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► **B** COMMISSION DELEGATED REGULATION (EU) 2021/1189

of 7 May 2021

supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species

(Text with EEA relevance)

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**COMMISSION DELEGATED REGULATION (EU) 2021/1189****of 7 May 2021****supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species****(Text with EEA relevance)***Article 1***Subject matter**

This Regulation establishes rules concerning the production and marketing of plant reproductive material of organic heterogeneous material within the meaning of Regulation (EU) 2018/848 which are seeds of agricultural and vegetable species, vegetable propagating material other than seeds, propagating material of ornamental plants, vine propagating material and fruit plant propagating material, within the meaning of Directives 66/401/EEC, 66/402/EEC, 68/193/EC, 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.

This Regulation shall not apply to any transfer of limited quantities of plant reproductive material of organic heterogeneous material intended for research on, and development of, organic heterogeneous material.

*Article 2***Definitions**

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

- (1) ‘organic heterogeneous material’ means a plant grouping within the meaning of Article 3(18) of Regulation (EU) 2018/848, which is produced according to the requirements of Article 3(1) of that Regulation;
- (2) ‘parental material’ means any plant material the crossing or propagation of which resulted in organic heterogeneous material;
- (3) ‘small packages’ means packages containing seed up to the maximum quantities provided for in Annex II.

*Article 3***Production and marketing within the Union of plant reproductive material of organic heterogeneous material**

Plant reproductive material of organic heterogeneous material shall only be produced or marketed within the Union, if all of the following requirements are fulfilled:

- (1) it complies with the requirements on:
  - (a) identity, as referred to in Article 5;
  - (b) sanitary and analytical purity and germination, as referred to in Article 6;

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- (c) packaging and labelling, as referred to in Article 7;
- (2) its description includes the elements referred to in Article 4;
- (3) it is subject to the official controls pursuant to Article 9;
- (4) it is produced or marketed by operators who comply with the requirements concerning information in Article 8; and
- (5) it is maintained in accordance with Article 10.

*Article 4***Description of organic heterogeneous material**

1. The description of organic heterogeneous material shall include all of the following elements:

- (a) a description of its characteristics, including:
  - (i) the phenotypic characterisation of the key characters which are common to the material, together with the description of the heterogeneity of the material by characterising the phenotypic diversity observable between individual reproductive units;
  - (ii) documentation of its relevant characteristics, including agronomic aspects such as regards yield, yield stability, suitability for low input systems, performance, resistance to abiotic stress, disease resistance, quality parameters, taste or colour;
  - (iii) any available results from tests concerning the characteristics referred to in point (ii);
- (b) a description of the type of technique used for the breeding or production method of the organic heterogeneous material;
- (c) a description of the parental material used to breed or produce the organic heterogeneous material and own production control programme used by the operator concerned with a reference to the practices as referred to in paragraph (2)(a) and, if applicable, in paragraph 2(c);
- (d) a description of the on-farm management and selection practices with a reference to paragraph 2(b) and, if applicable, of the parental material with a reference to paragraph 2(c);
- (e) a reference to the country of breeding or production, with information on the year of production and description of the pedo-climatic conditions;

2. The material referred to in paragraph 1 may be generated by one of the following techniques:

- (a) crossing of several different types of parental material, using crossing protocols to produce diverse organic heterogeneous material by bulking of the progeny, repeatedly re-sowing and exposing the stock to natural and/or human selection, provided that this material shows a high level of genetic diversity which is in accordance with Article 3(18) of Regulation (EU) 2018/848;

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- (b) on-farm-management practices, including selection, establishing or maintaining material, which is characterized by a high level of genetic diversity in accordance with Article 3(18) of Regulation (EU) 2018/848;
- (c) any other technique used for breeding or production of organic heterogeneous material, taking into account particular features of propagation.

*Article 5***Requirements concerning the identity of seed lots of plant reproductive material of organic heterogeneous material**

Plant reproductive material of organic heterogeneous material shall be identifiable on the basis of all of the following elements:

- (1) the parental material and the production scheme used in the crossing for creation of the organic heterogeneous material, as provided for in Article 4(2)(a) or, if applicable, in Article 4(2)(c), or the history of the material and the on-farm management practices, including whether the selection has occurred naturally and/or through human intervention, in the cases of Articles 4(2)(b) and 4(2)(c);
- (2) the country of breeding or production;
- (3) characterisation of the common key characters and of the phenotypic heterogeneity of the material.

*Article 6***Requirements concerning the sanitary quality, analytical purity and germination of plant reproductive material of organic heterogeneous material**

1. Plant reproductive material of organic heterogeneous material shall comply with the provisions of Regulation (EU) 2016/2031, Commission Implementing Regulation (EU) 2019/2072 <sup>(1)</sup> and the other relevant acts adopted pursuant to Regulation (EU) 2016/2031 concerning the presence, and the measures against, Union quarantine pests, protected zone quarantine pests and Union regulated non-quarantine pests.

2. For the production and marketing of plant reproductive material of organic heterogeneous material of fodder plant species listed in Article 2(1)(A) of Directive 66/401/EEC, the following provisions shall apply:

- (a) point 1 and the last column of the table in point 5 of Annex I to Directive 66/401/EEC, and
- (b) Section I, points 2 and 3 and Section III of Annex II to Directive 66/401/EEC.

3. For the production and marketing of plant reproductive material of organic heterogeneous material of cereal species listed in Article 2(1)(A) of Directive 66/402/EEC, the following provisions shall apply:

<sup>(1)</sup> Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

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- (a) point 1 and the last column of the table in point 6 of Annex I to Directive 66/402/EEC;
- (b) the third, sixth, tenth, thirteenth, sixteenth, twentieth and twenty-first row of the table in point 2(A) and point 2(B) of Annex II to that Directive,
- (c) the last column in the table in point 3 of Annex II to that Directive;
- (d) the third and the sixth row in the table in point 4 of Annex II to that Directive.

4. For the production and marketing of plant reproductive material of organic heterogeneous material of vine within the meaning of Directive 68/193/EEC, the following provisions shall apply:

- (a) Sections 2, 3, 4, 6 and 7 and point 6 of Section 8 of Annex I to Directive 68/193/EEC;
- (b) Annex II to Directive 68/193/EEC, with the exception of point 1(1).

5. For the production and marketing of plant reproductive material of organic heterogeneous material of ornamental plants within the meaning of Directive 98/56/EC, Article 3 of Directive 93/49/EEC <sup>(1)</sup> shall apply.

6. For the production and marketing of plant reproductive material of organic heterogeneous material of beet within the meaning of Directive 2002/54/EC, points A(1), B(2) and B(3) of Annex I to that Directive shall apply.

7. For the production and marketing of plant reproductive material of organic heterogeneous material of vegetable species listed in Article 2(1)(b) of Directive 2002/55/EC, points 2 and 3 of Annex II to that Directive shall apply.

8. For the production and marketing of plant reproductive material of organic heterogeneous material of seed potatoes within the meaning Directive 2002/56/EC, the provisions for the lowest category of seed potatoes in point 3 of Annex I and in Annex II shall apply.

9. For the production and marketing of plant reproductive material of organic heterogeneous material of oil and fibre plants as listed in Article 2(1)(b) of Directive 2002/57/EC, the following provisions shall apply:

- (a) point 1 and the last column of the table in point 4 of Annex I to Directive 2002/57/EC;
- (b) the table in point I(4)(A) of Annex II, except the requirements for basic seed of *Brassica* ssp. and *Sinapis alba*, and the last column of the table in point I(5) of Annex II to Directive 2002/57/EC.

<sup>(1)</sup> Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC (OJ L 250, 7.10.1993, p. 9).

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10. For the production and marketing of organic heterogeneous vegetable propagating and planting material, other than seed within the meaning of Directive 2008/72/EC, Articles 3 and 5 of Commission Directive 93/61/EEC <sup>(1)</sup>, shall apply.

11. For the production and marketing of plant reproductive material of organic heterogeneous fruit plant propagating material and fruit plants intended for fruit production within the meaning of Directive 2008/90/EC, the following provisions shall apply:

- (a) Article 23, except point (1)(b), Articles 24, 26, 27 and 27a of Commission Implementing Directive 2014/98/EU <sup>(2)</sup>;
- (b) Annexes I, II and Annex III and the requirements concerning CAC material in Annex IV to Implementing Directive 2014/98/EU.

12. Paragraphs 2 to 11 shall only apply with regard to the analytical purity and germination requirements for seed and the quality and health requirements for other propagating material, but not with regard to varietal identity and varietal purity and field inspection requirements for varietal identity and varietal purity of the plant reproductive material of organic heterogeneous material.

13. By way of derogation from the provisions of paragraphs 1 to 12, operators may place on the market seed of organic heterogeneous material, which does not satisfy the conditions with respect to germination, provided that the supplier indicates the germination rate of the seed concerned on the label or directly on the package.

**▼C1***Artikel 7***Requirements concerning packaging and labelling of plant reproductive material of organic heterogeneous material****▼B**

1. Plant reproductive material of organic heterogeneous material not contained in small packages shall be contained in packages or containers, which are closed in such a manner that they cannot be opened without leaving evidence of tampering on the package or container.

2. The operator shall affix on packages or containers of seeds or plant reproductive material of organic heterogeneous material a label in at least one of the official languages of the Union.

That label shall:

- (a) be legible, printed or written on one side, unused and easily visible;
- (b) include the information set out in Annex I to this Regulation;
- (c) be yellow with a green diagonal cross.

<sup>(1)</sup> Commission Directive 93/61/EEC of 2 July 1993 setting out the schedules indicating the conditions to be met by vegetable propagating and planting material, other than seed pursuant to Council Directive 92/33/EEC (OJ L 250, 7.10.1993, p. 19).

<sup>(2)</sup> Commission Implementing Directive 2014/98/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections (OJ L 298, 16.10.2014, p. 22).

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3. Instead of a label, the information set out in Annex I may be directly printed or written on the package or the container. In that case, point 2(c) shall not be applicable.
4. In the case of small, transparent packages, the label may be placed inside the package provided it is clearly legible.
5. By way of derogation from paragraphs 1 to 4, seed of organic heterogeneous material contained in closed and labelled packages and containers may be sold to final users in unmarked and unsealed packages up to the maximum quantities provided for in Annex II, provided that, on request, the purchaser is informed in writing at the time of delivery about the species, the denomination of the material and the reference number of the lot.

*Article 8***Requirements concerning information to be kept by operators**

1. Any operator producing or marketing plant reproductive material of organic heterogeneous material shall:
  - (a) keep a copy of the notification submitted in accordance with Article 13(2) of Regulation (EU) 2018/848, a copy of the declaration submitted under Article 39(1)(d) thereof and, where applicable, a copy of the certificate received in accordance with Article 35 thereof;
  - (b) ensure the traceability of the organic heterogeneous material in the production scheme as provided for in Article (4)(2)(a) or, if applicable, in Article (4)(2)(c) by keeping information allowing to identify the operators which have supplied parental material of organic heterogeneous material.

The operator shall keep those documents for 5 years.

2. The operator producing plant reproductive material of organic heterogeneous material intended for marketing shall also record and keep the following information:
  - (a) name of the species and denomination used for each notified organic heterogeneous material; type of technique used for the production of organic heterogeneous material as referred to in Article 4;
  - (b) characterisation of the notified organic heterogeneous material as provided for in Article 4;
  - (c) location of breeding of organic heterogeneous material and location of production of organic plant reproductive material of the organic heterogeneous material as provided for in Article 5;
  - (d) surface area for the production of organic heterogeneous material and quantity produced.

3. The responsible official bodies in accordance with 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 shall have access to the information referred to in paragraphs 1 and 2 of this Article.



#### *Article 9*

##### **Official controls**

The competent authorities of the Member States or the delegated bodies, where the competent authorities have delegated control tasks in accordance with Chapter III of Title II of Regulation (EU) 2017/625, shall carry out risk-based official controls in relation to the production and marketing of plant reproductive material of organic heterogeneous material to check compliance with the requirements of Articles 4, 5, 6, 7, 8 and 10 of this Regulation.

The testing of germination and analytical purity shall be carried out in accordance with the applicable methods of the International Seed Testing Association.

#### *Article 10*

##### **Maintenance of organic heterogeneous material**

Where maintenance is possible, the operator who has notified the organic heterogeneous material to the competent authorities pursuant to Article 13 of Regulation (EU) 2018/848, shall preserve the main characteristics of the material at the time of its notification, by maintaining it as long as it remains on the market. That maintenance shall be undertaken according to accepted practices adapted to the maintenance of such heterogeneous material. The operator responsible for the maintenance shall keep records of duration and content of maintenance.

At all times, the competent authorities shall have access to all records kept by the operator responsible for the material, in order to check its maintenance. The operator shall keep those records for 5 years after the moment the plant reproductive material of organic heterogeneous material is not marketed anymore.

#### *Article 11*

##### **Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from 1 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States





## ANNEX I

## INFORMATION TO BE SET OUT ON THE LABEL OF THE PACKAGES AS PROVIDED FOR IN ARTICLE 7(2)(b)

- A. The label shall include the following information:
1. the denomination of the heterogeneous material, together with the phrase ‘Organic heterogeneous material’;
  2. ‘Union rules and standards’;
  3. the name and address of the professional operator responsible for affixing the label, or its registration code;
  4. country of production;
  5. reference number given by the professional operator responsible for affixing the labels;
  6. month and year of closing, following the term: ‘closed’;
  7. species, indicated at least under its botanical name, which may be given in abridged form and without the authors names, in roman characters;
  8. declared net or gross weight, or declared number in case of seeds, except for small packages;
  9. where weight is indicated and pelleting substances, or other solid additives are used, the nature of the additive and also the approximate ratio between the weight of pure seeds and the total weight;
  10. information on the plant protection products applied to the plant reproductive material as required under Article 49(4) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(1)</sup>;
  11. the germination rate where, pursuant to Article 6(13) of this Regulation, organic heterogeneous material does not satisfy the conditions with respect to germination.
- B. The denomination referred to in point A.1. shall not cause its users difficulties as regards recognition or reproduction and shall not:
- (a) be identical or likely to be confused with a denomination under which another variety or organic heterogeneous material of the same or of a closely related species is entered in an official register of plant varieties or a list of organic heterogeneous material;
  - (b) be identical or likely to be confused with other designations which are commonly used for the marketing of goods or which have to be kept free under other legislation;
  - (c) mislead or cause confusion concerning the characteristics, the value or the identity of the organic heterogeneous material, or the identity of the breeder.

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<sup>(1)</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).



## ANNEX II

MAXIMUM QUANTITIES OF SEED IN SMALL PACKAGES AS REFERRED TO IN ARTICLE 7(5)

Species	Maximum net mass of the seed (kg)
Fodder plants	10
Beet	10
Cereals	30
Oil and fibre plants	10
Seed potatoes	30
Vegetable seed:	
Legumes	5
Onions, chervil, asparagus, spinach beet or chard, red beet or beetroot, turnips, water melon, gourd, marrows, carrots, radishes, scorzonera or black salsify, spinach, corn-salad or lamb's lettuce	0,5
All other vegetable species	0,1