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Seeds in the new EU Organic Regulation

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After more than three years of work and eighteen triologue negotiations, the European Commission, the Presidency of the Council and the European Parliament have finally reached agreement on new rules for organic production. The new EU Organic Regulation was approved by the AGRI Committee of the European Parliament and the Special Committee on Agriculture of the Council in November 2017. The text is now being translated into all the official languages of the European Union. It is expected that the Regulation will be officially adopted by the plenary of the European Parliament and the Council of Agriculture Ministers in April 2018. The new Regulation will be **applicable from 1 January 2021**.

In this note, we outline only the **provisions that impact the availability and marketing of seeds and plant reproductive material (PRM)**. The most welcome development is that “organic heterogeneous material” may, from 2021, be marketed in the organic sector without being a registered variety, but following a relatively simple prior notification to the national authority. These provisions should open the door to: (i) the marketing of a much wider variety of seeds and PRM on the market, thereby increasing the use of agro-biodiversity in agriculture; and (ii) a rise in the supply of organic seeds, reducing the widespread dependency on non-organic seeds and PRM in the organic sector.

The text of the Regulation itself is fixed. However, the European Commission has received the power to prepare several Delegated Acts and Implementing Acts that could determine how these provisions work in reality. **It is vital that these Acts, which are not compulsory, are not adopted unless developments on the ground create a necessity to guide the market. If such Acts are ever to be adopted, they have to be practicable and proportionate to ensure that the new seed provisions retain maximum impact on liberating crop diversity.**

1. Different types of organic seeds

The new Regulation creates two new categories of seeds that organic farmers may access, use, and/or market themselves. First, it creates the new category of “organic heterogeneous material” (**HM**). This material does not consist of plant varieties as defined in the UPOV/CPVO system or mixtures of such varieties, but rather refers to what are generally understood as populations or diversified genetic material. PRM needs to fulfil all the cumulative criteria set out in the Regulation to be considered as organic HM:

Article 1§18 (organic heterogeneous material)

“A plant grouping within a single botanical taxon of the lowest known rank which:

- a) Presents common phenotypic characteristics.*
- b) Is, however, characterized 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)¹ of Council Regulation (EC) No 2100/94*
- d) *Is not a mixture of varieties*
- e) *Has been produced in accordance with the requirements of this Regulation.”*

Second, the Regulation establishes “organic varieties suitable for organic production” (OV). Organic varieties are plant varieties as defined in the UPOV/CPVO system, developed as a result of targeted breeding efforts, which have to be undertaken under organic conditions from the outset. They are as a result varieties that are more tailored for organic agriculture, taking greater account of local agro-ecological conditions and are therefore not as distinct and uniform as their counterparts used in conventional agriculture. OV need to fulfil all the cumulative criteria set out in the Regulation:

Article 1519 (organic varieties)

- a) *A variety within the meaning of Article 5(2) of Regulation (EC) No 2100/94² which:*
- b) *Is characterized by a high level of genetic and phenotypical diversity between individual reproductive units.*
- c) *Results from organic breeding activities referred to in Annex II, Part I, point 1.8.4.”*

Organic breeding activities have been defined in the Annexes of the Regulation. Unfortunately, this definition leaves some ambiguity regarding the possibility to use techniques that are not accepted by the organic community, such as gene editing, but it has the benefit of being included and recognised in the text.

Annex II, Part I, point 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.

Diversity benefit The: Regulation recognises the shortcomings of the usual definition of “plant variety” (taken from an intellectual property rights regime) to the needs and efforts of organic farmers and plant breeders, who develop and use less uniform varieties, tailored for local or regional agro-ecological conditions and adapted to the needs of low-input agriculture.

2. Specific provisions on marketing of organic heterogeneous material

The new Regulation provides for revised rules on the marketing of seed and PRM in organic production, parallel to the “mainstream” rules that are applicable to the marketing of seeds in the European Union (variety registration). The rationale for this new approach is set out in the Regulation’s preamble:

(Preamble §37) 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

¹ Regulation No 2100/94 is the EU Regulation on plant variety protection; Article 5 concerns the definition of a variety: “a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be defined by the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged”.

² See footnote 1.

categories, as set out in Council 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, following a notification to the responsible bodies referred to in those Directives and, once the Commission has adopted harmonized requirements, provided that such material complies with those requirements.

A quite simple notification procedure has been established for the marketing and sale of organic heterogeneous material:

Article 13

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/EC³ 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 HM.

³ These Directives set out the principles of marketing of seeds and PRM, each relate to different species, i.e. vegetable, beet, potatoes, fodder, cereals, ornamentals, forest, and fruit trees. They set out variety registration criteria usually based on DUS, but also detailed labelling and quality control rules.

As the new marketing rules take the form of a Regulation, they are directly applicable in all EU Member States, i.e. the rules do not need to be transposed into national legislation. They will automatically enter into force on 1 January 2021 and exist hand in hand with national laws regulating variety registration prior to the marketing of seeds and PRM.

Diversity benefit: The right to market HM in itself and the relaxed nature of the marketing procedure will be extremely beneficial for the wider and sustainable use of crop biodiversity, as a greater range of genetic diversity will find its way to the market and to the fields. It will also increase the availability of organic plant reproductive material for farmers. These benefits might however be limited by the intervention of the European Commission, which may (or may not) produce a delegated act setting out further detail on the notification procedure; a procedure that is currently fairly straightforward.

3. Temporary experiment for the marketing of organic varieties

The Regulation does not set up a specific regime for the marketing of organic varieties, which will have to follow applicable European and national rules. However, it does recognise the limitation of these rules for OV, and thus provides for a seven-year temporary experiment allowing for their more relaxed marketing. In the experiment, the specific characteristics of OV will be evaluated and serve as the basis for subsequent adaptation of the horizontal legislation on the marketing of seeds for OV. This kind of experiment has already been running in relation to cereals with some success in the countries that chose to participate (UK, DE, DK, NL, IT and FR). While there is no formal obligation for the European Commission to start this experiment, it has already committed itself in its public statements to propose the experiment when the Regulation is formally adopted.

***Preamble, §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.*

Diversity benefit: The fruits of organic breeding are finally recognised as needing a specific regulatory space, which acknowledges the inadequacy of traditional variety registration rules for the organic sector. Crop biodiversity will definitely benefit from the temporary experiment to allow for easier market entry for organic varieties, and potentially, subject to the outcome of the experiment, also in the long-term benefit from the establishment of adapted criteria that could be taken up by seed marketing legislation EU-wide. With this in mind, it is vital to ensure that the temporary experiment happens and does so in an early, swift and efficient manner.

4. Databases on the availability of organic seeds and PRM

Next to the new seed categories, the Regulation also requires the establishment of national databases on the availability of organic seeds, which must be accessible free of charge to seed suppliers and users in all EU Member States. Member States will be responsible for establishing and regularly updating the databases.

(Preamble, §105) *In view of the phasing out of derogations to the use of non-organic plant reproductive material, non-organically reared poultry and non-organic livestock for breeding purposes, the Commission should consider the situation of the availability of such material in the Union. To this 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, the Commission should present, five years after the entry into application of this Regulation, 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.*

Article 26: Collection of data concerning the availability on the market of organic and in-conversion PRM, organic animals and organic aquaculture juveniles

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.

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.

Diversity benefit: Databases on the availability of organic seed and PRM do exist today, but their quality differs highly from one Member State to another. This provision, and the requirement for the Commission to report in 2026 on the availability of organic material and the reasons behind limited availability of organic seed and PRM, should help to tackle the systemic factors currently hindering the use of organic seeds and PRM.

5. Provisions on the origin of seeds & PRM in the organic sector

The new Regulation sets up a rule that “truly” organic seed and PRM, i.e. HM and OV, should be given clear preference in organic production, and limits the exemption allowing the use of conventional seeds to markets that are not mature or wide enough and cannot supply enough organic seeds. The aforementioned new databases will enable authorities and farmers to more easily assess the nature and configuration of the markets.

(Annex II §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 authorize 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 recognized in accordance with Article 46(1) may authorize 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.

The new Regulation also specifically provides that organic farmers are entitled to use seed and PRM saved in their own farms without having to worry about stringent regulatory requirements (except if the variety is protected by plant variety rights). If this material is protected by plant variety protection (also called breeders' rights), then stricter rules may apply, which may include monetary compensation for the use of the protected variety:

Article 6

“Organic production shall in particular be based on the following specific principles: [...]

i) Without prejudice to Article 14 of Regulation (EC) No 2100/94 [note from author: which sets out the conditions of use of farm saved seeds with regards to a variety protected by plant variety protection] 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”.

Diversity benefit: Through production rules that favour PRM suitable for organic production, and the possibility to use farm-saved-seeds, the recourse to conventional seeds in organic agriculture should significantly decrease in maturing markets, and in time have a true chance of disappearing altogether. Without question, provisions offering preferential treatment to PRM suitable for organic

production should be interpreted as designating HM and OV, and not plant varieties developed for the needs of conventional agriculture but multiplied under organic conditions.

6. Provisions for small operators

The new Regulation recognises the role of small actors, especially local traders who also offer unpacked products for the organic system, and thus provides for a certain degree of flexibility in the implementation of its provisions. Most notably, the Regulation allows Member State to adopt derogations for the direct sale of unpacked products by small traders, who would as a result not need to go through the stringent and costly certification procedure before selling products directly to the final consumer. It is important to understand that this derogation does not apply to the products sold, but to the traders selling these products. It can therefore be used to strengthen small local actors in the food supply chain. If there is no obligation for packaging and sealing of HM stemming from a Delegated Act, this derogation would also apply to the sale of such kind of unpacked seeds.

Article 35§8 (Certificate)

Member States may exempt from the obligation to be in the possession of a certificate, as referred to in paragraph 2, operators who sell directly to the final consumer unpacked organic products other than feed: (a) up to 5000 kg per year, or (b) representing an annual turnover not exceeding 20 000 EUR on unpacked organic products, or (c) with a potential certification cost exceeding 2% of the total turnover on unpacked organic products, provided that those operators do not produce, prepare or store such products other than in connection with the point of sale, do not import such products from a third country or have not subcontracted such activities to a third party.

In case MS decide to exempt the operators referred to in the 1st subparagraph, they may set lower limits than those set in the 1st subparagraph. MS shall inform the Commission and the other MS of their decision to exempt operators as referred to in the 1st subparagraph and on the limits up to which such operators are exempted.

Diversity benefit: Through this derogation, small operators involved in short supply chains may not have to go through costly certification procedures, thus potentially increasing their numbers, and through that offering more opportunities for the sustainable use of crop biodiversity.

The Regulation also allows for the so-called group certification of farmers or operators, who are too small to bear the cost of certification alone. The conditions that a group of operators need to fulfil in order to have access to certification and thus the organic market are detailed in the Regulation, but the European Commission has the power to modify or develop them further.

Article 36 Group of operators

1. Each group of operators shall:

(a) only be composed of farmers or operators producing algae or aquaculture animals and who in addition may be engaged in processing, preparation or marketing of food or feed;

(b) only be composed of members:

(i) of which the individual certification cost represents more than 2 % of its turnover or standard output of organic production and whose annual turnover of organic production is not more than 25 000 EUR or whose standard output from of organic production is not more than 15 000 EUR per year; or

(ii) which have each holdings of maximum: – 5 hectares, or – 0,5 hectares, in the case of greenhouses, or – 15 hectares, exclusively in the case of permanent grassland;

(c) be established in a Member State or a third country;

(d) have legal personality;

(e) only be composed of members whose production activities take place in geographical

proximity to each other;

(f) set up a joint marketing system for the products produced by the group; and

(g) establish a system for internal controls comprising a documented set of control activities and procedures, in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group.

2. Deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address noncompliance by individual members of the group of operators that affect the integrity of organic and in-conversion products, shall result in the withdrawal of the certificate referred to in Article 35 for the whole group.

Diversity benefit: Much like the derogation to market unpacked products directly and without certification, these provisions will allow smaller entities, such as fruit orchard owners or small farmers, to be certified and so market their products as organic, increasing the area where organic agriculture is practised and ensuring the diversity of actors involved in it. The European Commission has the power to modify and develop these provisions⁴, and therefore the power to assist and truly make groups of operators a reality on the ground.

⁴ Article 36 §3 *“The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 1 and 2 of this Article by adding provisions, or by amending those added provisions, in particular as regards: (a) the responsibilities of the individual members of a group of operators; (b) the criteria to determine the geographical proximity of the members of the group, such as the sharing of facilities or sites; (c) the set-up and functioning of the system for internal control, including the scope, content and frequency of the controls to be carried out and the criteria to identify deficiencies in the set-up or functioning of the system for internal controls.*

§4. The Commission may adopt implementing acts laying down specific rules concerning: (a) the composition and dimension of a group of operators; (b) the documents and record keeping systems, the system for internal traceability and the list of operators; (c) the exchange of information between a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55(2).