Milestone M18, M2.8:

Main outcomes and SWOT of experiences from marketing populations under the Temporary Experiment into the commercialisation of heterogeneous populations in the European Union (WP2, T2.1.3)

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Contents

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Summary

- A Temporary Experiment (Commission Implementing Decision 2014/150/EU) has allowed the marketing of heterogeneous populations of four species (wheat, barley, oats and maize) since March 2014.
- The Temporary Experiment aimed to assess whether information on breeding and production methods could ensure population identification, and traceability requirements and identification of the region of production were sufficient to identify the seeds of a population.
- A range of experiences were gathered across Member States, with 35 populations being registered in total in six countries. However, scope of the Temporary Experiment was somewhat limited due to lack of available funds and the low availability of seed for some registered populations.
- Italy and the UK marketed the largest volume of seed from populations and in turn found that innovation developed across the cereal supply chain in response to the increased availability of this material.
- Identification and description of populations remained a challenge during registration and certification, and the need for a strengthened approach to address this was identified in consultation, in particular, with the national authorities and DG-SANTE.
- 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) populations 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 a toolbox with an associated decision tree to aid tool selection has being proposed for use in registration and certification. This builds on the tools already tested within the Temporary Experiment which are critiqued in this report.
- This toolbox is being expanded to cover the broader category of Organic Heterogeneous Material, and to guide the development of the delegated acts for the new Organic Regulation, as part of ongoing LIVESEED activities.

Introduction and context

Seeds of genetically heterogeneous populations have been marketed in the EU thanks to, and under the directives of, the **Commission Implementing Decision 2014/150/EU** (hereinafter "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 core of the derogations disciplined in the Temporary Experiment has been 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). Those seeds are referred to as "populations". To make this possible, the Temporary Experiment sets as its **goal** to assess (Art. 1.1):

*"**whether the production […] and marketing**, under certain conditions, **of seed from populations** […] **may constitute an improved alternative to the exclusion of the marketing of seed not complying with the requirements** of […] Directive 66/402/EEC concerning **varietal aspects** of seeds of certain species";*

and as its **objectives** to assess (Art 1.2):

*"(a) whether the **identification of populations** of those species can take place on the basis of **information on their breeding and production methods, the varieties used in the crossing, and the main characteristics** of those populations; and (b) whether the **identity of seeds** from those populations marketed **can be based on traceability requirements and identification of the region of production**".*

The Temporary Experiment restricts its scope (Art. 2) to **four crop species** (wheat, barley, oats and maize) and to **specific genetic structures** of populations: (1) **bulked progenies of crosses** between all possible pairs of at least five parent genotypes exposed to natural selection in successive generations; (2) **bulked progenies of mixtures** of at least five predominantly **cross-pollinated varieties** exposed to natural selection until original

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varieties are no longer present; or (3) **inter-crossing** varieties via other crossing methods to produce a **similarly diverse population that does not contain varieties**. Emphasis is thereby placed on excluding the application of the derogation to plant groupings containing registered varieties, as in that case these would need to follow the general regulation.

The Temporary Experiment was originally set with a duration of four years (1st March 2014 to 31st Dec. 2018) and has been **extended until 28th February 2021**, with the latest applications to register populations to be received by 31st December 2019 (amendment from 9th October 2018: Commission Implementing Decision (EU) 2018/1519), after which it will **possibly be translated into a directive**.

In parallel, in recent years, the concept of **"Organic Heterogeneous Material" (OHM)** as marketable seed, with a definition not as restricted in terms of crop species or genetic structures, appears in in the **new Organic Regulation (EU 2018/848) that will come into force in January 2021**.

Whilst the Temporary Experiment is an obvious source of experiences and cases studies to inform the development of the delegated acts of the new Organic Regulation, as far as OHM is concerned, it is important to clarify that these are **two distinct and parallel legislative processes** with **two different definitions of the genetic material**:

1. **The Temporary Experiment**, and its potential development into future directives, addresses marketing of seeds of **wheat, barley, oats and maize** falling into specific genetic structures (as introduced above). Quantitative limitations are set (see below), and marketing is irrespective of organic certification:
    - **Full definition of heterogeneous populations in Commission Implementing Decision (2014/150/EU):**

      Art. 2 (a) *they result from a given combination of genotypes; (b) they are considered as units with regard to their suitability for being reproduced unchanged once established in a given region of production with specific agro-climatic conditions; (c) they are generated by one of the following techniques:*

      (i) crossing five or more varieties in all combinations followed by bulking of the progeny and exposing the stock to natural selection in successive generations;

      (ii) growing together at least five varieties of a predominantly cross-fertilising species, bulking the progeny, repeatedly re-sowing and exposing the stock to natural selection until plants of the original varieties are no longer present;

      (iii) inter-crossing varieties using crossing protocols different from those in (i) or (ii) to produce a similarly diverse population that does not contain varieties.

      Hereinafter such plant groupings are referred to as 'populations'

2. **OHM** is part of the **new Organic Regulation** and, as such, will enable certification of genetically heterogeneous seeds via organic certification. It has a broader definition, with no quantitative limitations and **irrespective of crop species**:
    - **Definition of Organic Heterogeneous Material (OHM) in the new Organic Regulation (EU 2018/848):**

      Art. 3 (18) *'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 (1);

      (d) is not a mixture of varieties; and

      (e) has been produced in accordance with this Regulation

The aim of this report is to consolidate a critical overview of the experiences of marketing genetically **heterogeneous populations** when carried out under the **Temporary Experiment,** to assess to which extent

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the suggested conditions and descriptions defined in the Temporary Experiment allow identification and traceability of such populations and avoid fraudulent parallel markets. A SWOT analysis will provide **critical input for respective amendments of the Council Directive 66/402/EEC** to enable the marketing of populations, as defined by the Temporary Experiment, beyond February 2021. Moreover, the report aims to highlight key points to develop further that can facilitate the development of the **delegated acts on the notification of OHM as defined in the new Organic Regulation**.

Key elements of the Temporary Experiment

The Temporary Experiment aims to find alternatives to the exclusion from the market of seeds not belonging to a variety *sensu* CD 66/402/EEC. The initiative arose from scientific evidence that "*shows that there could be benefits of using diverse material, in particular with regards to organic production or low input agriculture".* The main obstacle that the Temporary Experiment tries to overcome is the need to verify *"**whether the identification of populations** […] **can be ensured**, with guarantees similar to those resulting from the requirements concerning varietal aspects, on the basis of **information on their breeding and production methods**"* and "*whether the **identity of the seeds** […] **and the information to the user** can be ensured* […] *based on **traceability requirements** and **identification of the places of production**"*. Overall, considering that certifying genetically heterogeneous populations "*might imply a disproportionate burden"*, the Temporary Experiment tries to provide "***a system of controls** […] **not requiring certification**" sensu* CD 66/402/EEC. The Temporary Experiment sets out a quantitative restriction of the seed marketed for each species in each Member State as not exceeding the *"0.1% of seed of the same species produced in that year in the participating Member State"* (Art. 12).

Whilst seed quality and safety requirements *"should be similar to those set out for certified seeds in Directive 66/402/EEC as to ensure comparable level of quality"*, the focus of the temporary experiment is on the legal aspects of seeds and, specifically, on their identity. The **authorisation of a population** is based on a series of identity control aspects set out in Article 7 that the seed producer needs to provide to the national authority as part of the application for authorising marketing of a population's seed. The most relevant specifically for heterogeneous population identity are the following:

- *7.2.(c) "**description of the type of technique** used to generate the population […]"*
- *7.2.(d) "**objectives of the breeding programme**"*
- *7.2.(e) "**breeding and production method**: breeding scheme […], varieties used […] and own production control programme […]"*
- *7.2.(f) "a **description of its characteristics** […] which the applicant considers as important as regards yield, quality, performance, usability for low input systems, disease resistance, yield stability, taste or colour"* and *"**experimental trial results** concerning the characteristics […]"*
- *7.2.(g) "**region of production**"*
- *7.2.(i) "a **representative sample** of the population".*

The above is a series of **tools** that intend to **fill the information gap** that could arise with seeds that do not belong to an identifiable variety. They have been used in the authorisation and marketing of several populations in the timeframe of the Temporary Experiment.

Main outcomes of the Temporary Experiment

35 populations have been registered across Europe

By 2018, a total of 35 populations have been authorised as part of the Temporary Experiment across six Member States (DE, DK, FR, IT, NL UK; see Table 1). The involved populations were mainly based on composite cross populations (CCPs) of wheat (14 winter wheat, 8 spring wheat, 4 durum wheat). There was also 1 barley CCP, and 5 populations of outcrossing maize.

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Varying results across experimental trials of registered populations

In European (e.g. SOLIBAM, COBRA, DIVERSIFOOD) and national research projects (e.g. INSUSFAR) the advantage of heterogeneous populations has been demonstrated, e.g. higher levels of winter hardiness, reduced disease burden, and higher yield stability under organic or stressful conditions [1]. However, comparative field trials within the scope of the Temporary Experiment are still limited and have focussed more on phenotypic characterisation than the assessment of yield stability.

Authorised populations of winter wheat and barley tested in several countries (UK, France, Germany) showed good and comparable performance to the tested pure line varieties in terms of yield and quality, especially under organic conditions in Germany where trials were conducted in both conventional and organic conditions. However, spring wheat populations were 10 to 15% lower yielding in Germany in 2017. The 5 maize populations yielded up to 85% of the best F1 hybrids across 8 comparative trials in Germany in 2017, which was above expectation for outcrossing open pollinated populations. In DK in 2016 no clear advantages of heterogeneous populations of wheat, oat and barley were found compared to pure lines and registration of these populations was not completed, nor trials continued. Data on the new winter wheat population authorised in Denmark is not yet available. In the Netherlands yields of spring wheat populations were lower than reference varieties mainly due to yellow rust attack and lodging.

Overall, few trails have been conducted on station and/or in well managed organic and conventional trails. Within the timeframe of the Temporary Experiment, due to lack of available funds, official trial data is only available for 1-2 seasons and not all of the trials assessed the yield. Therefore, conclusive data, especially on yield stability under abiotic and biotic stress and under low input management, are still missing. We hope to receive the official reports on the Temporary Experiment for the first four years (March 2014 – December 2018) at the next meeting of the DG Sante working group on heterogeneous material (end of May 2019) to consolidate all the trial data reported to the national authorities.

Over 100 tonnes of population seed have been successfully marketed

By working with the national authorities, it has been possible for the first time to sell seed from specific populations officially to farmers. The largest volumes of seed from populations have been sold in Italy (65T of bread wheat from three populations by December 2017) and the UK (12T of bread wheat from one population by December 2017). At the beginning of the Temporary Experiment the quantity of seed available for marketing of the new populations was low, and problems were also encountered during seed multiplication (e.g. common bunt) reducing the market potential further. Most of the authorised populations have been marketed for the first time in autumn 2018 (including the French, German and some of the Italian populations). Therefore, experiences of valuation of the populations by end-users, e.g. farmers, in the field is still limited. Nevertheless, positive feedback has been received in Italy and the UK.

Innovation within the cereal value chain

The variable nature of population grain has led to innovations by processors and whilst scope has also been limited by the low quantities available, end-user feedback has been positive from those working with populations in this regard. For example, in the UK, interest in the 'story' of the grain beyond standard quality measures, e.g. protein content, has allowed an added-value market to develop with one bakery leading the way on wholegrain sourdough bread production. Alongside the appeal of the 'story', e.g. of increased genetic diversity and alternative breeding models, the baker describes the heterogeneous grain as having "increased flavour". The development of alternative routes to market (direct market chains, integration of breeding into the value chain etc), and increased demand for local grain, has been key to the success of initiatives marketing heterogeneous populations. The UK-registered ORC Wakelyns Population 'YQ' is now available from several

[1] Proceedings of EUCARPIA Symposium on Breeding for Diversification in Feb 2018. https://www.liveseed.eu/wp-content/uploads/2018/03/BREEDING_FOR_DIVERSIFICATION_February_2018_Witzenhausen.pdf

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artisanal millers/bakers and the 'Solibam populations' brand has been successfully developed for the populations registered in Italy.

Table 1: Overview of the crops with populations registered across the different Member States as of December 2018, and the organisation responsible for registering the population(s)

Crop	Country	Registered populations	Contact organisation
Barley	Italy	1	University of Perugia
Durum wheat	Italy	4	Rete Semi Rurali and University of Florence
Maize	Germany	5	FZ Dottenfelderhof, Getreidezüchtung Peter Kunz and LfL Bayern
Spring wheat	Germany	8	FZ Dottenfelderhof, Getreidezüchtung Peter Kunz
	The Netherlands	3	Louis Bolk Institute NL
Winter wheat	France	2	UBIOS
	Germany	7	FZ Dottenfelderhof, Getreidezüchtung Peter Kunz
	Italy	3	Arcoiris and Rete Semi Rurali
	Denmark	1	Agrologica
	United Kingdom	1	The Organic Research Centre
Total		**35**	

Constraints and envisaged solutions

The limited scale

Populations have been marketed far below the quantitative restrictions set out by Art. 12. Only a few cases of authorised populations have been marketed at a commercial scale (e.g. the UK ORC Wakelyns Population, and some French, German, and Italian populations, in particular the Solibam populations) whereas many others are still available at an experimental scale only. Moreover, most of the populations have only been authorised and marketed since 2017 or 2018. This creates a possible bias in interpreting the outcomes of the Temporary Experiment, whose preamble envisaged that *"quantity should be such as to allow for reliable and representative results",* which only Italy and the UK fulfilled, and that the experiment *"should have taken place over a period of at least three marketing seasons",* which only happened in the UK. Whilst the extension until 2021 should allow these expectations to be met, to produce strong evidence in the following seasons it would be essential, at present, to better focus and coordinate the activities based on the limited and fragmentary evidence available so far.

No direct financial support is provided to the actual players involved in the Temporary Experiment for the purpose of fulfilling its goals and objectives. The lack of dedicated funding mostly prevented a coordinated effort in establishing common protocols e.g. for basing the description of populations' characteristics on *"experimental trials results"* (Art. 7.2.(f)). This undermined the creation of a solid evidence base that in turn hampered investment in constituting new populations and/or producing seed at a significant scale.

In fact, since the utility of populations is envisaged explicitly for *"organic production and low input agriculture"*, description of characteristics and performance would possibly need the deployment of adequate testing, that is different from the standardised pre- and post-registration official variety trials in place in all Member States, and that needs to be developed and tested in turn. In the absence of a direct source of funding, many research institutions, seed networks and seed companies have cooperated and relied on either their own limited funding or on external funding through e.g. research grants such as EU FP& SOLIBAM, Core Organic COBRA, EU H2020 DIVERSIFOOD, and this has generated variable protocols and evidence across countries and years.

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It can also take time to develop close linkages with the value chain which, as stated above, is one of the key factors for successful marketing of heterogeneous populations.

The Temporary Experiment has been extended until February 2021 in order to collect sufficient data and experiences across different countries. Financial support by the EU for examination offices, breeders, seed multipliers and companies, as well as researchers, for implementing such Temporary Experiments could further facilitate the participation of more Member States. This would be important to get a better coverage and thus representation of the socio-economic and pedo-climatic regions of Europe allowing a harmonised implementation of the amendment of the EC Seed Directives.

LIVESEED is gathering the key actors involved in the Temporary Experiment and, as such, is committed, through this report, to consolidate the lessons learned from the constitution, registration and marketing of populations as well as looking forward to future developments in: (i) opening the overall seed market to the seed addressed by the Temporary Experiment on a long term basis through amendments of the EU Seed Directives and; (ii) providing grounded guidelines for the development of the delegated acts of the new Organic Regulation (2018/848/EU art. 54) as far as "Organic Heterogeneous Material" is concerned.

The problem of identification and description of populations and the idea of a toolbox to strengthen the Temporary Experiment

LIVESEED partners have been engaged in conversations with the responsible authorities at an EU and national level. For example, by attending the DG-SANTE working group on the Temporary Experiment held in Brussels on the 20th April 2018, and the next meeting to be held on the 29th May 2019 in Bologna. Partners have also interacted with involved examination offices like BSA in Germany, CREA in Italy, GEVES in France, Naktuinbouw in the Netherlands and APHA/NIAB in the UK. On 6th December 2018 LIVESEED organised, together with ECO-PB and CPVO, a special workshop on heterogeneous populations, OHM and organic varieties in the context of the new Organic Regulation. More than 50 people attended, mainly from national examination offices of the 22 Member States, as well as representatives of DG Sante, the European Seed Association (ESA) and UPOV.

One of the main outcomes of these meetings was the need to envisage identification and description procedures based on criteria that do not only rely on traceability and region of production but also on **common characteristic traits** or features, **purpose** and the **need to differentiate between populations**. Especially considering the aim of future implementation of the Temporary Experiment in the Seed Directives and the removal of quantitative restrictions. In fact, traceability alone is insufficient insofar as the administrative burden can increase disproportionately with increasing number and volume of populations, and associated actors for multiplication etc, without protecting against occurrences such as accidental mixtures of different populations (whereas accidental mixture of varieties can be immediately detectable). Varietal purity currently allows for a 'check' on traceability should a mistake occur, or fraudulent activity take place, but is not possible for heterogeneous material.

Region of production has been established as an attempt to limit the evolutionary nature of populations for the purpose of stabilising their 'shape' and performance. However, methodologies to define clear borders of such 'regions of adaptation' are still under investigation. Two of the main variables at play are the level of genetic diversity in the population and the climatic conditions[2], but this will vary on a case-by-case basis and requires further investigation across different species and various environmental scenarios to determine the extent of generalities. Clearly geographical areas alone, as applied in the Temporary Experiment, cannot be

[2] Petitti, M., Bocci, R., Bussi, B., Ceccarelli, S., Spillane, C. and McKeown, P., 2018. Future proofing decentralised evolutionary wheat populations' seed systems in Italy using a climate analogues approach: The example of Tuscany. In SYMPOSIUM ON BREEDING FOR DIVERSIFICATION

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assumed to be the main driver of a populations' evolutionary history, without considering evolutionary drivers, such as soil type, microclimate and agricultural management practices.

LIVESEED took on the work of developing a **toolbox** for the description and identification of populations that could facilitate the implementation of the Temporary Experiment more widely, as well as the development of the delegated acts for the new Organic Regulation (EU 848/2018) as far as OHM is concerned. For the 'toolbox' we aim to develop an integrated series of **different procedures and criteria** that can respond to potentially differentiated sets of needs, depending on e.g. the crop type, reproductive system of the crop, genetic structure and so on, and deliver the necessary information for the description and identification of individual populations to allow official seed certification and marketing to occur. This is based on the hypothesis that, **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) populations an individual plant cannot represent the population**, and therefore a range of **description and identification metrics must be addressed with a plurality of tools**. These tools are to be developed as a series of criteria and procedures that are, in turn, **to be integrated via a decision tree responding to multiple, specific description and identification needs.**

Identification and description tools in the Temporary Experiment

The Temporary Experiment sets out a number of concepts (art. 5) and tools (art. 7) that should allow population identification and description, provided that DUS protocols are not applicable (Table 2). These tools have been thoroughly scrutinised in LIVESEED in T2.1.3, as part of activities to develop a toolbox for identification and description of heterogeneous populations as defined in the Temporary experiment. This task was extended to the characterisation of OHM as defined in the New Organic Regulation (EU 848/2018). Tools already used in the Temporary Experiment (Table 2) 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 is presented in the following tables (2, 3, and 4), and a summary of the SWOT for each participating member state's experiences of marketing heterogeneous populations as part of the Temporary Experiment is in Annex I. These results have come out of LIVESEED T2.1.3 activities, including a workshop held in Paris on 7th June 2018, a second workshop held in Brussels on the 25th October 2018, several conference calls, written consultations a public workshop at Nürnberg Messe Biofach on 14th February 2019 the presentation slides for which can be found in Annex II.

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Table 2: SWOT analysis of 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 parental material 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 parental material 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. • 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.

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Table 3: SWOT analysis of tools related to traceability of populations

Region of 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 a 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.

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	• 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.

Table 4: SWOT analysis of 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.

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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.

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The Temporary Experiment and Organic Heterogeneous Material: common tools

OHM in the new Organic Regulation (EU 848/2018) is based on a much broader definition than the heterogeneous populations of cereals defined in the Temporary Experiment (see Introduction above). OHM is not as restrictive with respect to: (i) **crop species** (i.e. no limitation to certain crop categories); (ii) the **constitution** of the material (i.e. no minimum number of parental lines or crosses, *however note Art 2. (c), (iii)*); (iii) **selection methods** (i.e. not only exposure to natural selection in successive generations), and; (iv) **seed quantity**, but there is the requirement that OHM is produced (both breeding and maintenance) in accordance with the Organic Regulation.

The advantage of 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 material. Figure 1 highlights that there is some overlap between material 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.

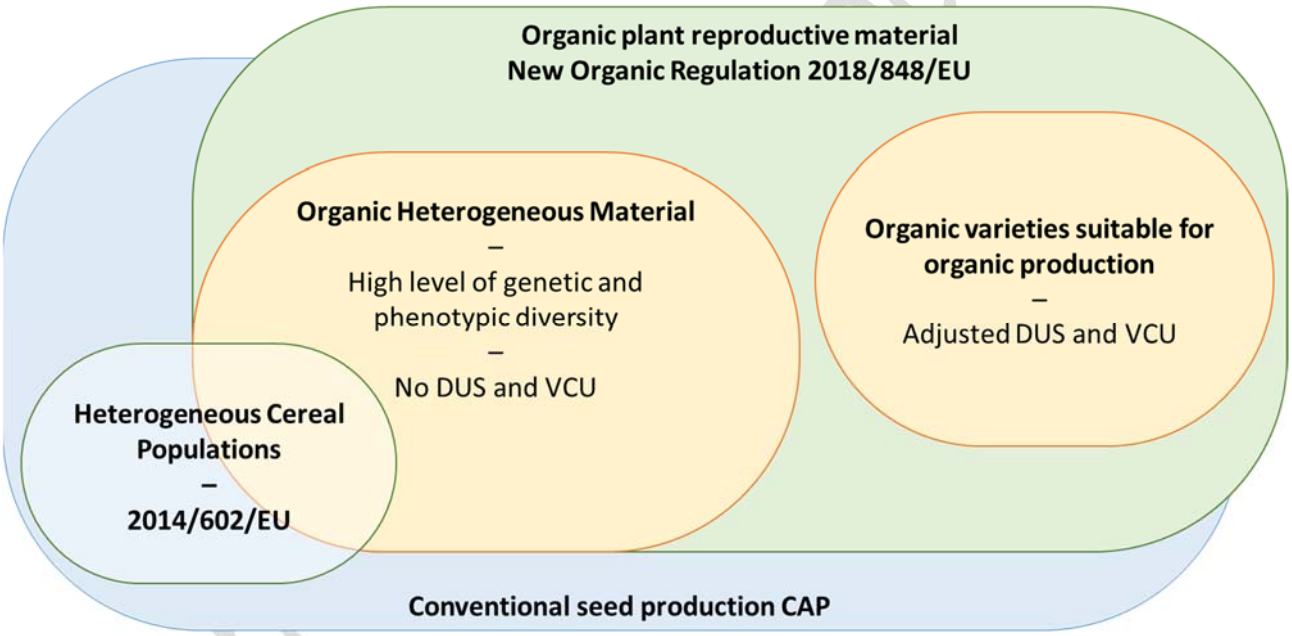

Figure 1. Schematic differentiation between populations defined in Temporary Experiment and new cultivar types of OHM and organic varieties implemented in the new Organic Regulation EU 848/2018

Annex III outlines the structure of a LIVESEED working document on OHM based on the above-mentioned workshops and exchanges with competent authorities, and different actors within the organic sector. 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) similar to those marketed in the Temporary Experiment on cereal seed. The structure of this document will also provide the framework for the decision tree that will inform the appropriate tool use depending on the OHM being certified. For example, at one step it will be necessary to distinguish between self-pollinating species and cross-pollinating (=outcrossing) species in order to develop a useful toolbox for identification and description (Annex III).

General recommendations are:

- Simple notification procedure;
- No intellectual property;

- Full transparency in breeding process;
- Breeding, selection, maintenance and seed multiplication need to be conducted under certified organic conditions;
- Breeding methods shall comply with organic principles;
- Parental material should also have been obtained through breeding methods in compliance with organic principles;
- Applicable for all crop species;
- No seed quantity restrictions;
- Truthful labelling and producer liability.

Based on the SWOT analysis we have also identified certain improvements for the identification and description of populations within the Temporary Experiment, which as well as informing preliminary recommendations for the delegated acts on production and marketing of seeds of OHM, we hope will be integrated into future amendments to the Seed Directives (Annex IV).

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Annex I. The Temporary Experiment: Overview of experiences from the participating Member States

<table>
<tr><th colspan="2">France</th></tr>
<tr><th>Strengths</th><th>Weaknesses</th></tr>
<tr><td>Good collaboration between involved stakeholders: UBIOS, GEVES, Ministry, GNIS (SOC), ITAB, INRA...
Evaluated over 2 growing seasons of 2 wheat populations (a 3rd is currently under way).
In 2018, a simplified phenotypic description was possible, despite the overall heterogeneity. This description includes the soil covering ability (weed competitiveness).
Seed multiplication of the 2 populations in 2 different areas (up to 10 ha multiplication fields).</td><td>Small quantities put on the market, not enough time to assess the commercial phase.
Difficulties for the seed company (UBIOS) to deal with small seed quantities (not compatible with the equipment of the seed station).
More time needed to conclude on current evaluations.
Further studies are needed with regards to the stability and/or the evolutionary potential of these populations over time and space. When can we consider a population to have sufficiently evolved to be named differently? It’s difficult to define the threshold to declare two populations as different.</td></tr>
<tr><th>Opportunities</th><th>Threats</th></tr>
<tr><td>This experiment led to the creation of a new wheat CCP, jointly developed by INRA and UBIOS, with parents carefully chosen for the area and use.
The database ‘Seeds History and Network Management System’ developed by INRA Moulon with a licence fee could be useful to ensure the traceability and seed lot descriptions. Would maybe need additional specific developments.
To integrate new species in the French experiments.</td><td>At this stage, no other actors that UBIOS applied for this experiment therefore the scope if somewhat limited.</td></tr>
<tr><th colspan="2">Germany</th></tr>
<tr><th>Strengths</th><th>Weaknesses</th></tr>
<tr><td>As a prerequisite for seed certification, yearly field visits were carried out by Federal State officials. According to representatives from the involved authorities guaranteeing seed quality with these tests is a viable option (esp. with regard to plant health, weed pressure, minimum distances from neighbouring fields).
For the registration of populations, seed samples of 5 kg in the case of self-pollinating crops, and 2 kg for maize, were successfully collated by the German Federal Plant Variety Office. Again, the focus was mainly on seed quality.</td><td>Neither field visits nor reference samples seem to be viable tools for the identification of populations (in the sense of being able to distinguish population A from population B by their appearance in the field or properties of the seeds). The officials carrying out the field visits remarked that they lacked concrete indicators telling them whether the population in the field could be the correct, registered, one.</td></tr>
<tr><th>Opportunities</th><th>Threats</th></tr>
</table>

• Proposal for an additional tool in the process of registration of populations: Government officials could require applicants/breeders to specify 'indicators' or 'clues' for the identification of populations. As indicators the applicant could choose, for example, 2 – 5 morphological traits (like those from standard DUS-protocols) for which values or frequencies or ranges have to be specified. Indicators could be of much help to government officials in field visits. • Proposal for another additional tool for the description of populations: Voluntary VCU-like performance tests could be offered (and financed) by government authorities. Can provide reliable information on yield, quality and other agronomic traits of populations and is of particular importance for farmers and other members of the supply chain.	• The tools of the toolbox (proposed above) should help to reach a well-balanced compromise between an open system, especially for small breeders and farmers (with no insurmountable bureaucratic barriers) on the one hand and the provision of consumer protection, as well as reliable information for all stakeholders, on the other. • There is a very real threat that if too much heterogeneous material (HM)/populations of inferior agronomic quality are introduced on the market the reputation of HM will be permanently damaged.
Italy	
Strengths	**Weaknesses**
• Offers a solution to the lack of dedicated breeding programmes for the Organic sector. • Populations have proven their ability to adapt and evolve in a variety of different environments. • Populations are adapting to climatic trends imposed by climate change. • Involving farmers in participatory evaluation activities with populations ensured high interest and excellent adoption of the material. • Encouraging results in terms of populations' yield and stability from field trials.	• Formal seed sector insufficiently prepared to invest in population breeding and seed production. • 'Conventional' long value chains don't have the right setup to accept products, which may vary from year to year in terms of quality.
Opportunities	**Threats**
• Opening for innovative seed systems to develop successful decentralised business models. • Support and cooperation from seed certification authorities facilitates emerging seed producers to start population seed production. • Implementation of innovative research models for population evaluation and design.	• Criticism from the 'official' academic establishment toward a breeding strategy which has a long and respectable history, but was never adopted at scale, mainly due to economic reasons. • Lack of clear rules regarding labelling of products deriving from populations can generate inaccurate perceptions in customers and commercial fraud. • Persuade famers and consumers of the importance of population registration and seed certification in the interest of quality.
United Kingdom	
Strengths	**Weaknesses**
• Functioning seed and grain supply chain(s) established with engagement from a range of chain actors (seed merchants, processors and bakers).	• Not commercially viable without research funding support.

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• Consistent field and quality performance of populations with some end-users showing a preference and becoming 'regular customers'. • Good relationship established with national authorities and collective interest in designing alternative approaches for 'different' types of material.	• End-users still struggle to accept the variability of such heterogeneous populations.
Opportunities	**Threats**
• Fostering of local direct supply networks. • Increased genetic diversity in farmers' fields leading to resilience of crops to e.g. unpredictable weather conditions.	• Work does not continue due to lack of financial self-sufficiency. • Seed companies lose interest due to the small scale of production and sales (so far). • Lack of integrity across the supply chain leading to reduction in quality e.g. increased risk of disease. • CCPs are likely to offer 'average' performance but their advantages become apparent over time and different environmental scenarios, and in challenging conditions. Yet they may be dismissed for not being the 'best' option around.
The Netherlands	
Strengths	**Weaknesses**
• Identity assurance only by traceability (audit of samples examined in control plots less useful).	• Differences between populations 1 and 2 very small (too small for identity check). • Yield of spring wheat populations 20% lower than reference variety (mainly caused by yellow rust and lodging). • Challenges associated with instability between years and sites.
Opportunities	**Threats**
• German populations were trialled in the Netherlands. There was some evidence of phenotypic shifts of the populations from one generation to the next which might indicate evolutionary potential of such material across different environments.	• Description of populations based on (general) morphological characters is not possible, or very difficult. • VCU parameters (testing) not distinctive enough from leading varieties. • Organic seed of spring wheat more prone to seed borne diseases especially loose smut (*Ustilago nuda*).

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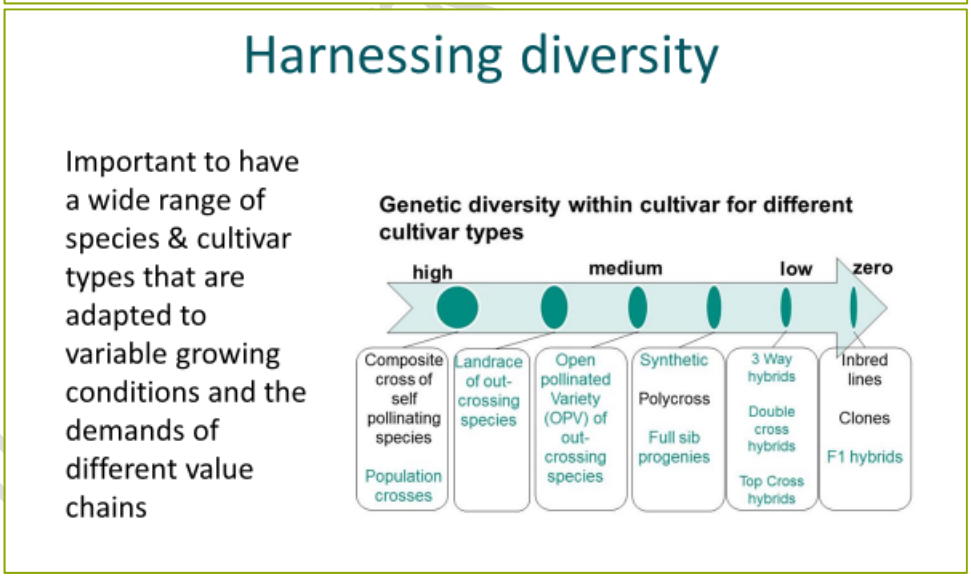
Annex II. Presentation on toolbox for heterogeneous populations at Biofach by Charlotte Bickler in Nürnberg on 14th February 2019

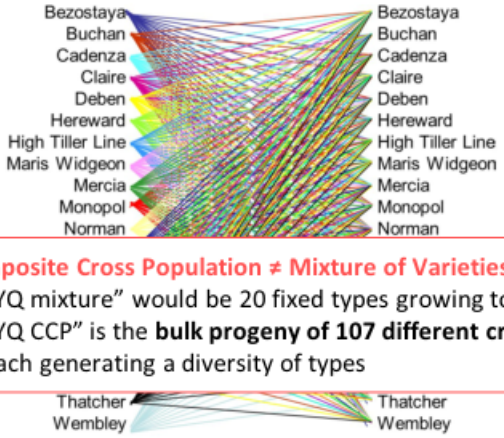


The Organic Research Centre

ORC's Experiment in heterogeneous material:

– An example of diversity-driven resilience

ORC Wakelyns Population



Composite Cross Population ≠ Mixture of Varieties

- "YQ mixture" would be 20 fixed types growing together
- "YQ CCP" is the **bulk progeny of 107 different crosses**, each generating a diversity of types

ORGANIC RESEARCH CENTRE ELM FARM

The Organic Research Centre

Evidence of resilience

Particularly under stressful conditions

"Normal" situation (early sowing)

ORGANIC RESEARCH CENTRE ELM FARM

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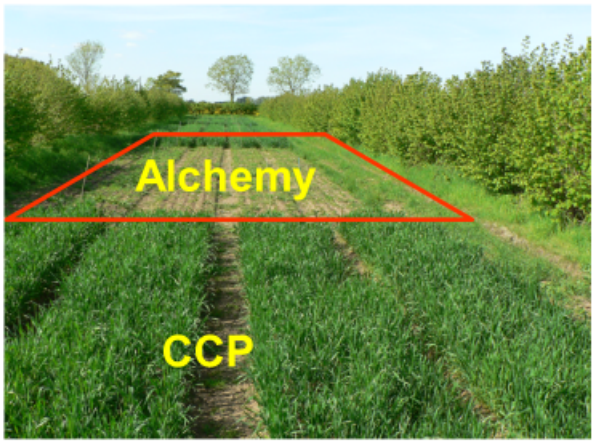
The Organic Research Centre



ORGANIC RESEARCH CENTRE ELM FARM

"Stressful" situation (late sowing)

The starting point – 2014/150/EU

Article 1

Subject matter

2. The following elements shall be assessed:

(a) whether the identification of populations of those species can take place on the basis of information on their breeding and production methods, the varieties used in the crossing, and the main characteristics of those populations; and

(b) whether the identity of seeds from those populations marketed can be based on traceability requirements and identification of the region of production.

Alternatives to DUS

'Certified traceability'

From Article 2 **"Scope"**

Populations = plant groupings that result from a **given combination** of genotypes; …considered as units with regard to their suitability for being **reproduced unchanged** once established in a given region of production with specific agro- climatic conditions; …generated by…

- Crossing **>5 varieties** and **bulking progenies**
- Growing together **>5 varieties** of cross-pollinated spp. and **bulking the progeny**
- Inter-crossing varieties with other methods to produce a population that **does not contain varieties**

Definition
'population' ≠ 'variety'

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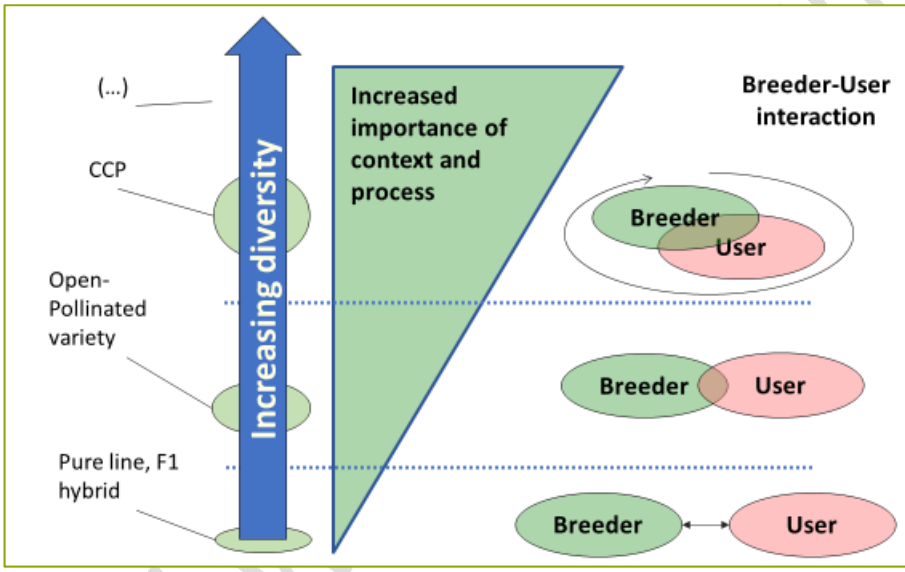
Identification – 2014/150/EU

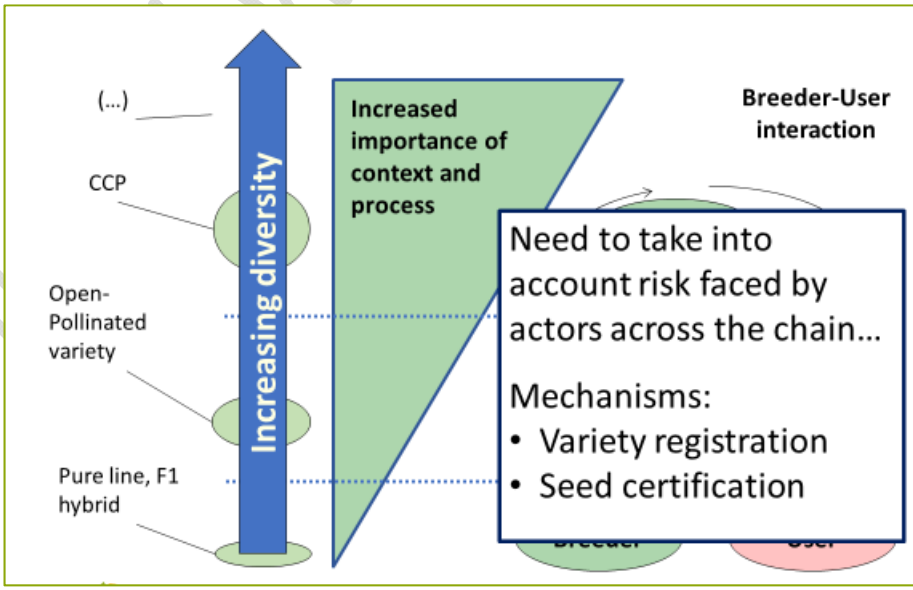
- Article 5
  - **Parent germplasms**
  - **Breeding scheme**
  - Region of production
  - Degree of heterogeneity
  - **Characteristics** (Article 7 (2)(f))

(f) a description of its characteristics:

(i) documentation of its characteristics which the applicant considers as important as regards yield, quality, performance, usability for low input systems, disease resistance, yield stability, taste or colour;

(ii) experimental trial results concerning the characteristics referred to in point (i);





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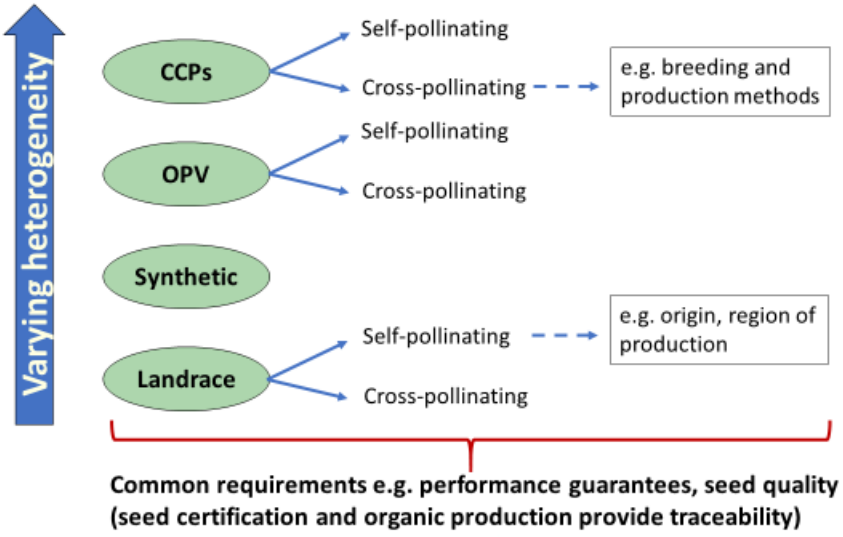
Reviewing progress

- Challenges with traceability – what can provide a back up if ID is not possible?
- Separating seed identity from population identity (when DUS is not possible)
- Preventing 'parallel market' – considering when the market grows
- Toolbox for 'population description and identification'
  - Different tools to address different challenges

Different tools for different tasks



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Tools for the toolbox

Identification (Art. 5)	Population authorisation (Art. 7)
	Species and denomination
Parent germplasm	Breeding objective(s) Breeding and production methods (selection)
Breeding scheme	
Region of production	
Degree of heterogeneity	Description of how the population was generated e.g. 5 parent CCP
Characteristics (trial results)	Characteristics (trial results)
	Representative sample
	Applicant details and declaration

For Organic Heterogeneous Material this will be certified

Identification (Art. 5)	Population authorisation (Art. 7)
	Species and denomination
Parent germplasm	Breeding objective(s) Breeding and production methods (selection)
Breeding scheme	
Region of production	
Degree of heterogeneity	Description of how the population was generated e.g. 5 parent CCP
Characteristics (trial results)	Characteristics (trial results)
	Representative sample
	Applicant details and declaration

Does this provide information of use and interest?

Identification (Art. 5)	Population authorisation (Art. 7)
	Species and denomination
Parent germplasm	Breeding objective(s) Breeding and production methods (selection)
Breeding scheme	
Region of production	
Degree of heterogeneity	Description of how the population was generated e.g. 5 parent CCP
Characteristics (trial results)	Characteristics (trial results)
	Representative sample
	Applicant details and declaration

Based on performance (etc) as outlined in Article 7 (2)(f)

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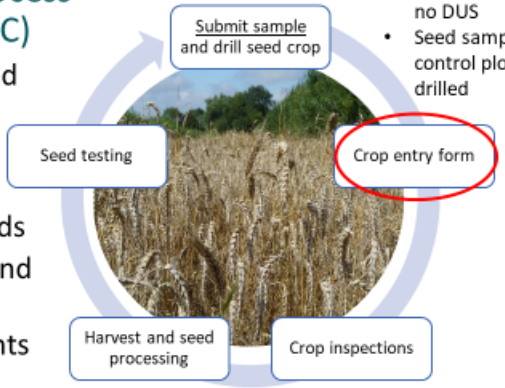
Identification (Art. 5)	Population authorisation (Art. 7)
	Species and denomination
Parent germplasm	Breeding objective(s) Breeding and production methods (selection)
Breeding scheme	
Region of production	
Degree of heterogeneity	Description of how the population was generated e.g. 5 parent CCP
Characteristics (trial results)	Characteristics (trial results)
	Representative sample
	Applicant details and declaration

Can this provide a back up? How about when a population evolves?

Identification (Art. 5)	Population authorisation (Art. 7)
	Species and denomination
Parent germplasm	Breeding objective(s) Breeding and production methods (selection)
Breeding scheme	
Region of production	
Degree of heterogeneity	Description of how the population was generated e.g. 5 parent CCP
Characteristics (trial results)	Characteristics (trial results)
	Representative sample
	Applicant details and declaration

It is a legal document and applicants will be committing fraud if they provide false information

- Seed certification process (Directive 66/402/EEC)
  - Sufficient identity and varietal purity
  - Diseases lowest possible level
  - Seed quality standards
  - Compliant seed lot and sample weights
  - Labelling requirements
  - Compliance with ID standards (Art. 5)



Region of seed production (can also tell us about ongoing selection environment)

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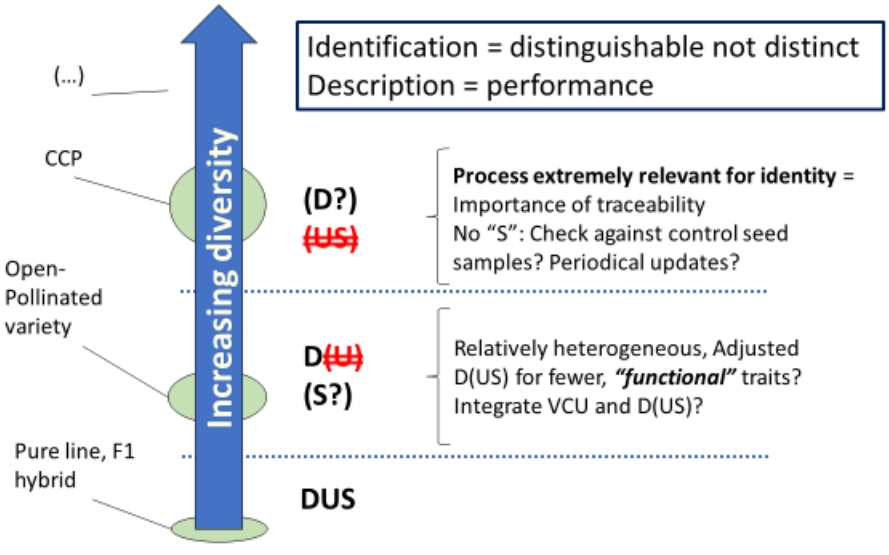
- Seed certification ensures:
  - Traceability (will also be given by organic certification)
  - Seed safety and quality standards
  - Identification of region of production for the seed lot(s)
- "Compliance with the **identification requirements** of Article 5 shall be concluded on the basis of **submitted documentation** and **inspections** in the premises where the population is produced."
- Varietal information generally being overlooked
- What does ID deliver anyway?
  - Characteristics/trial results can tell us about performance but are not checked via DUS
  - Whose interests are the processes serving?

Adjustments to be made

- Sticking points
  - Sufficient identity/'varietal purity' (back up to paper work?)
  - Region of production for population ID shouldn't be based on arbitrary borders
  - Degree of heterogeneity – how is it measured and what is its purpose? Will current definition be restrictive if adopted more broadly?
- What's missing (maybe)?
  - Trait frequencies – to support ID and provide details on heterogeneity
  - Performance monitoring
  - Registration committee & open description



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Next steps

- Broadening scope
  - Definition of HM to include different crops
  - Different 'degrees of heterogeneity'
- Adding clarity to terms and processes for tool use
  - For example, region of production
- Gathering evidence on distinguishable features
- Producing a decision tree for what tools are most appropriate to address different challenges in different crops
- Validated protocols for the release of heterogeneous populations (LIVESEED D2.4, Nov 2020)

Questions for discussion

- Are the tools presented useful in formation of a system for description and identification of HM?
- Do you think there is anything missing?
- Are there any clear problems with the tools from your perspective?
- Thoughts and ideas on how to implement – can we make a diversity of approaches for diverse material a reality?

LIVESEED

This project received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 727230.

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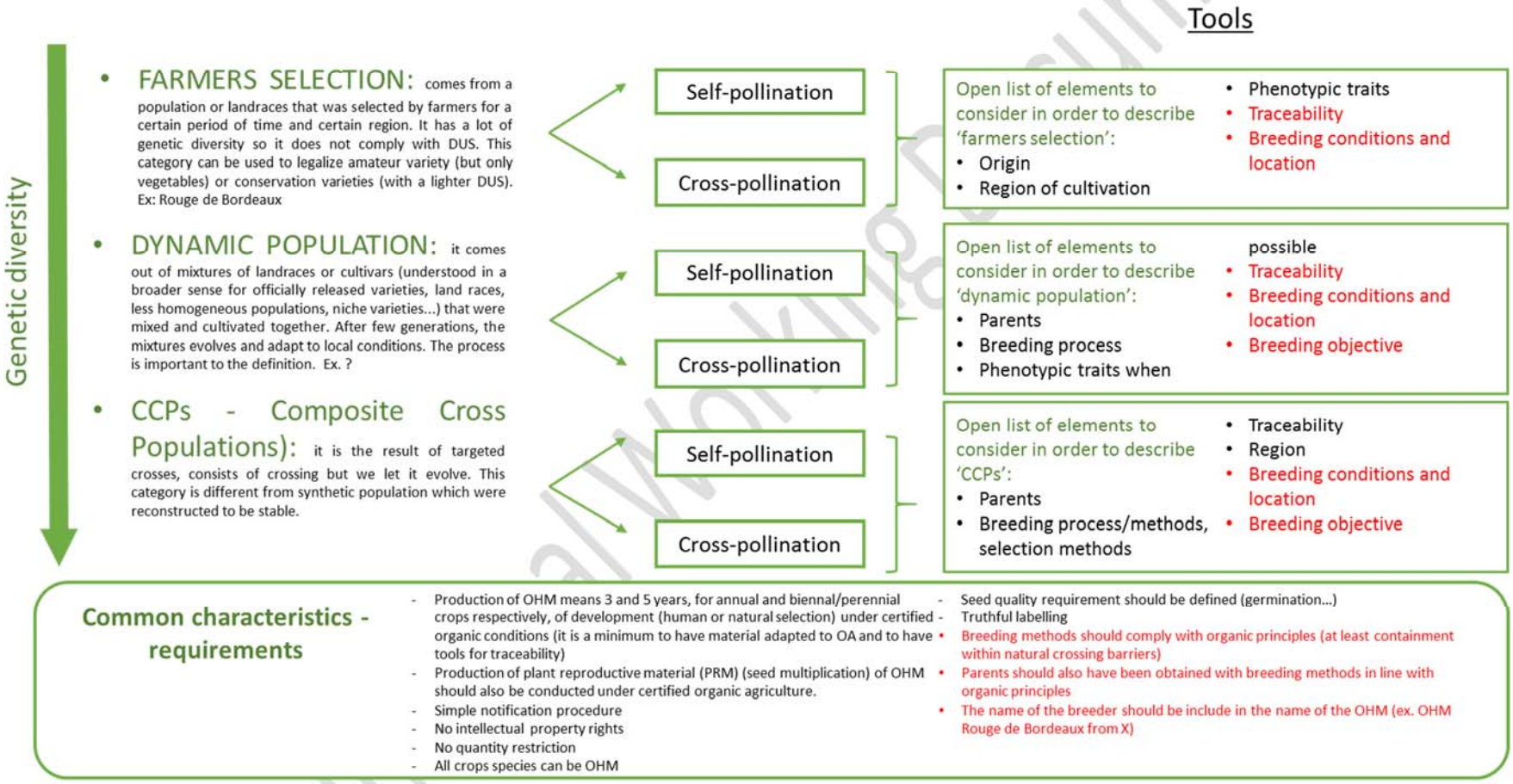
Annex III. Description and Identification toolbox for Organic Heterogeneous Material (OHM) under development as presented at the 2nd Annual Meeting in Zelechow on 15th May 2019

Working document on OHM description and identification including draft decision tree



Annex IV: Proposed amendment to the Seed Directives based on experiences from the Temporary Experiment

	Proposed changes (in red)
Article 2	(i) varieties according to UPOV is too restrictive and excludes unreleased breeding material like released varieties, landraces, heterozygous progenies, or already existing populations that shall be improved by crossings; (ii) cross-pollinating species have already a large genetic diversity if they have not been inbred for hybrid production, thus the number of crosses can be reduced in case of heterogeneous landraces and populations Justification: (i) varieties according to UPOV is too restrictive and excludes unreleased breeding material like released varieties, landraces, heterozygous progenies, or already existing populations that shall be improved by crossings; (ii) cross-pollinating species have already a large genetic diversity if they have not been inbred for hybrid production, thus the number of crosses can be reduced in case of heterogeneous landraces and populations
Article 5	a) the ~~*varieties*~~ *parental material* used in the crossing for the creation of the population; (b) the breeding schemes as defined by the respective protocols *and applied breeding techniques*; ~~*(c) the region of production*~~ (*c) Selection environments (pedoclimatic conditions, agricultural management)* *(d) Maintenance and multiplication conditions (pedoclimatic conditions, agricultural management)* *(e) Geographic sites of breeding and selection* ~~*(d) the degree of heterogeneity, in particular in self-pollinating species; and*~~ (e) its characteristics, as referred to in Article 7(2)(f).
Article 7	2 (e) breeding and production method: breeding scheme as defined by the respective protocols, *parental material (incl. released varieties, landraces, heterozygous progenies, populations), crossing design, breeding techniques and selection environments (pedoclimatic conditions, agricultural management, geographic site)* used to breed and produce the population, and own production control programme used by the operator concerned 2 (g) *conditions for maintenance and multiplication (pedoclimatic conditions, agricultural management, geographic site)* ~~*region of production;*~~
Article 12	(1) The quantities of seed marketed of the authorised population of each species, for each participating Member State per year, shall not exceed 5.0 % of seed of the same species produced in that year in the participating Member State. Justification: A quantitative limitation of 0.1% is too restrictive to promote new concepts for improved genetic diversity on field level in order to foster sustainable agriculture and counteract challenges of climate change. A limit of 5% will be sufficiently strict to avoid the development of parallel markets.
General	• Administrative burden and inspection should be kept to a minimum • Notification of heterogeneous populations instead of time-consuming and costly registration process • The producer shall guarantee and be liable for truthful labelling of the heterogeneous populations indication purpose or special features of the heterogeneous material and germination rate • Information on the whole breeding process shall be made transparent including parental material, breeding scheme, breeding techniques, the particular pedo-climatic conditions where the material was selected and multiplied

	• The option of marketing heterogeneous populations should be included also in Seed Directives of other crop categories like vegetable, legumes, forage crops, etc. as there is no scientific reason, why the concept should only work in cereals

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