Deliverable 2.8:

Proposal for a toolbox for identification and description of organic heterogeneous material (WP2, T2.1.3)

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Executive Summary

To improve the effectiveness of the Organic sector and its independence from conventional agriculture, the New Organic Regulation 2018/848/EU endeavours to make the seed legislation more inclusive of cultivars that could benefit organic production. In this context, "Organic Heterogeneous Material" is introduced and broadly defined as "*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 […]; (d) is not a mixture of varieties […]*". This aims to allow the sale and use of genetically diverse seed, that would not fulfil the variety definition but would provide significant benefits thanks to functional diversity. It also aims to follow a simple notification process that does not present an administrative or financial barrier to smaller breeding initiatives and individuals e.g. farmers.

This document aims to aid in the interpretation and implementation of the New Organic Regulation text and to be considered as scientific input in the discussion of associated delegated acts relating to Organic Heterogeneous Material.

Here, we provide, first, a summary of experiences of the temporary experiment 2014/150/EU allowing marketing of seed of heterogeneous populations of wheat, barley, oats and maize pursuant to Council Directive 66/402/EEC. A SWOT analysis of tools related to the constitution, the seed traceability, and the description of such populations, aimed to compensate for the non-applicability of DUS-based cultivar description, is included.

Second, we position Organic Heterogeneous Material into the context of a potentially confusing overlap between seed legislation and the New Organic Regulation, and clarify the general requirements of Organic Heterogeneous Material in terms of development and production compliant with organic principles and the non-applicability of Intellectual Property Rights.

Third, we propose and describe five key tools for characterisation of Organic Heterogeneous Material that can be used in the notification process: (i) origin, (ii) region of cultivation; (iii) breeding methods, in turn divided into constitution, development and multiplication; (iv) phenotypic traits and (v) traceability. The application and relevance of these tools is discussed with reference to three categories of Organic Heterogeneous Material:

- **Farmers' Selections**, originated from a population or landrace that were selected by farmers for a certain period of time within a given agro-climatic region. In this case we suggest focussing on origin, region of cultivation and phenotypic traits;
- **Dynamic Populations**, generated as a mixture of cultivars multiplied as a bulk for several successive growing seasons, thereby evolving and adapting to local conditions. In this case, main focus is on the breeding methods, especially the list of constituent cultivars (constitution) and the bulk multiplication (development), and on phenotypic traits where these are object of direct selection;
- **Composite Cross Populations** (CCPs), result of targeted half-diallel crosses whose bulked progeny the breeder has let diverge. Here, the focus is on origin (parent cultivars), breeding process (constitution) and, since CCPs are the most exposed category to natural selection, traceability.

The successful implementation of the New Organic Regulation in terms of increased diversity of seed choice will depend on effective information management, to be developed through open cooperation between organic certification bodies, national authorities and existing research-farmers-breeders partnerships.

Note on terminology:
The term '**material'** is used whenever there is direct reference to 'Organic Heterogeneous Material' (OHM) or 'Plant Reproductive Material' as part of the text of 2018/848/EU.
The term '**cultivar'** is used, as defined in the LIVESEED project, as the generic term of reference for any crop, including therefore 'heterogeneous cultivars' that fall into the category of OHM.
The term "**population**" is used with its ecological meaning, when referring to specific cultivar genetic structures, or to breeding populations. It is also used in quotes from, or direct reference to, the 2014/150/EU.

Contents

1. Introduction and context

The new Organic Regulation EU 2018/848 has recognised that *"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 such diverse material, in particular with regard to organic production, for example to reduce the spread of diseases, to improve resilience and to increase biodiversity."* This is supported by the research of several LIVESEED project partners and other researchers (e.g. Döring *et al.* 2015, Costanzo & Bárberi 2016, Weedon & Finckh 2019).

Up until now however, seeds of genetically heterogeneous cultivars have been marketed in the EU only thanks to, and under the directives of, the Commission Implementing Decision 2014/150/EU (hereinafter the "Temporary Experiment") 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"*. The LIVESEED milestone report 2.8 'Main outcomes and SWOT of experiences from marketing populations under the Temporary Experiment into the commercialisation of heterogeneous populations in the European Union' provides an overview of the definitions followed in this legislation and the requirements of the Temporary Experiment, alongside a critique of the experiences of participating countries.

The Temporary Experiment served to open the certified seed market to seeds that do not fulfil all the official conditions for cereal seed certification, namely the *"sufficient identity and varietal purity"* (Art. 1, 66/402/EEC). Within this it aimed to assess both whether information on breeding and production methods could ensure identification, and traceability requirements and identification of the region of production were sufficient to identify the seeds of a heterogeneous cultivar. Identification and description of heterogeneous cultivars remained a challenge during registration and certification, and the need for a strengthened approach to address this issue, was identified in consultation, in particular, with the national governmental executive authorities and DG-SANTE and DG-AGRI.

In milestone report 2.8 we have completed a SWOT analysis of both the identification and description tools applied in the Temporary Experiment (Liveseed M2.8, Tables 2, 3 and 4 and Annex 1 of this report), and different countries experiences of registering and marketing heterogeneous cultivars as part of the Temporary Experiment (Liveseed M2.8, Annex I. The Temporary Experiment: Overview of experiences from the participating Member States). We have identified certain improvements to the text for the identification and description of heterogeneous cultivars within the Temporary Experiment. We hope this legislation will ultimately be adopted into the Seed Directives once the Temporary Experiment reaches its conclusion in March 2021 to ensure the wider availability of heterogeneous cultivars.

The inclusion of Organic Heterogeneous Material (OHM) in the new Organic Regulation will however enable commercialisation of genetically heterogeneous cultivars produced under organic conditions. OHM has a broader definition than that of heterogeneous cultivars within 2014/150/EU, with no quantitative limitations and covers all crop species. In the new Organic Regulation (EU 2018/848, Article 3 (18)) OHM is defined as follows: *"'organic heterogeneous material' 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;*

d) *is not a mixture of varieties; and*

e) *has been produced in accordance with this Regulation"* .

The new Organic Regulation text states that *"operators should be allowed to market plant reproductive organs (seeds and reproductive vegetative organs) of organic heterogeneous cultivars without having to comply with the requirements for registration and without having to comply with the certification categories of pre-basic, basic and certified seed…"* and that *"…certain rules for the production and marketing…"* of OHM to *"…ensure quality, traceability, compliance with this Regulation…"* will be developed in *"certain acts … delegated to the Commission"*.

The spirit of OHM is to provide routes to market for more genetically diverse cultivars, that does not need to comply with DUS (Distinctiveness, Uniformity and Stability) or VCU (Value for Cultivation and Use) testing nor seed certification processes. It aims to follow a simple notification process that does not present an administrative or financial barrier to smaller breeding initiatives and individuals e.g. farmers.

The production and marketing requirements, and processes to follow, to ensure that OHM complies with the Organic Regulation are being outlined in the 'delegated acts' or 'rules governing the production and marketing of plant reproductive organs of organic heterogeneous cultivars, associated with the Regulation text, that are currently being developed. Having said this, *"Specific provisions for the marketing of plant reproductive material of organic heterogeneous material"* are outlined in Article 13 of the Regulation, this includes the requirements of the notification of OHM *"by the supplier to the responsible official bodies […] by registered letter, or by any other means of communication accepted by the official bodies, with confirmation of receipt requested"*.

The aim of this report is to facilitate the development of the delegated acts for the notification of OHM as defined in the new Organic Regulation, and aid in their implementation.

2. Background

Whilst in (genetically homogeneous) varieties one individual plant can represent the whole plant grouping, therefore making a univocal description and identification possible and relevant for a plurality of needs, in genetically heterogeneous cultivars an individual plant cannot represent the population, and therefore a range of description and identification metrics must be addressed with a plurality of tools. Hence the concept of a 'toolbox' with an associated decision tree to aid tool selection has being proposed to facilitate the 'registration and certification' of OHM. This has been extensively explored with the Temporary Experiment on plant populations within 2014/150/EU, that is the only legislative and official marketing experience of seeds not complying with DUS so far, although only limited to wheat, barley, oats and maize.

2.1. Tools used in the 2014/150/EU Temporary Experiment

The 'tools' used in the Temporary Experiment on plant populations (2014/150/EU) can be grouped in three categories:

1. **Information on constitution**, namely (i) breeding goal (Art. 7.2.(d)), (ii) breeding method (Art. 5(b) and 7.2(e)), (iii) parent varieties (Art. 5(a) and 7.2(e));
2. **Traceability information**, namely (i) region of production (Art. 5(c) and 7.2(g)), (ii) registration of actors / documentation / paper trail (Art. 10, 13, 15, 16), (iii) representative sample (Art. 7.2(i));
3. **Description**, namely (i) degree of heterogeneity (Art. 5(d)) and (ii) performance testing (Art. 7.2(f), Art. 16).

A SWOT analysis of these tools, from LIVESEED milestone M2.8, can be found in Annex I. The main challenges identified with the existing tools were the difficulty in providing clear or qualifiable information for some of the tools (e.g. breeding goal or parent varieties), and a general lack of clarity on the usefulness of a number of the requirements in their current state without clearer guidance on what aim the information is trying to fulfil. Thorough record keeping by the breeders, applicants and regulators of the heterogeneous cultivars is essential for useful application of the legislation. We therefore see this as a continuing challenge as OHM is rolled out into general use.

2.2. Extending tools for the characterisation of OHM

OHM in the new Organic Regulation (EU 848/2018) is based on a much broader definition than the heterogeneous cultivars of cereals defined in the Temporary Experiment (see Introduction above). In fact, OHM is not as restrictive with respect to:

(i) **crop species:** no limitation to certain crop species shall be enforced;
(ii) **constitution** of the plant breeding population: i.e. no minimum number of parental lines or crosses shall be set (*however note Art 2. (c), (iii) in 2014/150/EU*);
(iii) **selection methods:** exposure to natural selection in generations successive to the constitution shall not be the only selection method allowed;
(iv) **seed quantity**: no quantitative restriction on what the overall national yearly production of seed shall be.

There is however the requirement that OHM is produced (both during breeding and maintenance) **in accordance with the Organic Regulation**.

The advantage with OHM is that there is already a well-developed **organic certification system** in place for all actors producing under the Organic Regulation, which should allow full traceability of the process of developing OHM and the amount of seed produced and commercialised from such cultivars. Figure 1 highlights that there is some overlap between cultivars marketed via the Temporary Experiment and that within the remit of the Organic Regulation. Therefore, some of the tools used in the Temporary Experiment will also be useful for the identification and description of OHM. Nevertheless, the need for further tools has been identified in consultation with LIVESEED partners, national governmental executive authorities and DG-SANTE.

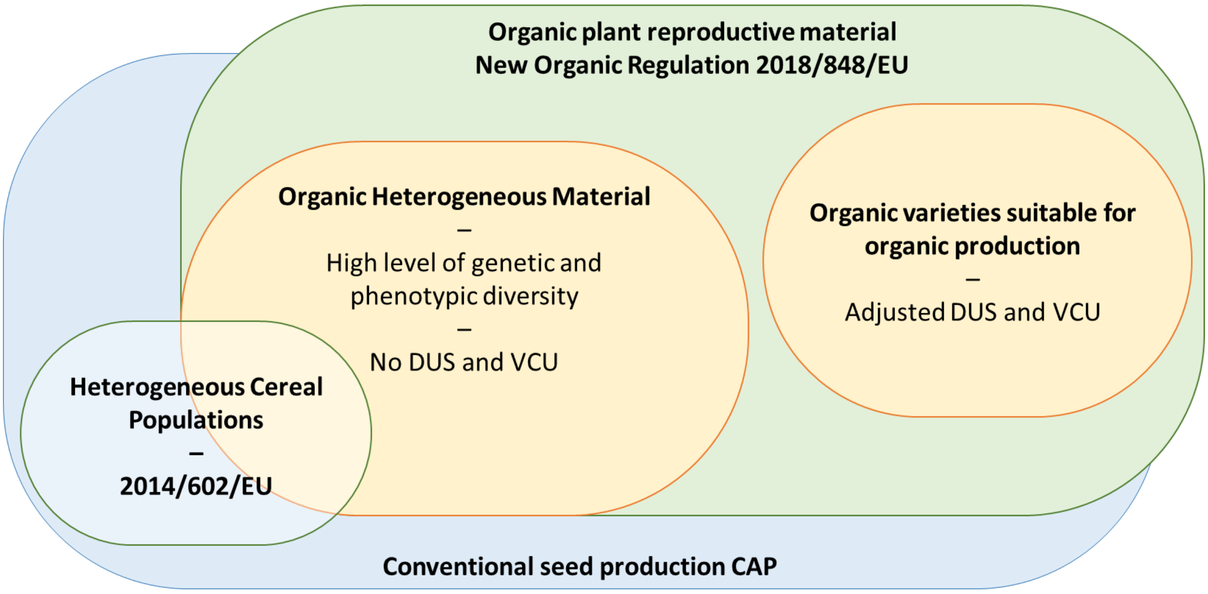

Figure 1. Schematic differentiation between heterogeneous cultivars defined in Temporary Experiment and new cultivar types of OHM and organic varieties implemented in the new Organic Regulation EU 848/2018

3. Proposal for tools for notification and description of OHM

3.1. General requirements of OHM

“Organic Heterogeneous Material”, as any organic seed, shall first comply with general requirements regarding development and production:

- **Development:** the heterogeneous cultivar shall be developed, i.e. subject to natural or human selection, under organic conditions for three and five years for annual and biennial/perennial species, respectively, and this shall be guaranteed by the organic control and certification system.

- **Production:** the production of 'plant reproductive material (PRM)' (*sensu 2018/848/EU*) of OHM shall also be conducted under controlled organic agriculture.

We also suggest some important specific recommendations to be followed by those producing, marketing and regulating OHM:

- **Breeding methods** should comply with organic principles, at least to the "containment within natural crossing barriers";
- **Parents** should also have been obtained with breeding methods in line with organic principles;
- **Intellectual property rights** shall not be applied relating to the OHM.

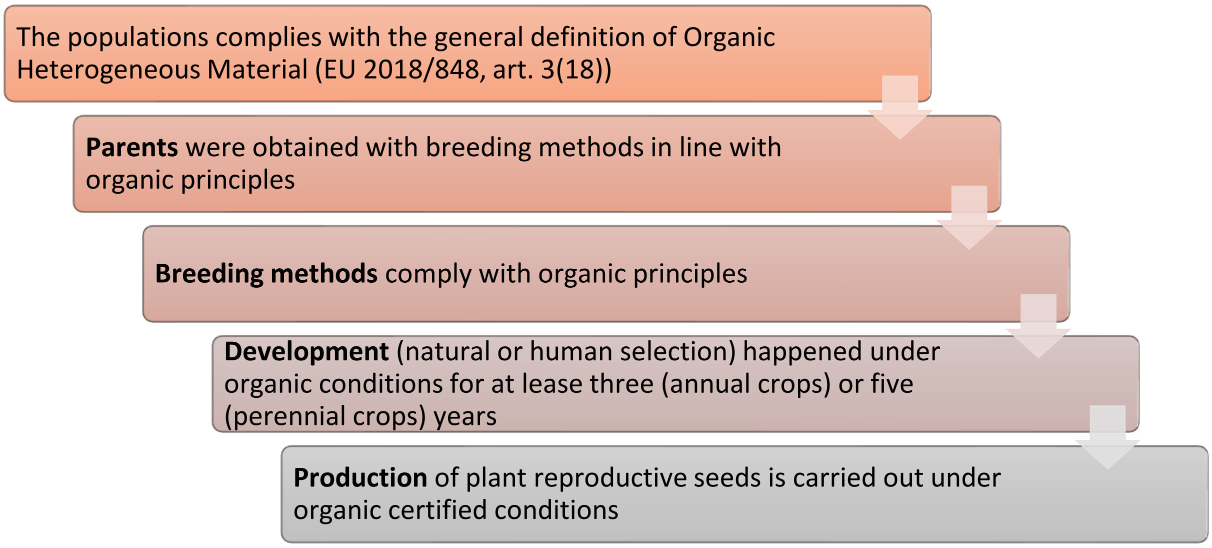

Figure 2. Checklist in successive steps of the general provisions for registration of "Organic Heterogeneous Material".

3.2. Categories of OHM and related recommendations for notification

Whilst acknowledging that there are provisions for notification and description that are valid for whichever organic seed or propagation organ, namely those related to sanitary quality and safety and the compliance with organic principles, notification and description needs to be adjusted for Organic Heterogeneous Material and its inherent non-compliance with DUS. Hence the idea of a 'toolbox' to address the fact that a plurality of crops can/should fall under the classification of OHM. Starting from the experience of the Temporary Experiment on plant population of cereals (2014/150/EU) and of non-cereal heterogeneous plant populations generated for research / non-commercial purposes, we outline how these tools can be implemented on five key dimensions: (1) Origin; (2) Region of cultivation; (3) Breeding methods; (4) Phenotypic traits; (5) Traceability.

Within the definition of OHM we visualise three categories with increasing genetic diversity: (i) farmers' selection; (ii) dynamic populations, and; (iii) composite cross populations (CCPs). Each of these categories is described in more detail below to highlight how the possible application of tools related to the above five dimensions can be modulated. Following examples are deliberately focusing on crops other than wheat, barley, oats or maize as these species have been extensively explored during the 2014/150/EU, whereas here we highlight how the OHM can be extended to further species and cases.

3.2.1. Farmers' Selections

Farmers' selections originate from a population or landrace that were selected by farmers for a certain period of time within a given agro-climatic region. They have a lot of genetic diversity, so do not comply with DUS. Existing examples that could fall into this category are the different Farmers' Selections derived from wheat e.g. '*Rouge de Bordeaux*', as far as cereals are concerned, or the *'Magic Chard'* and *'Kaibi Sweet Peeper'* developed by Real Seeds in the United Kingdom (Table 1). In this case human selection might have an important role, therefore the certification might consider verifying that the phenotypic traits targeted during selection remain present in the 'farmer selections''. Therefore, three key elements to consider for certification are:

- Origin, i.e. what original breeding population has the selection been applied to, and which selection methods was followed?
- Region of cultivation, i.e. where has the selection taken place?
- Phenotypic traits, i.e. which traits have been targeted during selection?

Table 1. Two examples of cultivars that could fall into the Farmers' Selection category, courtesy of "The Real Seeds" (UK)

	Magic chard	Kaibi Sweet Peppers
Crop Species	*Beta vulgaris*	*Capsicum annuum*
Fertilisation biology	Cross pollination	Mainly self pollination
Life cycle	Biennial	Annual
Origin	Fordhook Giant, a beetroot, an F1 yellow chard and an unknown pink chard	A sweet pepper from a family farm in the town of Sahzne in central Bulgaria, acquired in 2003
Region of cultivation	n.a.	Originally Bulgaria
Breeding method	Diverse population generated by a cross that was then further selected	Selection for UK conditions: earliness to maturity and thickness of fruit walls, flavour, divided the resulting population by fruit shape into 'rounder', 'pointier' and 'blockier', sub-groups, which are subsequently multiplied separately
Description of main agronomic and phenotypic characteristics that are common to that plant grouping	It is called 'Magic Chard' due to the unexpected appearance of two rare colour combinations (pink-white stripe, and vivid orange) that regularly occur in the heterogeneous cultivar but are not practically obtainable as stable pure-breeding lines due to the interaction of multiple recessive genes. These were not expected and became very popular.	Appearance of the main phenotypes from the original population: 
Production methods	n.a.	For each of the subcategorises, a population of 60 or more plants is maintained, deliberately keeping a mixture of moderately varying shapes within the overall criteria of 'rounder' or 'pointier'

3.2.2. Dynamic Populations

Dynamic populations are generated as a mixture of cultivars, where cultivars are understood in a broader sense than officially released varieties and thereby include, besides varieties, landraces, niche varieties, breeding lines, genebank accessions and so on. The key distinction from a cultivar mixture is the process following the initial mixture, in that, to become a dynamic population, the initial mixture is multiplied as a bulk for several successive growing seasons, thereby evolving and adapting to local conditions.

In this case, unlike the "farmers' selection" category, the parents used in the constitution has more importance as well as the subsequent phases of the process. A focus on phenotypic traits to be targeted during selection might not be possible. Therefore, key elements for description are:

- **List of parents** , i.e. the varieties, landraces, genebank accessions etc. that have been included in the original mixture;
- **Breeding process**, i.e. the bulk multiplication of the mixture, which can vary according to whether annual or biennial, self- or cross-pollinated species are considered;
- If the breeding process includes active selection, the **phenotypic traits** that have been targeted by such selection.

Existing examples that could fall into this category for vegetable species include cultivars of spinach developed in the Netherlands (Table 2) and lettuce developed in Germany (Table 3). For cereals and pseudo-cereals, the dynamic populations of bread wheat developed in France (Ceccarelli et al. 2018, p. 18) and a dynamic population of buckwheat developed in Brittany (Table 4) are examples.

Table 2. Example of a Spinach cultivar that could fall into the category of Dynamic Population courtesy of Edwin Nuijten (the Netherlands)

Crop Species	Spinach
Fertilisation biology	Cross pollination
Life cycle	Annual
Parents used	About 20 varieties
Region of production	The Netherlands
Breeding method	Open pollination among varieties
Description of main agronomic and phenotypic characteristics that are common to that plant grouping	Speed of growth (earliness), bolting tolerance, leaf attitude and stem length (all traits relevant to allow easy and simultaneous harvesting)
Production methods	Varieties are grown alongside each other. Best plants are selected (in particular above-mentioned traits and mildew tolerance) and are allowed to cross-pollinate. This process will be repeated several cycles till a population develops that is suitable for easy and simultaneous harvesting.

Table 3. Example of a lettuce cultivar that could fall into the category of Dynamic Population, courtesy of "Kultursaat" (Germany)

Crop Species	Lettuce (*Lactuca sativa*)
Fertilisation biology	Highly self-pollinated
Life cycle	Annual
Parents used	Existing varieties
Type of OHM	Farmer's selection

Country of production	Germany (Kultursaat)
Breeding method	Crosses between a number of varieties, followed by selection of F3-F4 lines (that still have some diversity) that can be grown in mixed stand
Description of main agronomic and phenotypic characteristics that are common to that plant grouping	Speed of growth (earliness), Bolting tolerance, leaf attitude, disease tolerance (in particular mildew tolerance) (all traits relevant to allow easy and simultaneous harvesting)
Production methods	Progenies are evaluated. Best plants are selected (in particular above-mentioned traits and mildew tolerance) and are allowed to set seed. This process will be repeated several cycles till a population can be constituted of multiple lines that is suitable for easy and simultaneous harvesting. Lines are reproduced separately and can be put together before sowing. This can also be done by farmers themselves

3.2.3. Composite Cross Populations

Composite Cross Populations (CCPs) are the result of targeted half-diallel crosses whose bulked progeny the breeder has let diverge. This is different from a synthetic population which are reconstructed to be stable. This is the only category for which seeds have been certified so far under the Temporary Experiment 2014/150/EU for wheat, oats, maize and barley species. As such, we suggest that the tools for certification and description under the Temporary Experiment, adjusted according to the SWOT proposed in annex 1, can be applied. In particular, the focus is on parents, breeding process and (since CCPs might be subject to faster and larger differentiation due to natural selection) traceability.

Wheat CCPs and their evolutionary dynamics are widely documented (Döring *et al.* 2015, Weedon & Finckh, 2019). Here we report the example of a buckwheat CCP developed in France, which is particularly interesting as compared to a Dynamic Population originating from the same parents (Table 4).

Table 4. Examples of two potential OHM generated from the same parents and developed as a Dynamic Population and a Composite Cross Population. Courtesy of INRA-Rennes (France), further details in the reference.

	Buckwheat Dynamic Population	Buckwheat CCP
Crop species	*Fagopyron esculentum*	*Fagopyron esculentum*
Fertilisation biology	Cross pollination	
Life cycle	Annual	
Parents used	1) 'Le petit gris': local population (from Bain de Bretagne) adapted by farmers to the pedoclimatic context of north-western France (Brittany) with a good rate of flour extraction. 2) 'Le petit prussien': early local population with low branching potential. 3) Billy: commercial population which has a large seed size and therefore a good dehulling potential. 4) Spacinska: commercial population with relatively stable yields and good processing potential either for flour (good rate of flour extraction) or for dehulling (relatively large seed size).	

	5) Kaimochasta: population multiplied from genetic resources accessions and with good rusticity Phenotypic characterisation of parents based on: • Seed colour (proportions of 'silver', 'brown', 'cream' 'black' and 'red'): dominant silver in (5) and (1) with all other colours present in smaller proportions, brown in (4), brown and black in (3) with other colours in smaller proportions, silver and black in (2). • Mean grain weight (g/1000 grains) ranked (from the highest) (3)-(4)-(5)-(1)-(2)	
Region of production	Brittany (France)	Brittany (France)
Breeding method	Mixing components in equal proportion.	Half-diallel cross between all parents by manual pollination, mixing and seed saving from the progeny
Description of main agronomic and phenotypic characteristics that are common to that plant grouping	Progressively increased dominance of intermediate sized grains over large and small grains. Progressive increase of prevalence of silver-coloured grains, appearance of beige-coloured grains in 2018. According to the authors' observation, in the dynamic population Billy, Kaiomchasta and Spacinska traits are less represented.	Progressively increased dominance of intermediate sized grains over large and small grains. Progressive increase of prevalence of silver-coloured grains, appearance of beige-coloured grains in 2018. According to the authors' observation, the CCP seemed to have a better distribution of all the parents' diversity.
Production methods	Seed saving from the open-pollinated population distributed to three farms in 2017. Each farm saved its own seed for 2018.	Progeny distributed to three farms in 2017. Each farm saved its own seed for 2018.
Reference: Villard A-L, Cormery A, Chable V. **Five populations/landraces used to create new populations – France.** In Costanzo A (2019) *Searchable database on performance results of underutilised genetic resources. Deliverable 2.5. H2020 DIVERSIFOOD Project.* http://www.diversifood.eu/wp-content/uploads/2019/03/DIVERSIFOOD-D2.5_Searchable-database-available-from-project-website.pdf		

3.3. Targeting tools for notification and description to the type of OHM

From the exploration of existing examples of potential "Organic Heterogeneous Material", we propose that a flexible toolbox can be applied and adjusted to the three different categories of OHM.

3.3.1. Origin

The origin of the OHM relates to the starting point of its constitution and development and, as such, is highly relevant for all three categories but may address different aspects. In fact, for Farmers' Selections the starting point is generally an original population/landrace selected by a farmer or group of farmers in a given agro-climatic region, and these are the details that need to be known and declared. For both Dynamic Populations and CCPs, the starting point is instead either a mixture or a manual cross among a set of parents, and the most critical information is listing the set of parents themselves.

3.3.2. Region of cultivation

This tool, already present in the 2014/150/EU, can be fairly ambiguous unless is better specified to target the different categories of OHM. For Farmers' Selections it is an integral part of the selection and co-evolution process that leads to the Farmers' Selections "identity", and as such is highly relevant in retrospect (in which region has this cultivar evolved?) and in terms of future use (in which agro-climatic conditions will this cultivar keep its identity?). For Dynamic Populations, region of cultivation is definitely irrelevant in retrospective terms, and may only have some relevance in terms of future use. However, since for Dynamic Populations and, even more, for CCPs, the evolutionary potential is a key feature of their heterogeneity, the 'region of cultivation' can be important as a containment of unwanted evolutionary drift but should not be a limit for adaptation of the cultivar to a wider array of agro-climatic conditions. CCPs and Dynamic Populations are in 'continuous breeding', therefore it is crucial to understand at which generation of progeny reproduction the plant population is notified and commercialised: region of development before that generation will therefore be an important descriptor, but we suggest not to apply geographical restrictions to its commercialisation. Seed production might be restricted geographically if specifically advised by the breeder in the notification.

3.3.3. Breeding methods

'Breeding methods' bears a high level of ambiguity for OHM unless what 'breeding' means is clearly specified. We suggest to clearly split 'breeding methods' into three subsequent steps: Constitution, Development and Production.

- **Constitution** is the technical starting point of the new OHM: it is irrelevant for Farmers' Selections as it overlaps with the origin; it is irrelevant for a Dynamic Population as it always starts from a physical mixture; it is highly relevant for CCPs in terms of crossing scheme as well as crossing techniques that need to comply with organic principles.
- **Development** refers to the subsequent generations after constitution and *before* notification. This is extremely relevant for Farmers' Selections as this is when the direct selection is applied, and for the two other categories if direct selection is applied. If no direct selection is applied, what is critical for Dynamic Populations and CCPs overlaps with the region of cultivation, with the addition of describing the cropping systems used during development as they may add further indirect selection pressure. Likewise, it was elegantly proved that early (starting from F_2) wheat populations subjected to either a grain-only or a dual-purpose system including cattle grazing, undergo divergent evolution progressively adapting to the two different systems (MacKown & Carver, 2005).
- **Production** refers to how the seeds (or other plant reproductive organs) are made available to farmers *after* the notification. The key message here is that **breeding for OHM does not end with notification and commercialisation**. Production methods may change significantly according to the life cycle and cropping system of the target species. Whilst for e.g. self-pollinating cereals this may not change across any of the three OHM categories, as it will always be a bulk progeny of the previous generation, the situation may change for vegetable species: the example Table 3 shows how a Dynamic Population is reproduced and continuously selected, and then seed production is carried out by separate lines.

3.3.4. Phenotypic traits

Phenotypic traits that constitute the 'visual identity' of a heterogeneous cultivar are those related to the direct selection applied during constitution and development, that perhaps need to be maintained during the cycles of seed production. Examples could be a specific ripening time, or disease resistance, or occurrence of given colours and shapes (see Table 1). It is important to note that ensuring some phenotypes are present in the cultivar does not imply that the cultivar is homogeneous for other than these traits. When no direct selection is applied (as e.g. for a very diverse CCP), it may be a trivial and useless DUS-like exercise to identify key phenotypic traits that need to be checked against. We suggest that the breeder, during notification, will advise on key features that will inform on the 'distinguishability' of their new OHM.

3.3.5. Traceability of seed lots

Traceability is the key tool when no physical identification is possible or advisable, and its relevance for notification and commercialisation increases with increasing heterogeneity. In fact, tracking seed lots might be very important for CCPs and still be important for Dynamic Populations, insofar as it might compensate for the difficulty of phenotypic identification and inform on the (intentional) phenotypic change driven by natural selection. We suggest that embedding seed production in organic certification should ease the traceability by better data integration between the normal certification of farm productions and acreage and the information requirements to track the seed lots.

Table 5. Key tools of certification and description and their relevance/specification for the three proposed categories of OHM

	Farmers' selection	Dynamic population	CCP
Origin	**Highly relevant** Original population	**Highly relevant** List of parents	**Highly relevant** List of parents
Region of cultivation	**Highly relevant** in terms of e.g. geographical origin	**Medium relevance** as related to natural selection during development	**Medium relevance** as related to natural selection during development
Breeding method 1: constitution	**Not relevant**	**Low relevance** as the starting point is always a physical mixture	**Highly relevant** for the methods used in the initial crosses
Breeding method 2: development (pre-notification)	**High Relevance** to describe which selection has been applied	**Medium relevance** if direct selection is applied, otherwise related to region of cultivation specifying management	**Medium relevance** if direct selection is applied, otherwise related to region of cultivation specifying management
Breeding method 3: production / multiplication (post-notification)	**Medium relevance**, and it may change significantly according to the species life cycle	**Medium relevance** and might change if self- or cross-pollinated species	**Low relevance** as progeny is supposed to be multiplied as bulk
Phenotypic traits	**High relevance** as related to selection as advised by the 'breeder'	**Medium relevance** if direct selection is applied as advised by the 'breeder'	**Medium relevance** if direct selection is applied as advised by the 'breeder'
Traceability	**Low relevance**	**Medium relevance** as also keeps track of natural selection	**High relevance** as also keeps track of natural selection

4. Conclusion

To apply the provision of Article 3 (18) of the Organic Regulation, which allows the sale and use of Organic Heterogeneous Material (OHM), we must understand that there is a wider variety of cultivars that will be made available to the market. We have identified three categories of OHM: Farmer's Selections, Dynamic Populations and Composite Cross Populations (CCPs). Increasing diversity and choice is indeed a key aim of the legislation but presents some challenges in how the release of such cultivars will be regulated in terms of e.g. consumer protection. By outlining the different types of cultivars that is likely to be released, and therefore needs to be recognised by the national governmental executive authorities as part of the notification process, we aim to ease this process and highlight some of the considerations that will need to be made in relation to the different features of such cultivars. Different description and identification tools will be of greater or lesser relevance depending on the type of population to be marketed as OHM (Table 5). Here the role of the certification bodies will be critical in facilitating the availability of information for traceability, without documentation overburden, as well as to certify the organic development of OHM. We must continue to develop case studies to understand the performance of these cultivars over space and time. Engagement in an open dialogue with the national authorities to ensure that the notification process remains simple, as intended, is important and will ensure that the Regulation and associated delegated acts are effectively implemented. The description of the main relevant characteristics (tools) of notified OHM together with the availability of its organic plant reproduction material could be integrated in the Europe wide router database for organic seed developed within LIVESEED (Task 1.3).

5. References

- **Ceccarelli S, Chable V. Goldringer I. (2018).** Assessment of the potential of the diverse methods to create relevant diversity for plant breeding. Deliverable D3.3 DIVERSIFOOD project: www.diversifood.eu

- **Costanzo A. (2018)** Main outcomes and SWOT of experiences from marketing populations under the Temporary Experiment into the commercialization of heterogeneous populations in the European Union (with input from Charlotte Bickler, ORC; Monika Messmer, FiBL; Frederic Rey, ITAB; Matteo Petitti, RSR; Carl Vollenweider, FZD; Nanna Karkov Ytting, Agrologica. 2018). LIVESEED Project: Milestone 2.8 report. https://www.liveseed.eu/wp-content/uploads/2019/07/LIVESEED_MS2.8_heterogeneous_material_marketing_May_version_internal-document.pdf

- **Costanzo A & Barberi P (2016)** Field scale functional agrobiodiversity in organic wheat: Effects on weed reduction, disease susceptibility and yield. Europ J Agron . DOI: https://doi.org/10.1016/j.eja.2016.01.012

- **Doring T, Annichiarico P, et al. (2015)** Comparative analysis of performance and stability among composite cross populations, variety mixtures and pure lines of winter wheat in organic and conventional cropping systems. Field Crops Research 183 (2015) 235–245

- **MacKown CT and Carver BF (2005)** Fall Forage Biomass and Nitrogen Composition of Winter Wheat Populations Selected from Grain-Only and Dual-Purpose Environments. Crop Sci. 45:322-328. doi:10.2135/cropsci2005.0322

- **Weedon O & Finckh M (2019)** Heterogeneous Winter Wheat Populations Differ in Yield Stability Depending on their Genetic Background and Management System. Sustainability 11, 6172; doi:10.3390/su11216172.

Annex I: SWOT analysis of tools identified in the Temporary Experiment from LIVESEED Milestone 2.8.

Tools related to the constitution of populations

Breeding Goal	
Strengths	**Weaknesses**
• Can describe and declare the added value of a population • Useful to inform choice of parental lines holding desirable traits in populations designed for specific purposes (e.g. nutritional quality, disease or drought resistance)	• Mostly based on intentions rather than evidence. • For many traits it is difficult to predict performance of progenies. • Often breeding goal is broad and not an explicit quantifiable/qualifiable target. • May not provide sufficient information on the end product for farmers/processors.
Opportunities	**Threats**
• If set out as a tangible, quantifiable/qualifiable breeding goal, this can be verified in respective performance trials • Can be reformulated as “intended use” or “recommended purpose” to provide additional information to farmers.	• Farmer might assume that the declared breeding goal is identical to the actual characteristics of the population. Thus, this could be misleading information for users. • Seed of populations constituted with no explicit goal but that have an added value, e.g. increasing crop genetic diversity, could be excluded.

Varieties used in the crossing	
Strengths	**Weaknesses**
• Declaration of parents and the breeding process prevents breeders from registering varieties with off-types or variety mixtures as populations. This can prevent fraud and parallel markets. • For populations based on complex crosses of limited number of parental inbred lines (Art. 2 c (i)) whether the population is more phenotypically diverse than the line mixtures can be tested .	• For outcrossing species such as maize, the parents are themselves heterogeneous populations and difficult to describe. It will be very difficult to check pedigree information. • Parents may not be fully known/characterised if they are not registered varieties but e.g. individuals from landraces or new breeding lines. • Parental lines might no longer be available to make comparisons. • Declared parental lines might be not 100% true to type due to risk of unintentional selfing, outcrossing or conservation bottlenecks.
Opportunities	**Threats**
• Useful information for end-users, in particular for the organic sector, that want to ensure the seed they use are not derived from parental lines that do not comply with organic production standards. • The information on parental lines of self-pollinating species can be verified by molecular marker analysis which can avoid fraud and parallel markets. For cross-pollinating species markers can be used to identify unique frequencies of the involved parental populations.	• A restrictive interpretation bears the risk of limiting authorisation to populations of crosses between registered varieties only, and might exclude many other useful populations from e.g. uncharacterised plant genetic resources. • Breeders might not be willing to declare parental lines and crossing schemes. • Molecular markers might detect minor deviations from indicated pedigree (e.g. some parental lines might be missing, or other parental lines might be unintentionally introgressed). This can happen during crossing

	processes, therefore a minimum of e.g. 70% agreement should be a sufficient threshold.
Breeding schemes & Production method	
Strengths	**Weaknesses**
• Can provide full and transparent information on the origin and genetic history of a population.	• Present requirement does not include detailed description of selection and multiplication environment(s) and conditions. • Does not necessarily convey information for use and purpose of the population. • It can be difficult to validate this information.
Opportunities	**Threats**
• Can provide useful information for end-users, in particular for the organic sector that wants to ensure the seed they use complies with their standards. • Can provide information about evolutionary processes (steps of natural selection) if it includes a description of selection environments and multiplication methods/conditions. • Could be used as protocol or quality control for maintenance breeding of populations.	• Art. 2. can be too restrictive in its definition of heterogeneous populations, excluding many other approaches aiming for increased genetic diversity, e.g. participatory selection for local adaptation. • Documentation burden may be off-putting to smaller breeders. • The disclosure of breeding techniques is not specifically mentioned other than “crossing” and “natural selection”. This bears the risk that seed of populations might be put on the market that was derived from breeding techniques that do not comply with private/organic production standards. Therefore, full transparency on breeding techniques and traceability of certain techniques, like protoplast fusion and CRISPR-Cas9, should be compulsory.

Tools related to the traceability of populations

Region of seed production	
Strengths	**Weaknesses**
• Can inform end-users on the nature of the area(s) where the seed was produced, allowing them to evaluate its potential performance on their own land. • Can control/constrain the seed lot in a ‘space’ where potentially undesired evolution can be limited.	• ‘Region’ is an utterly confusing concept that is difficult to frame/quantify and may not fit within strict geographical boundaries. • Spatial and temporal variation in environment cannot be simply encompassed by boundaries.
Opportunities	**Threats**
• Useful when considered in context of breeding goal and ‘target environments’ and ‘target management’ (specific adaptation). • Can provide ‘predictive’ advice on environmental coverage for optimal performance (e.g. soil, climate, management). • Can include the agro-climatic context of a populations’ breeding and multiplication (which may differ).	• ‘Region’ might be defined as a certain geographic area. However, evolution of populations is only in part driven by geographic features. • Every ‘predictive’ description can become overly ‘prescriptive’ and restrictive. • Bears the risk that marketing of populations might be restricted to certain areas, which would unnecessarily limit access. • High administrative burden for breeders and producers to document all selection, multiplication sites, sales and so on.

Documentation - database	
Strengths	**Weaknesses**
• Provides guarantees to users. • Provides evidence of history in the light of evolution.	• Essential but not enough in representing population history in the light of evolution.
Opportunities	**Threats**
• Can work better if linked to seed lots rather than an individual population.	• Open to fraud. • Challenging from an administrative point of view if number of populations, actors and/or users increases significantly. • A restrictive control system might be put in place.

Representative sample	
Strengths	**Weaknesses**
• Provides basic info on seed quality (germination, health) • Provides a reference in case of commercial conflict.	• May not bear (all) the characteristics of an evolutionary population (due to possible genetic drift, divergent evolution) and might deviate over time from evolving population on the market.
Opportunities	**Threats**
• Can work better if linked to seed lots rather than an individual population.	• Open to fraud. • Challenging from an administrative point of view if number of populations, actors and/or users increases significantly. • A restrictive control system might be put in place.

Tools related to the description of populations

Degree of heterogeneity	
Strengths	**Weaknesses**
• It recognises that populations need to be heterogeneous.	• It does not prevent parallel market. • So far not required for application - only defined by number of parents, the crop and its mating system, and crossing schemes. • Unclear: heterogeneity of what? • No targeted funding has been provided to find exhaustive and simple replicable protocols, so inconsistent evidence so far.
Opportunities	**Threats**
• Useful when considered in context of breeding goal and ‘target environments’ and ‘target management’ (specific adaptation). • Can provide ‘predictive’ advice on environmental coverage for optimal performance (e.g. soil, climate, management). • Can include the agro-climatic context of a populations’ breeding and multiplication (which may differ).	• ‘Region’ might be defined as a certain geographic area. However, evolution of populations is only in part driven by geographic features. • Every ‘predictive’ description can become overly ‘prescriptive’ and restrictive. • Bears the risk that marketing of populations might be restricted to certain areas, which would unnecessarily limit access. • High administrative burden for breeders and producers to document all selection, multiplication sites, sales and so on.

Performance characteristics, experimental data	
Strengths	**Weaknesses**

• Useful for farmers and end-users to know what to expect from a given population. • In line with national lists protocols, can address same parameters as for varieties.	• Performance is season, location and management dependent. • Attempts to distinguish different populations using performance data have been difficult/unsuccessful. • No targeted funding has been provided to develop such trials, so inconsistent evidence so far. • Populations are mostly organically bred seed, but if only official conventional or organic high input on-station testing is considered, performance in such trials may not be indicative of true field performance.
Opportunities	**Threats**
• Trials can be conducted on-farm in a decentralised network covering a wide spectrum of environments with defined management regimes. • Yield stability and reliability over time are important parameters to assess but need to be tested in a large number of environments and seasons. • Can be linked to verify the 'breeding goal' and allow farmers to make an informed choice.	• Adequate performance trials, especially for organic and low-input farming, needs innovative design to account for increased environmental variability and sufficient funding. • Limited funding for comparative performance trials leads to fragmented trials that do not provide sound data to describe the performance of populations. Farmers might need to take a risk to try them. • Disagreements on purpose of such trails: some players opinion is that performance testing is not necessary for populations, as their aim is also to be further locally adapted by end-users.
Representative sample	
Strengths	**Weaknesses**
• Provides basic info on seed quality (germination, health) • Provides a reference in case of commercial conflict.	• May not bear (all) the characteristics of an evolutionary population (due to possible genetic drift, divergent evolution) and might deviate over time from evolving population on the market.
Opportunities	**Threats**
• Can work better if linked to seed lots rather than an individual population.	• Open to fraud. • Challenging from an administrative point of view if number of populations, actors and/or users increases significantly. • A restrictive control system might be put in place.