



**Plant Reproductive Material  
in the new Organic Regulation (EU) 2018/848**

IFOAM EU position paper

May 2019

Organic farming needs more diverse organic Plant Reproductive Material (seeds and vegetative propagation material), and harmonised and true access to a wider range of cultivars adapted to regional climatic and organic growing conditions. The possibilities in the new Organic Regulation (EU) [2018/848](#) are an important step towards the increase and diversification of the seeds and other plant reproductive material available for organic farmers, but all depends on the implementations of the new provisions. On the other hand, there have been only limited improvements on the derogation process on the use of organic seed, and additional rules are needed to ensure the phasing out of the use of conventional untreated seed.

With this position paper, IFOAM EU intends to highlight the areas of the basic text of the new Organic Regulation that require more attention and possible actions.

IFOAM EU would like to provide recommendations on the future implementation of the new Organic Regulation, be it through delegated & implementing acts or interpretation notes and guidelines.

## Overview: Categories of Plant Reproductive Material available for Organic Farming

According to IFOAM EU, the new Organic Regulation defines different options for Plant Reproductive Material (PRM) available for organic farmers:

1. **Organic PRM**
  - a. organic varieties suitable for organic production multiplied under organic conditions (Article 6 (g))
  - b. organic heterogeneous material multiplied under organic condition (Article 6 (g))
  - c. farm saved seed for own use multiplied under organic condition (Article 6 (i))
  - d. conventional varieties multiplied under organic conditions (Annex II, Part I, 1.8.2)
2. **In-conversion PRM**, when a derogation is granted (Annex II, Part I, 1.8.5.1).
3. **Untreated conventional PRM**, when a derogation is granted. Derogation for the use of treated Plant Reproductive Material can be granted if chemical treatment has been prescribed by authorities for phytosanitary purposes (Annex II, Part I, 1.8.5.3).

## Organic Heterogeneous Material – Articles 3(18) and 13

The recognition that organic heterogeneous material (OHM) can be marketed and used by organic farmers is a good step forward, as it will increase the availability of plant genetic resources suited to organic farming. This new category is important for the organic agriculture as OHM are better adapted to organic farming systems and have a better capacity to adjust to climate change.

Organic Heterogeneous Material in compliance with Article 3(18) of Regulation (EU) 2018/848, means material with a high level of genetic diversity, intended for the market and for which DUS criteria<sup>1</sup> are not applicable. OHM as defined in the Regulation (EU) 2018/848 is not congruent to the former description of [Commission Implementing Decision 2014/150/EU](#), on the organisation of a temporary experiment providing for certain derogations for the marketing of populations of the plant species wheat, barley, oats and maize pursuant to Council Directive 66/402/EEC. According to IFOAM EU, OHM

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<sup>1</sup> DUS criteria assess Distinctness, Uniformity and Stability (cf Directive 2003/90/EC).

includes Organic Farmers selections, Organic Dynamic populations and Organic Composite Cross populations. A detailed description of these three categories is provided in Fig. 1.

The diversity in different types of OHM is important. Many of these have long traditions (farmers' selections and heirloom cultivars) and are of great value in terms of the dynamic utilization and conservation of biodiversity. Dynamic populations, outcrossing as well as composite cross populations are of great importance for breeding of organic crops. Several new and highly innovative breeding approaches offer great potential for the development of resilient OHM particularly suitable for organic growing conditions.

According to the new Organic Regulation, OHM must be '*produced in accordance with*' the Regulation. For IFOAM EU, '*production*' includes two steps:

- production of OHM meaning the development (human or natural selection) of the genetic material;
- production of PRM meaning the multiplication of seeds from the genetic material.

Increased diversity is needed for organic farming systems as it can improve performance and yield stability (Ceccarelli et al. 2010; Raggi et al. 2017). Results from EU research projects on heterogeneous material (e.g. SOLIBAM, COBRA, DIVERSIFOOD, INSUSFAR) show the potential benefits of such heterogeneous material with respect to resilience to stress conditions in the field. Experiences from different countries (e.g. the Netherlands, Italy, UK) show that heterogeneous material adapts to the local environmental conditions over time and thus, can have a different appearance than initially described.

### **IFOAM EU recommendations regarding delegated acts on OHM - article 13(3)**

The process of notification for OHM should be kept simple and easy and be accessible also for smaller breeders. The description of OHM should be based on traceability, breeding history and seed production processes and performance characteristics. It must not be based on the usual DUS parameters used for variety registration in the seed catalogue (see Fig. 1 below).

Since the aim of using heterogeneous material is to have evolving populations, the description provided for the notification should be based on:

- the information on parental line(s) or populations (pedigree),
- the history of the population (including potential breeding steps such as crossing design and/or natural and manmade selection) which lasts at least 3 years for annual and 5 years for biennial/perennial crops under certified organic conditions,
- the selection sites (including pedoclimatic conditions, years, region and country).
- additional descriptions of phenotypic gradual uniformities or frequencies, based on a few typical characteristics, which are relevant for organic farmers, (i.e. ripening time, resistance level, food quality) and purpose of OHM (i.e. suitability for high or less fertile soils, for fresh or industry markets, etc.).

The organic farming management in the different generations is crucial because it ensures both i) the adaptation of the population to organic conditions; ii) the traceability of the process through the organic control and certification system. Indeed, the traceability of the evolution and multiplication of such heterogeneous material can be guaranteed by the organic control and certification system, which is also process-based and which allows traceability and transparency on the amount of seed produced from certain heterogeneous material as area of OHM are indicated in the organic certification. Thanks to the process-based organic control system, fraud (i.e. by just mixing conventional varieties and grow them one generation under organic conditions) can be ruled out. Organic controls also allow to estimate the potential PRM derived from a given OHM from the supplier, on the basis of the field size of OHM under organic cultivation.

OHM should be subject to mandatory labelling: breeding methods, date and site (region and country) of multiplication, name of the multiplier, and germination rate. Description of OHM provided during notification should be made publicly available.

It is also important to extend soon the existing temporary experiment on heterogeneous materials to all crop groups (e.g. vegetables, forage crops, grain legumes) as well as to Organic Farmers selections, Organic Dynamic populations to be ready for practical implementation by 2021. To speed up this process financial resources should be made available for organic breeders and farmers organisations in collaboration with examination offices to conduct such trials and develop crop specific protocols. There should also be close collaboration with the upcoming EU Horizon 2020 Project on Innovations in variety testing starting in 2019.

OHM should have to be developed for at least 3 to 5 years (for annual and biennial/perennial crops respectively) under conditions subject to the organic control system. This is a minimum duration to have material adapted to organic agriculture and tools for traceability. Production of PRM (i.e. seed multiplication or production of vegetative planting material) of OHM must also be conducted under agriculture subject to the organic control system. Considering the evolving nature of heterogeneous material, development and multiplication are not necessarily distinct. In any case before marketing, OHM must be subject to 3 to 5 years of management under organic conditions, depending on the crops. When maintenance is required, it shall be undertaken under organic conditions.

Breeding methods used to develop OHM have to comply with the organic regulation and with organic principles, guided by the [IFOAM breeding standard](#). Therefore, the use of GMOs, of transgenesis and new genetic engineering techniques must be excluded. OHM must be freely reproducible by the end-user (no legal or technical barriers). Thus, OHM shall not be protected by Plant Variety Protection or any patents.

Within the H2020 research project LIVESEED, guidelines will be developed on how to describe OHM. Knowledge from a broad range of EU member states (e.g. UK, France, Italy, Netherlands, Denmark, Germany) and crops (durum and soft wheat, barley, and maize) will be collected and analysed to provide procedures that can be useful for the work of the Commission and national authorities. However, there is no funding for experimental trials available at the moment. Therefore, additional funding is needed to foster the implementation of marketing OHM. In addition, the notification requirements for OHM needs to be kept simple and not too expensive to avoid unnecessary obstacles for breeders including farmer breeders.

# ORGANIC HETEROGENEOUS MATERIAL

This document details the position of IFOAM EU regarding the definition of Organic Heterogeneous Material in compliance with the definition of Regulation 2018/848, Article 3, 18:

'means a plant grouping within a single botanical taxon of the lowest known rank which:

- (a) presents common phenotypic characteristics;
- (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that 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 (1);
- (d) is not a mixture of varieties; and
- (e) has been produced in accordance with this Regulation;'

OHM concerns material with a lot of genetic diversity, intended for the market and which is not covered by DUS.

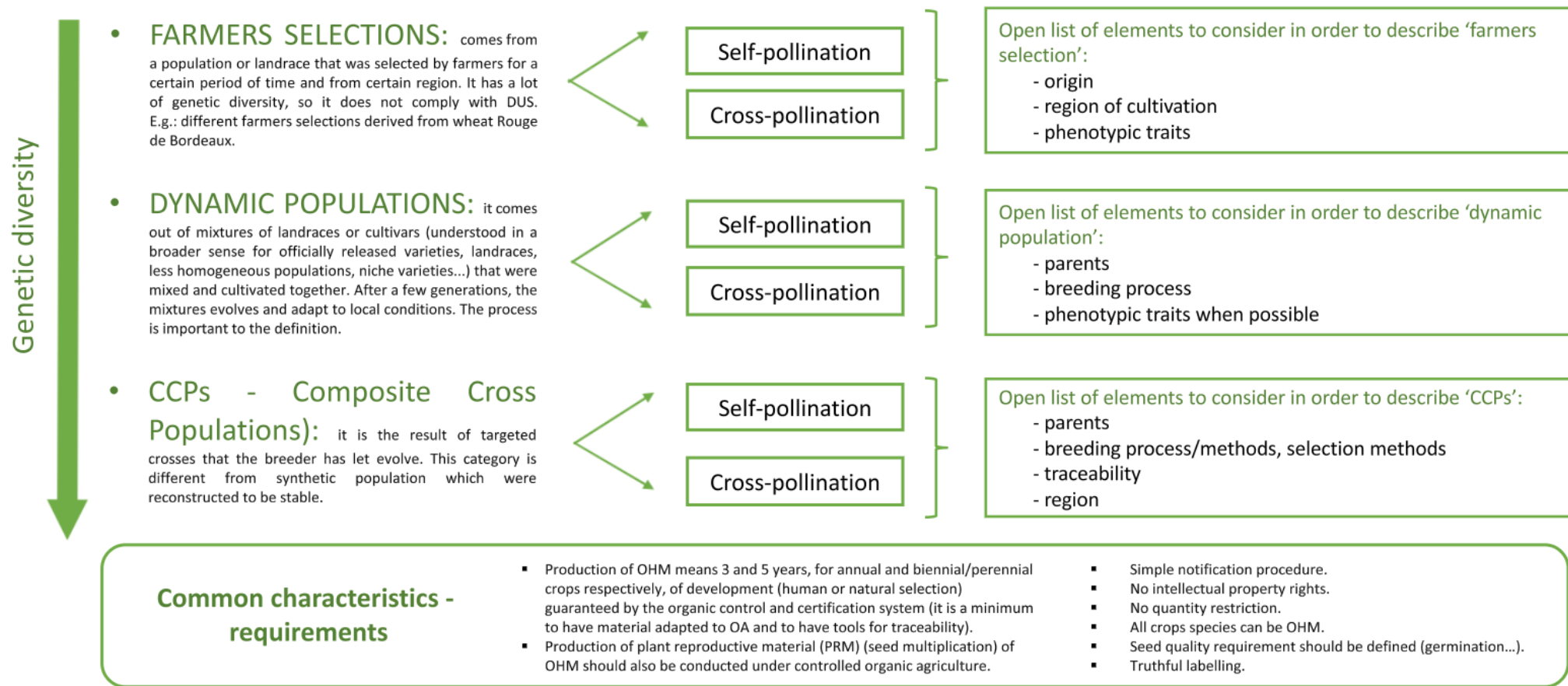


Figure 1: Description of Organic Heterogeneous Material in compliance with Article 3.18 of Regulation 2018/848 including Organic Farmers selections, Organic Dynamic populations and Organic Composite Cross populations

## Organic varieties suitable for organic production - Art. 3(19), Rec. 39

Organic breeders aim to breed varieties that are optimally adapted to organic growing conditions and that can be reproduced as farm saved seed. This includes inbred lines and open pollinated cultivars—depending on the biology of the species and market demand. Based on the nature of outcrossing species, open pollinated cultivars will never reach the same level of homogeneity as F1 hybrids derived from crosses of two inbred lines. Actually, organic breeders try to maintain a certain level of genetic diversity to avoid inbreeding depression and to create more robust (adaptive and flexible) varieties. Those open pollinated organic varieties are less homogenous and often do not comply with the criteria set out in the current EU horizontal legislation on the marketing of seeds, in particular with the uniformity criteria of the DUS registration. For arable crops the cultivar also needs to pass the national thresholds defined for the value for cultivation and use (VCU). Here the organically bred cultivars are discriminated, as these VCU tests are in most cases performed under conventional farming systems. Adjusted DUS and VCU criteria are therefore needed for organic varieties suitable for organic production.

### IFOAM EU recommendations

IFOAM EU is looking forward to the planned 7-year temporary experiment, to be conducted by DG SANTE to foster research and development of organic varieties. Incentives and financial support are needed from national and European authorities for the experiment. This experiment should include a broad range of crops, especially vegetables, legumes and arable crops. The organic movement is willing to contribute to the preparation of the experiment with technical input from the European Consortium for Organic Plant Breeding (ECO-PB) and research outcomes from the H2020 LIVESEED project.

IFOAM EU has already identified that it is necessary to adapt the protocols for variety registration:

- For DUS registration, use less parameters for uniformity and stability
- Include parameters relevant for organic agriculture
- Work with trait frequencies instead of qualitative parameters (yes or no)
- Set up a network of testing sites managed under organic conditions to assess VCU for organic varieties of arable crops in their target environment.
- Adapt parameters and thresholds for organic VCU testing

In the temporary experiment adapted DUS protocols should be developed for the main crops as soon as possible. Within the 7 years, adapted protocols should be established for nearly all crops and species. To achieve a successful implementation and uptake of the experiment, incentives and financial support are needed to stimulate national authorities and breeders to participate. Timely start of the experiment is needed to collect sufficient knowledge and expertise within the timeframe of 7 years to draw conclusions for permanent implementation to ease the registration of organic varieties.

We propose that DG SANTE in cooperation with DG Research set up a similar research scheme as was successfully done for the implementation of conservation varieties: “Farm Seed Opportunities (FSO), a research project in the FP6 European Research Framework (2007-2009) targeted to support the implementation of seed regulations on conservation varieties (directive 98/95/EC and new directives 2008/62/EC, 2009/145/EC and 2010/60/EC) and to propose complementary seed regulation scenarios taking into account the diversity of the European seed systems”<sup>2</sup>.

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<sup>2</sup> [http://www.farmseed.eu/Farm\\_Seed\\_Opportunities/home.html](http://www.farmseed.eu/Farm_Seed_Opportunities/home.html)

## Breeding techniques (Art. 6, Annex II Part I point 1.8.4)

The principles specified in Article 6 (f) of the new Organic Regulation emphasize the importance for organic operators to use plant varieties focusing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and to choose varieties from breeding processes that respect natural crossing barriers. Article 6 (h) states that production of organic varieties shall focus on the containment within natural crossing barriers.

These references to the respect of “natural crossing barriers” reflect the definition of genetically modified organisms (GMOs) in Directive 2001/18/EC on the deliberate release of GMOs into the environment (Article 2.2. “*genetically modified organism (GMO)*’ means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”) and underline that the use of all genetic engineering techniques, old and new, is excluded from organic plant production and from organic plant breeding activities as defined by the decision of the European Court of Justice released on 25 July 2018. Therefore, such techniques are also forbidden in the development of OHM and Organic varieties suited for organic production.

### IFOAM EU recommendations

On 25 July 2018<sup>3</sup>, the European Court of Justice (ECJ) released a decision which clarifies the legal status of some new genetic engineering techniques from mutagenesis: techniques/methods of mutagenesis that have been developed after the adoption of the GMO legislation (Directive 2001/18) and which do not have a ‘long safety record’ are within the scope of the EU legislation on GMOs.

The ECJ clarified that new genetic engineering techniques used for plant (and animal) breeding, developed after 2001 and with no long safety record, fall under the scope of the EU legislation on GMOs (Directive 2001/18 and Regulation 1829/2003). IFOAM EU welcomed this clarification, as there are no scientific or legal reasons why these new techniques could be excluded from the scope of the GMO legislation. The Commission should urgently take the necessary steps to ensure that this ECJ decision is effectively and properly implemented.

All these new genetic engineering techniques should be subject to a risk assessment and to mandatory traceability and labelling requirements. It is of crucial importance for the organic sector that no new cultivars derived from genetic engineering techniques are marketed before appropriate detection methods and surveillance tools have been made available. The Commission should fund research projects to develop reliable detection methods and approaches for products obtained through these new genetic engineering techniques.

IFOAM Organics International adopted a [position paper](#) that clarifies the criteria to judge which breeding techniques can be used in organic production, and in organic breeding. All technologies that interfere at the sub-cellular and genomic level are considered by the organic sector as incompatible with the principles of organic agriculture, as the integrity of the cell is not respected<sup>4 5</sup>.

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<sup>3</sup> [European Court of Justice, Confédération Paysanne and others, 25 July 2018, C-528/16.](#)

<sup>4</sup> Position of IFOAM EU:

[http://www.ifoam-eu.org/sites/default/files/ifoameu\\_policy\\_npbt\\_position\\_final\\_20151210.pdf](http://www.ifoam-eu.org/sites/default/files/ifoameu_policy_npbt_position_final_20151210.pdf)

<sup>5</sup> Position of IFOAM Organics International:

[https://www.ifoam.bio/sites/default/files/position\\_paper\\_v01\\_print\\_ca\\_0.pdf](https://www.ifoam.bio/sites/default/files/position_paper_v01_print_ca_0.pdf)

## Database for organic Plant Reproductive Material (Article 26)

National databases for organic PRM are a legal tool to manage the derogation process for use on non-organic PRM (Article 26, Annex II, Part I, 1.8.5). Furthermore, they provide transparency in showing the wide offer of organic seed and vegetative material, and they can facilitate farmers' search for organic PRM. It is positive that putting offer on the database will be free of charge for operators.

### IFOAM EU recommendations

IFOAM EU is of the opinion that it is sufficient if PRM suppliers indicate the availability of organic and in-conversion PRM for individual varieties and OHM and it should be on a voluntary basis of the PRM suppliers to include the quantity in weight of the available material. We do not see the added value of displaying this information. First, the information is confidential, and its disclosure can disturb competition. Furthermore, in the fast business of PRM, the quantities can change every hour. Including the quantity in weight of seed available can be a high burden for PRM companies and database managers (authorities). The risk is that seed suppliers will not register their offer on the database for PRM, as they face high burden, but are also asked to share confidential information which might influence price forming and competition. Further, it might have the unwanted side effect that farmers wait ordering until the organic PRM is sold out to be able to ask for derogation (it is already the case in some Member States).

To be an efficient and comprehensive tool, regular and frequent updates of the database would be necessary from the suppliers. For example, if some PRM is not available anymore, it should be directly withdrawn from the database. Such practice would be more efficient for PRM suppliers and farmers than indicating the quantities.

It should always be possible to add additional information and to indicate if the material is organic heterogenous material, organic varieties, conservation or amateur variety.

The organic movement understands the database for organic PRM as operational tool for competent authorities, suppliers and farmers. National authorities should monitor the usage (quantity) of organic PRM, in-conversion PRM, and untreated conventional PRM per species in each Member State.

The following articles describing the operation of the seed databases of the Regulation (EC) No 889/2008 should be included:

- Art. 48(2) Suppliers of organic PRM shall be obliged to update their supply frequently and inform immediately if they are out of stock. To do so, easy access to the database shall be granted to registered suppliers of organic PRM. The database administrator must implement a warning system alerting the suppliers in case of insufficient update of their offers.
- Art. 48(3)
- Art. 49(1) and 49(2) with the addition of OHM, varieties suited for organic agriculture, conservation varieties and organic farm saved seed. Point 49(3) should not be included
- Art. 50 Condition for registration, with the addition that minimum quality criteria for inclusion are to be defined by national seed and other PRM experts for all species to be added. The decision to include or not seed/PRM suppliers in the database must be discussed beforehand with experts and representatives of the organic sector.
- Art. 51 Registered information, with addition of information on subgroup of species based on growing season (e.g. spring or winter type) or usage (e.g. fresh market, dry market): whether the material was organically bred, information on technical specification (e.g. potted plants, naked seed, pilled seed), as well as information on the quality criteria defined by national expert groups.
- Art. 51(1) and (2).



- Art. 51(3) with the addition of the list of the species listed in European Annex X, as well as a list of subgroup of species for which no derogation (except for experiments) are granted on national level.
- Art. 54 Annual report, specifying that the annual report needs to include both single as well as general derogations on both species and variety level. National authorities should monitor the usage (quantity) of organic PRM, in-conversion PRM, and untreated conventional PRM per species in each Member State. The national authorities shall develop and update annually a 20 years road map on how to reach 100% organic PRM. To foster this process working groups consisting of farmer organisations, breeders, seed producers, producers of vegetative propagation material, national authorities, organic and seed certification bodies shall be established to develop such roadmaps.
- Art. 55 Annual report, adding that the annual report should further include species for which no derogation is possible at national level as well as species for which derogations are foreseen in the near future (3 years forecast) will not be possible. The annual reports from member states should be collected, synthesized and made available on a central Commission website.

### The derogation process (Annex II. 1.8.5)

The lack of details on how to authorise the use of PRM not obtained by organic production method can hinder the harmonised implementation and the phasing out of derogations. Article 45 of Regulation (EC) No 889/2008 provides clear guidelines and tools on the process for granting derogations. The paragraphs in Annex II point 1.8.5 of the new organic regulation are not sufficient. Key elements implemented in several EU member states are missing: a national annex system listing species for which no derogation is possible, reasons for granting authorisation, possibility for granting general authorisation. [Results](#) of Horizon 2020 [LIVSEED](#) project revealed that establishment and facilitation of national seed/PRM expert groups including main stakeholders like farmer organisations, breeders, seed/PRM producers, certification bodies, advisors and national authorities are key to foster production and use of organic PRM.

### IFOAM EU recommendations

The implementation of Article 45 of Regulation (EC) No 889/2008 is today the main tool for Competent Authorities and control bodies/authorities to grant derogations. To achieve a harmonised implementation and the phasing out of derogations it is important to:

- include reasons for authorising derogations as it is in the current regulation (Art. 45(5) of Regulation (EC) No 889/2008) but clarify the use of conventional PRM for trials by farmers on their own land. The permissible percentage of area on which these trials can be carried out are to be defined by national expert groups.
- implement national Annex systems (adapted version of Art. 45(3) of Regulation (EC) No 889/2008): in several EU member states, national annexes are established to list species for which enough organic PRM is available and for which no derogation is therefore possible. This national annex system has shown to be very useful to stimulate organic PRM production, increase organic PRM use and to reduce derogations.
- facilitate national seed/PRM expert groups to evaluate the availability of organic PRM annually and give recommendations for national Annex to the national authorities.
- general authorisation (Art. 45(8) of Regulation (EC) No 889/2008) should be possible only if very limited amount of organic PRM of limited number of varieties is available. To reduce

the bureaucratic burden of granting single derogations, several countries developed a list of cultivar types for which a general derogation applies.

- Member States should be obliged to monitor the percentage of organic PRM usage per crop species and develop a road map how to achieve 100% organic RPM as the derogation should phase out latest by 2036. Status quo and progress in organic PRM usage need to be reported annually to the Commission.
- Annex II, Part 1, 1.8.5.3. is very problematic for vegetative propagation material as for a large amount of crop species there is a profound undersupply of organic propagation material. This system today only applies to seed and seeding potatoes. With the new organic regulation, it will apply to all PRM, seemingly without consideration for market realities. When no organic propagation material is available, a derogation for conventional material is impossible, when no chemical treatment other than Annex II listed substances are allowed, as no such conventional material exists. It would be necessary to clarify that general derogations for vegetative material are given, as long as organic markets are not established nationally. The delegated act could state: *“This provision is in place for seeds after seed production and for vegetative propagation material after harvest of the propagation material.”*

Generally, a big difference in derogation practices exists among EU Member States. A harmonised approach is needed and this demands support, best practice exchange and involvement from the Commission and improved monitoring system. The funding of research projects like Horizon 2020 project [LIVSEED](#) helps to collect information of the different member states and identify bottlenecks and incentives for the production and use of organic seed and other PRM. Also, the planned development of a European-Router database will improve transparency of the availability of organic PRM.

### Clarification needed for certification, labelling, mixtures and in-conversion PRM (Article 10 (4), Annex II. 1.8.5)

There are some unclear and contradictory provisions regarding labelling and conversion of plant reproductive material:

- Article 10(4)(a) reads that a conversion period of 12 months must be complied with before the PRM can be marketed as in-conversion
- At the same time in Annex II, Part I, point 1.8.2 reads that organic PRM is obtained after the mother plant has been produced in accordance with the organic regulation for at least one generation (two generations for perennial crops)

Those two articles are contradictory and a clarification is needed.

In addition to the contradiction, in article 10(4)(a) it should be clarified that a conversion period of 12 months ***before the harvest*** must be complied with. (See Article 62(a) of Regulation (EC) No 889/2008). This unclarity risks bringing more complexity to the database system.

Furthermore, contrary to what it is required today, the new organic regulation require an authorization (derogation) for using in conversion PRM. It is also possible to include them on the database of organic PRM and on the certificate, but still an authorization from the Member State is needed to use it.

Finally, it is not clear whether mixtures of non-organic/in-conversion/organic seed of different species are allowed and how they should be labelled (labelling rules for seed mixtures are missing).

### **IFOAM EU recommendations**

A clarification is needed to solve the contradiction between Article 10(4)(a) and Annex II, Part I, point 1.8.2.

It should be clarified that in conversion seeds are seed harvested 12 months after the notification and the submission of the operator under the organic control system. For any seed obtained in the first 12 months, no derogation should be needed according to Annex II, Part I, point 1.8.2. After 12 months, the in-conversion seed should be available on the database of organic PRM labelled as in-conversion PRM and available for farmers without any derogations as well. Mixes of conventional/in-conversion/organic seeds of different species should be allowed and rules for labelling should be established (the list of ingredients clearly has to identify the status of the single components). This is very urgent because currently the rules differ very much between Member States and this creates problems in the trade of seed mixtures. The aim should be to have as high percentage of organic seed as possible, there should be a mechanism to gradually achieve this purpose, monitor and stimulate more organic seed production and use for mixtures.