material shall be communicated to other Member States and the Commission.

The organic heterogeneous material shall comply with the delegated acts adopted in accordance with paragraph 3.

3. The Commission is empowered to adopt delegated acts in accordance with Article 54 supplementing this Regulation by setting out rules for the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species, as regards:
 - (a) the description of the organic heterogeneous material, including the relevant breeding and production methods and parental material used;
 - (b) the minimum quality requirements of seeds lots, including identity, specific purity, germination rates and sanitary quality;
 - (c) labelling and packaging;
 - (d) information and samples of production to be kept by the professional operators;
 - (e) where applicable, maintenance of the organic heterogeneous material.

Article 26

Collection of data concerning the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles

1. Each Member State shall ensure that a regularly updated database is established for the listing of the organic or in-conversion plant reproductive material, except seedlings but including seed potatoes, which is available on its territory.
2. Member States shall have in place systems that allow operators who market organic or in-conversion plant reproductive material or organic animals or organic aquaculture juveniles and who are able to supply them in sufficient quantities and within a reasonable time period, to make public on a voluntary basis, free of charge, together with their names and contact details, the following data:
 - (a) the organic and in-conversion plant reproductive material, such as organic heterogeneous material, organic varieties suitable for organic production, except seedlings but including seed potatoes, which is available; the quantity in weight of that material and the period of the year of its availability. That material shall be listed using at least the Latin scientific name;
 - (b) the organic animals for which derogation may be provided in accordance with point 1.3.4.4 of Annex II, part II; the number of available animals categorised by sex; information, if relevant, relating to the different species of animals as regards the breeds and strains available; the races, the age of the animals and any other relevant information;

(c) the organic aquaculture juveniles available on their holding and the production capacity for each aquaculture species and their health status in accordance with Council Directive 2006/88/EC (*Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14)*).

3. Member States may also set up systems which allow operators who market breeds and strains adapted to organic production in accordance with point 1.3.3 of Part II of Annex II or organic pullets, and who are able to supply these animals in sufficient quantities and within a reasonable time period to make public the relevant data on a voluntary basis, free of charge, together with name and contact details.
4. Operators who opt to include plant reproductive material or animals or aquaculture juveniles in the systems referred to in paragraphs 2 and 3 shall ensure that the information is updated regularly and that the information is withdrawn from the lists once the plant reproductive material or animals or aquaculture juveniles are no longer available.
5. For the purpose of paragraphs 1, 2 and 3, Member States may continue to use already existing relevant information systems.
6. The Commission shall make public the link to each of the national databases or systems in a Commission dedicated website, thus allowing users to have access to such a data throughout the Union.
7. The Commission may adopt implementing acts
 - (a) to provide technical details for establishing and maintaining the databases referred to in paragraph 1 and the systems referred to in paragraph 2;
 - (b) to provide specifications as regards the collection of data referred to in paragraph 1 and 2;
 - (c) to provide specifications as regards the arrangements for participation in the databases referred to in paragraph 1 and in the systems as referred to in paragraph 4; and
 - (d) to provide details as regards the information to be provided by Member States in accordance with Article 53(5).

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

Article 53

Derogations, authorisations and report

1. The derogations to the use of organic plant reproductive material and of animals, provided in points 1.8.52 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 end 15 years after the date of application.
2. As of 7 years after the date of application, based on the conclusions as regards availability of organic plant reproductive material and animals presented in the report provided for under paragraph 3, the Commission shall be empowered to adopt delegated acts in accordance with Article 54 amending this Regulation as follows:
 - (a) ending at an earlier date or extending the derogations referred to in points in point 1.8.5 of Part I of Annex II and in points 1.3.4.3 and 1.3.4.4 of Annex II, Part II, with the exception of point 1.3.4.4.2 of Part II of Annex II, beyond 15 years after the date of application or;
 - (b) ending the derogation referred to in point 1.3.4.4.2 of Part II of Annex II.

Annex II

Detailed production rules referred to in Chapter III

Part I: Plant production rules

In addition to the production rules laid down in Articles 9 to 12, the rules set out in this Part shall apply to organic plant production.

1. General requirements

(...)

1.8 Origin of plants including plant reproductive material

1.8.1 For the production of plants and plant products other than plant reproductive material, only organic plant reproductive material shall be used.

1.8.2 To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production 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.

1.8.3 When choosing organic plant reproductive material operators shall give preference to organic plant reproductive material suitable for organic agriculture.

1.8.4 For the production of organic varieties, the organic breeding activities shall be conducted under organic conditions and focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.

All multiplication practices except meristem culture shall be under certified organic management.

1.8.5 Use of non-organic plant reproductive material

1.8.5.1 By way of derogation from point 1.8.1, where the data collected in the database referred to in Article 26a(1) or the system referred to in Article 26(2)(a) shows that the qualitative or quantitative needs of the operator regarding relevant organic plant reproductive material, excluding seedlings, are not met, competent authorities may authorise the use of in-conversion or non-organic plant reproductive material under the conditions laid down under points 1.8.5.3 to 1.8.5.4

Prior to requesting any such derogation the operator shall consult the database as referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) in order to verify whether his or her request is justified.

1.8.5.2 For operators in third countries, control authorities or control bodies recognised in accordance with Article 46(1) may authorise the use of in-conversion or non-organic plant reproductive material on an organic production unit, when organic plant reproductive material is not available in sufficient quality or quantity in the territory of the country where the operator is located and under the conditions laid down under points 1.8.5.3 to 1.8.5.4.

1.8.5.3 Non-organic plant reproductive material shall not be treated with plant protection products, other than those authorised for treatment of seed in accordance with Article 24(1) of this Regulation, unless chemical treatment is prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authority of the Member State for all varieties of a given species in the area where the plant reproductive material is to be used.

1.8.5.4 The authorisation shall be granted before the sowing of the crop.

1.8.5.5 The authorisation shall be granted only to individual users for one season at a time and the competent authority responsible for authorisations shall list the quantities of plant reproductive material authorised.

Temporary experiment for the marketing of ‘organic varieties’

Commission declaration

The Commission acknowledges the need to establish conditions under which organic varieties suitable for organic production shall be developed.

For the purpose of establishing criteria for the description of the characteristics of ‘organic varieties suitable for organic production’, as well as defining the conditions under which ‘organic varieties suitable for organic production’ may be produced with a view to marketing and marketed under derogatory conditions, the Commission shall organise at the latest 6 months after the date of application of the present Regulation a temporary experiment.

This temporary experiment will establish adapted criteria for describing the distinctness, uniformity, stability, and, where applicable, the value for cultivation and use of organic varieties suitable for organic production and address other marketing conditions such as labelling and packaging. These conditions and criteria will take into account the specific needs and objectives of organic agriculture such as enhancing genetic diversity, disease resistance and adaptation to soil and climate conditions. Yearly reports will be produced to monitor the progress of the temporary experiment.

In the framework of such an experiment, which shall have a term of seven years and foresee sufficient quantities, Member States may be released from certain obligations laid down in Directive 66/401/EEC, Directive 66/402/EEC, Directive 68/193/EEC, Directive 2002/53/EC, Directive 2002/54/EC, Directive 2002/55/EEC, Directive 2002/56/EEC, Directive 2002/57/EEC, Directive 2008/72/EEC and Directive 2008/90/CE.

The Commission will assess the result of this experiment with a view to propose the adaptation of the requirements of the horizontal legislation on the marketing of seeds and other plant reproductive materials to the characteristics of the ‘organic varieties suitable for organic production’.