

INnovations in plant Varlety Testing in Europe



Socio-economic and environmental assessment of INVITE innovations criteria selection

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Summary

Variety testing is a fundamental innovation process for improving the productivity and quality of plant products and the sustainability of food systems It comprises several main components which are plant breeding, variety registration, and post-registration stages. The results of variety testing at each stage are very important to deliver relevant information to the farmers as regards variety performance. Over the past three years, INVITE has focused on developing technological and institutional innovations aimed at improving the plant variety testing process. Work Package 6 (Improved Variety Testing Networks) includes a task to assess the economic, social, and environmental impacts of INVITE's innovations through a cost benefit analysis (CBA). This deliverable aims to identify a set of suitable criteria to perform the impact assessment and the CBA of putative innovations in variety testing. The results of the CBA will facilitate the decision- making process regarding INVITE's innovation and scaling up.

The assessment will be performed on a rather homogeneous process to be replicated. Therefore, our approach is limited to variety registration and does not take into consideration the private *exante* breeding activities or the post-registration (public and/or private) activities. Hence, to identify the relevant criteria, first, the methodological approach is described. Then, the state of the art of the registration process is contextualised at the European level focusing on two countries (Switzerland and Spain), and two crop species (apple and wheat). Then, a list of challenges in the registration process was presented and key stakeholders were identified to provide data for the selected criteria. In addition, a set of innovations developed/tested within INVITE is described and defined based on their maturity stage or readiness level. For each innovation, a list of expected impacts is identified. To define the analytical framework, a literature review of previous approaches to assess innovations in agricultural research is presented. Then, for each set of expected impacts of innovation, a set of criteria to consider is listed.

In addition to this classical impact assessment approach, a CBA will be conducted for technological innovations including phenotyping and genotyping tools, whose expected impacts in terms of cost, resource, and time use are measurable. For institutional innovations such as new protocols for variety testing and the standardisation of guidelines across the EU will be assessed through an Analytical Hierarchical Process (AHP) that prioritises stakeholders' perceptions based on criteria that are relevant in decision making for the development of new plant varieties. Through a choice experiment, farmers' willingness to pay sustainability traits and to be included as criteria in variety testing will be elicited. The document concludes with a series of final recommendations, highlighting the importance of collaboration among the project partners and other stakeholders to obtain high quality indicators that can assist in an objective assessment of the innovations.





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1. Introduction

There is an increasing pressure to develop new plant varieties that combine higher yield with improved quality, resiliency to biotic and abiotic stresses, high resource use efficiency, and that are more adapted to sustainable management practices. In the European Union (EU), productivity growth has been able to meet the increasing food demand, and plant breeding has been a major contributor to this growth (Noleppa & Cartsburg, 2021).

Breeding a new variety is an extensive and costly innovation process for which mechanisms to safeguard breeders' investment, facilitate the commercialisation of varieties, and provide adopters with valid information for decision-making have been developed. At the core of the process is the registration of new varieties, a required step for a variety before its commercialisation. The system relies on the fulfilment of the Distinctiveness, Uniformity, and Stability (DUS) criterion, and some crop groups must meet the Value for Cultivation and Use (VCU) criterion. These parameters are evaluated through tests that need additional time and resources along with those already invested in the breeding process.

Variety registration is foreseen for most of the crop species through the so-called seed marketing directives of the European Commission (EC). Such directives (12 in total) are transposed at the Member State level, so each Member State has its registration system. Moreover, each Member State (at the national level) and the Community Plant Variety Office (CPVO) (at the European level) can also grant intellectual property rights to plant varieties (Plant Variety Rights), based on DUS trials performed by the Examination Offices (EO) at the Member State level. The CPVO has developed standardised technical protocols for DUS testing that most Member States apply at the national level, while each Member State establishes its own VCU assessment protocols for each crop species covered by VCU obligations. For the last 15 years, the EC has initiated a revision of its legal framework. Debating points include new methodologies for the evaluation of DUS and VCU criteria, creating a more integrated system, and adapting the existing guidelines for the evaluation of traits oriented towards more sustainable production measures. A proposal to modify the regulation on the production and marketing of Plant Reproductive Material in the Union was just published on July 5, 2023 (European Commission, 2023).

The Horizon 2020 project "Innovation in Plant Variety Testing in Europe" (INVITE) aims at improving the efficiency of variety testing, to develop new varieties better adapted to more sustainable management practices and resilient to climate change. To this end, during the last three years, the project has been developing tools to improve efficiency and accuracy and integrate sustainability criteria in variety testing. Moreover, INVITE will elaborate on recommendation to policymakers to include new methodologies and criteria into the DUS and VCU testing of varieties adapted to the current agricultural challenges.





One of the main objectives of WP6 is to assess the economic, social, and environmental impacts of the innovations developed for variety testing under INVITE. This task relies on an *ex-ante* Cost-Benefit Analysis (CBA) of proposed innovations. Thus, a fundamental first step in this process is the selection of criteria to consider for the CBA. To set up the baseline of the approach, first, we reviewed the current registration system and identified stakeholders involved in the process. Second, we present the main innovations under development in INVITE. Third, we reviewed previous attempts to assess the CBA of similar technologies and other innovations in agriculture. Fourth, we proposed methodologies and a set of criteria for the impact assessment and the CBA.

2. Methodological approach

2.1. Scope of the assessment

The CBA consists of determining whether and at what levels the benefits of a given technology outweigh the costs relative to other alternatives. It entails a discounted free cash flow model that yields financial profitability indicators. To construct it, is necessary to identify the costs and benefits associated with the elements to be evaluated and related financial, environmental, and social indicators to estimate such costs and benefits. The selection of such criteria involved several steps. At an early stage of the project, the assessment was delimited, given the wide amount of crop species (10) and countries (17) involved in the project. Therefore, registration of new wheat (*Triticum aestivum L.* emend. Fiori & Paol.) and apple (*Malus domestica Borkh.*) varieties in Spain and Switzerland were selected as case studies, although for the assessment of certain innovations, the list will be extended to other crops and countries.

Both crops are of economic and food security importance in the EU. Selected crops represent contrasting examples when it comes to the registration of new varieties. Time and costs for registering perennial species (apple) are considerably higher than for agricultural crops (wheat), which have a shorter growth cycle. VCU tests are only required for agricultural crop species and industrial chicory, while there are no such requirements for other species. Moreover, different technologies for phenotypic and genotypic evaluation of traits are already routinely used in both crops for breeding and can be scaled up to registration trials.

Countries were selected due to the involvement of INVITE members in both countries in the registration process and high interaction with other local stakeholders, the relative importance of both crops at the national level in terms of production and consumption, and the presence of breeding programs of different natures. In addition, since Switzerland is not an EU member, it represents an interesting case study to contrast results with the ones of Spain, which is expected to





provide approximately similar results to other EU countries being subjected to the common Directives.

To select the criteria needed for the assessment, a deep literature review was conducted. This step aimed at understanding the registration process, mapping the stakeholders involved, and identifying the main aspects that could be improved. Then, we look at innovations and methodologies developed within INVITE and their potential impacts of in the registration process and its application at the crop level. Previous attempts to assess the impact of innovations similar in nature and other types of technologies were reviewed to define the approach to follow for the assessment, considering factors such as the scope of the assessment, lifetime of technologies, and expected data availability.

Information collected in the previous steps helps us to build an evaluation framework considering the hypothetical impact of selected technologies. For each innovation, expected impacts were listed, and for each impact, relevant criteria to assess the costs and benefits were identified. Furthermore, different approaches to assess the impact were described for some innovations, due to the limitations that conducting a classical CBA entail. The list was completed by identifying relevant stakeholders to be contacted in future phases of the project for data collection. The whole process was complimented and validated through a series of expert consultations that involved a questionnaire with 54 stakeholders and regular meetings with members of INVITE.

2.2. Methodological tools

Three different methodological tools will be used to assess the impact of selected innovations. First, to evaluate the impacts that the implementation of new technologies would mean in terms of cost, time, and resource savings in variety evaluation testing, a classical CBA analysis will be carried out. To this end, related financial costs and benefits of different scenarios of technology implementation will be identified and quantified to the extent possible. Then, the values are discounted using the time value of money, allowing meaningful comparisons to be made between different periods. Finally, the net present value of the project is calculated by subtracting the discounted total costs from the discounted total benefits. Other indicators can also be calculated, such as the internal rate of return, the benefit/cost ratio, and the payback period.

The environmental impact of selected innovations will also be addressed by estimating how actions such as reduced resource use for the evaluation of selected traits translate into environmental impacts, such as reduced greenhouse gas emissions or savings in water use. However, due to the relatively small size of the cultivated area involved in such trials, these impacts are significantly smaller about the environmental impacts at the producer level that the release of varieties with traits oriented to more sustainable production systems could have. Both levels of impacts will be translated into monetary terms using secondary economic valuation data of environmental



variables. In addition, different scenarios will be drawn, allowing us to outline different hypotheses considering variables such as the implementation of new regulations in variety testing or the degree of substitution that registration offices will adopt regarding the measurement of traits in variety testing.

The second methodology will focus on evaluating the set institutional arrangements proposed to improve variety testing networks and integrate sustainability criteria in variety testing by examining the preferences of different stakeholders regarding the implementation of such arrangements. Using a multi-criteria decision-making method, we will prioritize the implementation of institutional arrangements by considering the factors that decision-makers prioritize for the development of new variety plans. Although the outcome of this prioritization will not quantify the impact of such innovations, the results will not only help us to provide recommendations for policy making but will also allow us to prioritize scenarios for carrying out CBA. Such methodology will be implemented with all types of stakeholders involved in the variety testing and will not be limited to a specific country or crop.

To this end, the Analytical Hierarchy Process (AHP) will be used. The AHP is a mathematical framework that decomposes a decision-making problem (overall objective) into a system of hierarchies of alternatives to achieve it, and a set of factors or criteria that relate the alternatives to the objective. The criteria can be further decomposed into sub-criteria, and each level of the hierarchy is evaluated using comparative judgments (T. L. Saaty, 1977). The method is suitable for the prioritization of institutional arrangements since it allows the assessment of qualitative data in a discrete environment and captures situations involving subjective judgments and multiple decision makers (Eynizadeh & Dehghani, 2020).

Conducting the AHP involves several steps. First. the criteria and sub-criteria associated with decision-making factors for the development of new varieties will be identified to construct the structure of the AHP. Then, scenarios based on proposed arrangements for the registration system (alternatives) will be identified. This will be based on actions described in sections 4.3 and 4.4. Then, an online survey will be distributed to stakeholders in the registration of new varieties to compare the relative importance of factors at one level concerning each criterion at the higher level of the decision structure, and with the alternatives that will be defined. Results will be used to estimate importance weights for each criterion and alternatives to obtain a final prioritization. A sensitivity analysis will be conducted to further refine a list of recommendations for policy implementation.

The third methodology will focus on assessing the impact of integrating sustainability criteria into VCU testing. This is done considering the hypothesis that such action is expected to increase the number of varieties oriented towards more sustainable means of production in the seed market. Thus, our approach will focus on eliciting the willingness to pay (WTP) of local farmers for such traits. In parallel, the methodology will also be used to learn farmers' preferences for varieties registered under new variety testing methods. For this, Discrete choice experiments (DCE) will be conducted.



Discrete choice experiments (DCEs) are a widely used method in the field of experimental economics to elicit stated preferences through hypothetical scenarios that systematically vary the key factors that are supposed to determine choices. This is useful when revealed preference data are unobtainable or uninformative, such as when predicting demand for a new product where it is impossible to use revealed preference data on actual choices made by farmers (Sanou et al., 2019), such as in the case of varieties with sustainability traits.

To conduct a DCE, first, the objectives of the study and the population of interest must be defined. For this case, the objective will be to identify the WTP of apple and wheat farmers for attributes related to the application of new technologies in variety testing and traits related to sustainability traits. The next step is to define the relevant attributes and levels for each attribute. For each attribute, category levels describing characteristics should be defined. Since obtaining the economic value of the attributes is a fundamental part of the research, it is essential to price the options set. For this, in-depth interviews will be conducted with relevant stakeholders in both countries.

Once the attributes have been defined, the survey must be constructed by establishing the set of choice sets that will be presented to participants and which should include different combinations of attribute levels. The survey will be distributed through INVITE partner organisations in both countries, in collaboration with relevant stakeholders such as farmers' organisations, breeders, and research centres. The last step is the analysis and interpretation of the data. The specific model for data analysis will be defined at a later stage of the research once the experimental design has been constructed and the nature of the data collected has been analysed.

3. State of the art of plant variety registration

3.1. Variety registration in the EU

In the EU, variety registration for most of the crop species is covered by 12 directives of the EC. These comprise a Directive on the Common Catalogue of varieties of agricultural plant species and 11 marketing Directives covering seed (5 directives), plant propagating material (3), and forest reproductive material (2). In addition, three derogations to the Directives were introduced, which include modifications to the registration process for organic varieties and regulating the registration of conservation varieties.

Varieties marketed/commercialised in the EU have to be included in the Common Catalogues covering agricultural plant and vegetable species. To meet this condition, a variety needs to be registered in a National Catalogue, which is controlled by an official authority at the Member State level, often referred to as the Registration Office. Registered varieties must have their own denominations, be novel (not commercialized for more than a certain period inside or outside the EU) and be distinct (from varieties of common knowledge), uniform, and stable (DUS). In the EU,





technical protocols for DUS of many crops are given by CPVO, thus harmonised across most Member States and consistent with those established by UPOV. Trials are usually conducted in a field or a glasshouse for a certain number of successive growing seasons depending on the crop (often 2, up to 5 and more). DUS applies to all crop species (agricultural, vegetable, fruits).

VCU testing is also required for agricultural crops and industrial chicory, but not for fruit and vegetable species. The assessment of the VCU is based on yield improvement, resistance to biotic and abiotic stresses, and end-use quality of the candidate variety. Other factors may be considered depending on national rules/requirements, like sustainability (VCUS). VCU testing is performed under replicated trials of the candidate variety over two to five years, depending on the plant species. To set the scale of notations independently from the environmental conditions, control varieties (already registered and/or protected) are included in the trials.

3.2. Variety registration in Spain

The responsible entity for the registration of new plant varieties is the Spanish Plant Variety Office (OEVV), which is under the General Secretariat of the Ministry of Agriculture, Fisheries and Food (MAPA). Guidelines for the registration of commercial varieties are specified through the Royal Decree 170/2011. Criteria for DUS are established by the OEVV, which are based on the CPVO technical protocols, and when not available, on UPOV guidelines, and ultimately on national guidelines established by the OEVV considering the guidance of the National Variety Evaluation Commissions. The OEVV has set relevant parameters to assess VCU.

To register a variety an application must be submitted to the OEVV, who then handles the application to the competent technically qualified body (TQB). TQBs are designated by OEVV for each species according to the relative importance of the crop in the designated area. After completion of the trials, examination offices submit a technical report to the OEVV. A provisional registration may be approved by OEVV within one year of the application, given that varieties have passed the first round of DUS tests and completed VCU tests.

3.3. Variety registration in Switzerland

The Federal Office of Agriculture (FOAG) is the authority responsible for the registration of new varieties in Switzerland. The legal framework for registration is provided by the Ordinance of 7 December 1998 on the production and release of plant propagating material (RS 916.151). For the case of wheat and apple, the legal basis is given by FOAG's Ordinance of 7 December 1998 on seeds and seedlings of arable crop species and fodder plants (RS 916.151.1), and of 11 June 1999 on the production and release of propagating and planting material of fruit species (916.151.2). The guidelines for DUS testing are those of the CPVO and, in the absence of CPVO, those of UPOV. For



the required species, VCU tests are often conducted by Agroscope. The registration is valid for ten years, but can be renewed, provided that the required DUS conditions are still met.

Switzerland is a member of UPOV but is not represented in the Administrative Council of CPVO as not being an EU country. However, under Annex 6 of the Agriculture Agreement between the Swiss Confederation and the European Community on the trade of agricultural products (RS 0916.026.81), varieties registered in Switzerland are listed in the National Catalogue of Varieties as well as in the EU Catalogue, and are therefore marketable in the EU. Indeed, all varieties registered in the EU can be marketed in Switzerland. The case of wheat and apple ???

3.4. Wheat variety registration in the EU, Switzerland and Spain

Wheat is the most important agricultural crop in terms of harvested area in Europe and Switzerland, and the third in Spain. It is also the most consumed food in Europe and in both countries (FAO, 2022). Breeding a new wheat variety involves several crossings across multiple generations, implying significant investments and time. The process can take between 10 and 16 years (Brennan & Martin, 2006; Byamba & Sandui, 2018), although strategies to accelerate breeding have begun to be widely adopted (Tadesse et al., 2019). Investment in genetic improvement and increasing private sector participation have accelerated the number of released varieties in Europe (Curtis et al., 2012). In the EU, the Commission Directive 66/402/EEC set the legal basis for the marketing of cereal seed, and the Commission Directive 2003/90/EC states the minimum characteristics and conditions for examining wheat and other agricultural species. Registered varieties are recorded on the common catalogue of varieties of agricultural plant species. Parameters for DUS assessment are set out in the CPVO-TP/003/5 guideline, which follows the UPOV TG/3/12 guideline.

DUS is carried out in two independent growing cycles at the same location. The test design should result in a minimum of 2,000 plants, divided into at least two replicates. For distinctness, the differences observed between varieties should be so clear that no more than one growing cycle is required to assess for distinctness unless the influence of the environment requires ensuring sufficient consistency. Most of the traits are assessed based on phenotypic evaluation, though special conditions are required for some traits, such as for vernalization. In total, 27 traits are listed on the CPVO guidelines for DUS.

Parameters for VCU vary among countries. These are defined to evaluate the agronomic performance about yield improvements, behaviour concerning factors in the physical environment, and resistance to harmful organisms. Moreover, other parameters can be considered to assess quality characteristics. VCU is usually conducted in parallel with DUS, and the whole process can last between two and three years. For the selection of common knowledge varieties to be grown in the

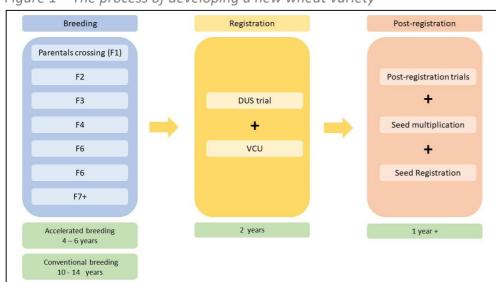




trials, these can be grouped according to lower glume, ear, ear colour, and season type. Figure 1 illustrates the process of releasing a new wheat variety.

In Spain, the designated authority for DUS testing is the National Institute for Agricultural and Food Research and Technology (INIA). Applicants must submit 3 kg of seed for the DUS and 40 kg for the VCU. For VCU, the following parameters are considered: Agronomic characteristics (earliness, plant height, lodging, and frost damage); Yield (Yield and moisture content), pest and disease resistance (Leaf Septoria, Powdery Mildew, Brown Rust, Yellow Rust, and Yellow Leaf Spot), and Quality parameters (specific weight, thousand grain weight, protein on dry matter, sedimentation index, vitreosity, yellow index and gluten content). For spring wheat, VCU trials are divided into two zones, north, and south, while for winter wheat the zones correspond to high and low production zones. Varieties must meet VCU standards in at least one of the zones to be granted registration. Varieties registered in Spain with the highest certification or adoption rates are selected for the reference collection. A one-time fee of 359.35€ is paid when submitting applications, plus 672.95€ for DUS and 1,233.72€ for VCU, per year.

In Switzerland, DUS testing is delegated to a designated EU authority. VCU for wheat is conducted by Agroscope. Guidelines are set by the FOAG Ordinance of 7 December 1998 on seeds and seedlings of arable crop species and fodder plants (RS 916.151.1). Applicants must handle 10 kilograms of seed for testing. One-time fee of 150 Fr Must be paid for application processing and 100 Fr for examination approval and variety of denominations, a yearly fee of 2500 Fr for VCU. VCU for wheat is performed every year and must be conducted over two growing cycles. Parameters for VCU are yield grain, earliness, plant height, lodging, vernalization, wintering, sprout damage, resistance to pests and diseases (Oidium, Yellow Rust, Black rust, *Brown rust, S. nodorum, Septoria tritici*, Fusarium head blight), and quality features (specific weight, sedimentation index, baking quality, thousand grain weight, gluten content).







Source: Authors' elaboration

3.5. Apple variety registration in the EU, Switzerland and Spain

Apple is the third most important perennial crop in Europe in terms of harvested area and among the top ten in Switzerland and Spain. It is also the second most consumed fruit in Europe and in both countries (FAO, 2022). The whole breeding process can take 15 to 25 years, involving significant costs. New methods such as molecular selection of genotypes (Peil et al., 2010) and introducing known traits into existing cultivars (Krens et al., 2015) are being used to speed up breeding, however, limitations such as traits that can only be assessed phenotypically beyond juveniles' stages remain a limitation to further speed up the process. The breeding sector in the EU has the presence of many small companies in Europe, mostly private or under a public-private figure. Despite large investments and breeding advances, half of apple production in Europe comes from only four cultivars (Laurens et al., 2018).

In the EU, guidelines for the marketing of apple propagating material are given by Council Directive 2008/90/EC23, and DUS assessment criteria by the CPVO-TP14/2 guidelines. Fruit varieties are not registered in the Common Catalogue, but are registered in the Fruit Reproductive Material Information System (FRUMATIS), a sui-generis form of Common Catalogue for registered varieties of fruit species across the EU. DUS trials should be conducted over the period it takes to have at least two satisfactory harvests, which usually takes from four to five years. For varieties resulting from crossing test designs must result in a total of at least five trees per variety, or ten for the case of mutants. In total, 57 traits are listed on the CPVO guidelines for the DUS assessment of apples. Candidate varieties are compared against those of common knowledge based on grouping characteristics such as tree morphology, fruit characteristics, and growing habits. VCU is not required for apple. Figure 2 illustrates the process of releasing a new apple variety.

In Spain, for DUS testing applicants must submit 10 grafted seedlings (15 in the case of mutants) for DUS testing. The guidelines for DUS are those given by the CPVO. Tests should be conducted during two consecutive fruiting periods. Varieties registered in Spain with the highest certification or adoption rates are selected for the reference collection. A one-time fee of 359.35€ is paid when submitting applications, plus 560.81€ per year for the DUS. In Switzerland, the guidelines for the registration of apple varieties are laid down in the FOAG Ordinance of 11 June 1999 on the production and release of propagating and planting material of fruit species (916.151.2). DUS testing is not carried out in Switzerland, as FOAG entrusts it to a competent authority of an EU country. In Europe, DUS testing for apple is conducted in only three designated centres.



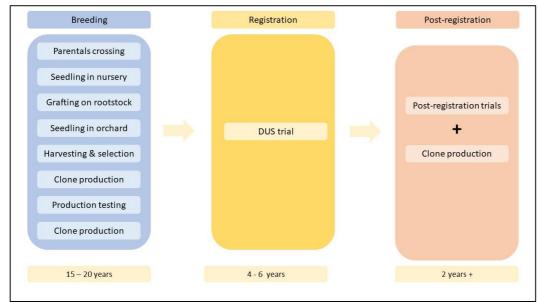


Figure 2 – The process of developing a new apple variety

Source: Authors' elaboration

3.6. Challenges in the registration of new varieties

The registration system has allowed for maintaining an active and diverse breeding industry, protect private sector investment (Srinivasan, 2004), increasing productivity, assuring harmonisation at the European level and boosting competitiveness (Noleppa & Cartsburg, 2021). However, understanding the challenges the system faces, it is crucial to assess the hypothetical impact of innovations to improve it.

Registration trials are the central components of the process and account for most of the time and investment required for registration (Jamali et al., 2019; Winge, 2015). In addition to administrative fees and burdens, field trials involve the use of various resources (e.g., land, water, inputs, and labour) implying significant costs for the applicant. This might be a major barrier, especially for small breeding companies and those serving relatively small markets about the investment needed for the development of a new variety (FCEC, 2008). It may also lead breeders to limit registration to a few varieties, which might not be sufficient to keep up with the market demands and might also affect the crop genetic diversity present in the fields (Pedersen et al., 2020).

The criteria set for VCU favour high-yielding varieties over those with traits more focused on other agronomic aspects such as resource use efficiency traits (Jamali et al., 2019). Similarly, current DUS criteria favour genetically uniform varieties, and therefore meeting DUS requirements can be problematic for species with high morpho-physiological variation within the crop, which has



consequences for the maintenance and further development of crop genetic diversity (Bocci, 2009; Jamali et al., 2019; Winge, 2015). In addition, as more varieties are approved for registration, more reference varieties are required in trials, especially in DUS trials, which increases the cost and complexity of the process (Wang et al., 2016). At the EU level, one institutional aspect that needs to be addressed is the harmonisation of VCU guidelines, as there is controversy over whether the flexibility of Member States to adapt testing criteria could be leading to unequal restrictions on obtaining registration in different countries.

One of the main challenges in DUS testing for apple is assessing mutant varieties. Mutants are genetic or epigenetic variations of a cultivar that differ from the original cultivar. In apple, these variations may express phenotypic variations observed in clonally propagated plants such as fruit colour or size (Bai et al., 2016; Jiang et al., 2019). There is a growing number of mutants submitted for registration. The issue with mutants is that given their high genotypic and phenotypic similarities with the original cultivars, assessing distinctiveness can be challenging. This adds to the fact that the current list of traits to be assessed in DUS has been criticized for considering unimportant traits, while not including other economically important characteristics that might be expressed by mutants considered in that case as not distinct and excluded from registration/protection. Conversely, closely related mutants can be deemed eligible to registration/protection based on differences in unimportant characteristics alone (CPVO et al., 2016).

3.7. Stakeholders mapping

The registration process involves a wide range of stakeholders which were identified when setting up the project. Given the objectives of the analysis, selected stakeholders will henceforth be delimited to those who will grasp the benefits and/or incur costs of innovations to improve the registration process. Mapping these stakeholders is important to determine the most suitable CBA criteria. The following is a description of the main stakeholder groups and how they may be impacted by the implementation of innovations in the registration process.

The legitimization of the registration process is overseen by the registration offices, which are responsible for receiving and granting registration. However, they are not always the agencies in charge of testing, as in some cases this responsibility is delegated to designated testing centres. The nature of the registration offices and designated testing centres varies from country to country, but they are mainly public sector based. Equally important are the policy-makers, in addition to UPOV and CPVO, which act as umbrella organizations setting the guidelines for variety testing, to whom the results of this assessment will be useful for decision making. These are all the main stakeholders to consider, as they can be seen as the "adopters" of the innovations to be evaluated or the results of such. This implies that in addition to capturing the benefits of increased efficiency in variety testing, they are also the ones who must invest in such innovations for that purpose. For the CBA, the baseline will be the status quo on how such entities currently conduct variety testing.





Once registration is granted, approved varieties go through a series of processes called postregistration before commercialization, which include post-registration trials and certification of plant reproductive material. Post-registration and certification are separate processes from registration. In some countries, the agencies in charge of this process are the same as those assigned to plant registration, while others have separate entities for this purpose. Although the regulation of crop species subject to these steps is quite heterogeneous across countries, these organizations can reap the benefits of an improved registration system in the sense of receiving improved information from a variety trials that can be integrated with that obtained within their processes. These organizations can also be considered another group of adopters where innovation can be scaled up, as some traits evaluated in registration trials are also evaluated post-registration.

Other relevant actors and potential beneficiaries of the process are the plant breeders. Improvements in the efficiency and accuracy of the process could reduce the time needed to release a new variety, lower the costs incurred by breeders in variety testing, and generate a fairer evidence-based system. In both countries under study, breeding is carried out by a mix of public and private entities, including public-private schemes and non-profit organizations, with a very heterogeneous composition in terms of size, funding, and markets to be served.

At the end of the process are the farmers. Although their participation in the development and registration process is limited, they are the main drivers of demand for new varieties and, therefore, another important group of beneficiaries of an improved registration process. This benefit can be perceived from various angles, such as a greater supply of varieties in general or access to varieties better adapted to their needs. It is also important to consider that although this group is not the main adopters of innovations, their decisions, and preferences can greatly influence the success of adopting such innovations in the registration process, as they may express their rejection of the use of varieties that have been registered under such innovations. Producer associations and those representing their interests at the national and regional levels are also part of this group.

4. Innovations developed within INVITE to improve the registration process

INVITE innovations are being tested for different crops, addressing different challenges and/or pointing towards more efficient ways to evaluate traits and parameters in DUS and VCU. The following sections summarize the type of innovations developed/tested, the specific actions to be implemented for each innovation for apple and wheat, and the expected impacts in the registration process.



4.1. Phenotyping tools

INVITE-WP2 is working on low-cost mobile RGB sensors to examine the colour of fruit and apple trees. For wheat, traits to be assessed include length and shape of stems, leaves, and ears, disease score (Septoria), speed of emergence, and flowering period. In addition, low-cost non-RGB field phenotyping tools are being developed, including the use of airborne LIDAR to estimate different traits to assess yield potential in VCU and hyperspectral fluorescence imaging systems to assess fusarium in wheat in DUS, and tree volume and fruit characteristics for DUS in apple. Moreover, to start implementing VCU in apple, architectural type, leaf area density concerning tree health, and crop load for apple have been investigated. The work will be complemented by the development of a classifier and regression software to automate DUS and VCU measurements.

The technologies will be tested in DUS and VCU trials at different locations and compared with conventional measurements. To the extent that the technologies are more efficient than conventional measurements, they will be able to automate measurements or complement the results obtained conventionally. Effects such as increased accuracy in variety of trials and a reduction in costs, labour, and resources used in recording trials are expected (Erreur ! Source du renvoi introuvable.).

Innovation Crop		Specific actions	Variety testing	Expected measurable impacts	
Mobile phenotyping tools coupled with RGB cameras	Apple	Assess plant architecture, crop load, and fruit characteristic associated traits	DUS		
	Wheat	Assess length and shape of stems, leaves and ears, disease scoreDUS a DUS a DUS a flowering period		 Improved accuracy in variety testing Improve efficiency (reduction in costs, 	
Drones coupled with	Wheat	Assess growth, height, and biomass	VCU	labour and	
RGB and multispectral cameras	Apple	Tree volume, fruit, architectural type, leaf area density, crop load	DUS & VCU*	resources)Automation of	
Hyperspectral and fluorescence sensors	Wheat	Fusarium incidence		manual scoring procedures in	
Phenotyping platforms for variety testing	Wheat apple	Assess the gain of information and related costs of using HT phenotyping platforms	VCU & DUS	variety testing	

Table 1. Expected measurable effects of phenotyping tools in a variety testing

*To be tested as VCU is not required for apple

4.2. Genotyping tools

INVITE-WP 3 is working on evaluating genotyping tools for biomarker characterization that can speed up the process and improve the accuracy and efficiency of variety testing. Specific genome-wide markers related to disease resistance (apple scab, powdery mildew) and fruit quality in apple have been identified for use in DUS. In addition, WP1 is exploring the use of epigenetic marks for



variety identification. This will be tested as a low-cost method for assessing the distinctness of apple mutants, which with conventional methods of measurement is quite difficult, as discussed in a previous section. In wheat, work has been done on genome-wide marker mapping and genomic prediction to improve the robustness of phenotypic prediction of DUS traits. New methods using dense genome-wide markers for the examination of distinctness and homogeneity have been developed and implemented in software prototypes. Likewise, SNP markers significantly associated with at least one high heritability trait will be identified for both apple and wheat.

For highly heritable traits that can be more effectively predicted by genotyping rather than phenotyping, automating the measurement of these traits would hypothetically mean less use of resources for their measurement. However, molecular markers could also be used to increase the robustness of manual measurements. In the specific case of epigenetic markers for mutant distinction, the potential impact would represent an advance in increasing the robustness of DUS testing by facilitating the differentiation of mutants that conventional methods could easily reject. More importantly, the use of genotyping tools will not be limited to trait evaluation, but also to the efficient management of reference collections and the reduction of the size of the trials(Table 2).

Innovation	Сгор	Specific actions	Variety testing	Expected measurable impacts
Biomarker characterization (SNP markers)	Wheat <i>,</i> apple	Identify SNP markers associated with high heritability traits used in variety testing		Improved accuracy in variety testing Deduce the number of
Molecular markers	Apple	Disease resistance (apple scab, powdery mildew) and fruit quality The distinctiveness of coloured mutants	DUS	 Reduce the number of reference varieties to sow Automation of manual scoring procedures in a variaty tecting
Genome-wide marker mapping and genomic prediction	Wheat, apple	Improve the robustness of phenotypic prediction of DUS traits and assessment of uniformity		 variety testing Reduction in the number of reference varieties in collections

Table 2. Expected measurable effects of genotyping tools in a variety testing

4.3. Integrate sustainability and resilience criteria in a variety testing

WP1, WP5, and WP6 are working on evaluating the feasibility of including new bio-indicators as criteria for assessing sustainability in VCU and including new traits for DUS assessment. The work focuses on measures for resource use efficiency, adaptability to harsh environments, and resistance to biotic stress of new varieties. Water use efficiency in wheat is being evaluated by identifying root traits related to plant response to drought. Parameters for phenotyping quantitative disease resistance in wheat are also being explored, and apple is being used to evaluate the role of epigenetic changes in phenotype differences and plant response to climatic changes.





Unlike the previous sets of innovations, this corresponds to an institutional and not a technological innovation per se, since it implies a change in guidelines for variety evaluation. The objective of such a change, and therefore from which a hypothetical impact can be drawn, is to facilitate the generation of more resilient varieties adapted to more sustainable production systems. The impacts of improving varieties with these characteristics are difficult to trace, however, they will certainly contribute to crop production that demands fewer resources and is less vulnerable to biotic and abiotic stresses, among other factors (Table 3).

Innovation Crop		Specific actions	Variety testing	Expected measurable impacts		
Recommendations to evaluate varieties for organic farming	Wheat, apple	Procedures that are more appropriate for the evaluation of varieties for organic farming		 Improved and standardize protocols for a variety testing 		
Recommendations to evaluate heterogeneous plant material	Wheat & apple	Procedure for the evaluation of heterogeneous material in DUS and VCU testing	DUS & VCU	 Improve information and recommendations on a variety 		
Integrate multi criteria evaluation	All crops	Procedures that are more efficient for the assessment of variety sustainability		performanceVarieties better adapted to		
	Wheat	Phenotyping quantitative disease resistance and drought stress	VCU	sustainable production systems		
of sustainability traits in variety testing	Apple	Role of epigenetic changes in phenotype differences and plant response to climatic changes	DUS	 Varieties more adapted to specific environments and more resistance to biotic and abiotic stresses 		

Table 3. Expected measurable effects of new protocols to integrate sustainability and resilience criteria in a variety testing

4.4. Improved variety testing networks

Among the putative innovations to improve VCU testing at European level are: i) design variety testing networks taking into account ecological zones, ii) strengthen the integration of stakeholders (in particular the examination offices), iii) harmonise among countries the assessment scales to evaluate variety traits, iv), and improve the efficiency of both DUS and VCU assessments by avoiding duplication of efforts. To this end, trial networks based on a common set of varieties and contrasting environmental conditions will be proposed for DUS and VCU testing. Results from validated genotyping and phenotyping tools will be used to assess the feasibility of integrating such data into VCU networks for more efficient measurement in variety performance evaluation and for the management of reference collections.

A more efficient and integrated VCU evaluation network can lead to important changes. On the one hand, there is a reduction in costs and resource use due to a more efficient evaluation network,



with, under given circumstances, fewer environments are required for evaluation and a reduced number of reference varieties to compare in each environment. Finally, there is greater integration of assessment networks and associated stakeholders, who benefit from information sharing and greater standardization of methods. Moreover, more information is also generated in terms of variety performance that can be transmitted to producers and other decision-makers in the chain (Table 4).

Innovation	Сгор	Specific actions	Variety testing	Expected measurable impacts
New methods and tools for optimized VCU testing networks		Multi-environment testing based on zonation according to common environmental conditions	VCU	 Improved and standardize protocols for variety testing Reduced number of
	Wheat &	Integration of phenotyping platforms results into VCU testing networks		 environments for variety testing Reduced costs of DUS and VCU testing
Harmonization of assessment scales for variety characterization in VCU	Apple (and for all crops)	Lists of varieties that can be straightforwardly compared among European countries		 VCU testing More environment-specific varieties Improve information and recommendations on variety performance
Avoid duplication of efforts in DUS and VCU assessment		Identify opportunities to increase synergies between DUS and VCU testing	DUS & VCU	 Further integration of actors and strengthening of evaluation networks

5. Selection of criteria

5.1. Assessing the costs and benefits of INVITE innovations - State of the art

Measuring the impacts of agricultural research on plant variety development is not new. Plant breeding outcomes are often used as benefits from agricultural research in several studies. For the case of wheat, Azzam et al. (1997) estimated the returns of breeding wheat as a measure of returns to agricultural research in Morocco using the reasonable, least favourable case approach. For the case of apple, Edge-Garza et al. (2015) developed a model to estimate the cost and time efficiency of implementing molecular markers in breeding, and Wannemuehler et al. (2019) conducted a CBA of genotyping tools for breeding through a simulation model using itemized costs.



Regarding the implementation of technologies, Brennan & Martin (2007) conducted a CBA to calculate the returns of investment on new genotyping tools for breeding. An economic surplus model was used to expand the approach of the CBA by estimating the welfare impacts that an improved yield resulting from investments in breeding could have in rice (Alpuerto et al, 2009) and maize (Dreher et al., 2003). In terms of phenotyping, Reynolds et al. (2019) made cost estimation of different scenarios to implement such tools in breeding, while Awada et al. (2018) constructed a decision-making model to elicit decisions regarding the adoption of such tools in conventional breeding programmes.

As evidenced, most of the existing literature has focused on assessing the impact of such innovations in the breeding stage. Regarding the registration process, studies have mainly focused on measuring the stringency and assessing the impacts of plant variety protection on crop productivity. Nhemachena et al. (2019) and Campi (2017) estimated the effects of the plant breeder rights system on wheat and maize productivity in South Africa. Kolady & Lesser (2009) and Alston & Venner (2002) did the same for the United States. For all cases, approaches such as the economic surplus model to measure the welfare impacts at the whole economy level were conducted.

In Europe, Noleppa & Cartsburg (2021) also conducted a study on the impact of plant breeding using the economic surplus model but did not include any aspect regarding the registration process. Likewise, the study made by the CPVO & EUIPO (2022) focused on the registration process, but on assessing the efficacy of the system itself, not specific innovations to improve it. In Spain the Fundación Institut Cerdà (2021) assessed the contribution of breeding in the wheat value chain, but without focusing on the registration process. In Switzerland, Vallier (2021) made a review of the plan variety protection system, focusing on several institutional and regulatory aspects, but without examining the economic, social, or environmental impacts of such.

5.1. Analytical framework

One of the challenges in defining the framework for the evaluations was how to measure the potential impacts of the selected innovations. On the one hand, the set of potential impacts is broad and subject to different factors. For example, the degree of impact of genotyping and phenotyping tools in terms of time and cost savings depends on the number of traits that can be assessed with these methods for DUS and VCU testing, their ability to replace current manual measurements, and even whether the use of these tools in variety testing is approved at the regulatory level.

Moreover, different innovations may share the same impact. For example, both the application of molecular markers and low-cost phenotyping tools may represent time and cost savings in variety testing, but the magnitude of these savings may vary according to species and application scenarios. Finally, some impacts are difficult to quantify. For example, the effects of increased precision in variety testing and the effects of having more varieties suitable to sustainable production systems





may be difficult to quantify. The same can be said for the impact of institutional arrangements aimed at amending the system.

Hence, based on the level of advancement of the innovations, their potential application in both crops of study, expected impacts at different levels, data availability, and time and budget constraints, the following methodological framework for the impact assessment was defined.

Three different methodologies will be used. First, a classical CBA will be conducted that considers the financial costs and benefits of phenotyping and genotyping tools in variety testing. This methodology is expected to address measurable impacts of these tools, such as savings in reference collection management and reduced costs and resource use in variety testing due to hypothetical automation of measurement of selected traits in DUS and VCU trials. The second methodology will focus on evaluating the set institutional arrangements proposed to improve variety testing networks and integrate sustainability criteria in variety testing by examining the preferences of different stakeholders regarding the implementation of such arrangements. The third methodology will focus on assessing the impact of integrating sustainability criteria into VCU testing by estimating the WTP of local farmers for varieties with such traits, in addition to their acceptance towards varieties registered under new methods for variety testing.

5.2. Identification of criteria

Considering the three methodologies that were proposed for the assessment in section 2.2, relevant criteria that will be needed to perform them have been identified. The list of innovations and expected impacts to address with each methodology is presented, describing all relevant criteria that will be needed for the analysis. Each criteria have been categorized according to its type (economic, social or environmental). Moreover, tools to collect data and targeted stakeholders to consider for this purpose are described. Since technologies of different nature share the same type of impacts and considering that the measurement of these impacts is associated to each methodology, the indicators are presented at the level of expected impact and not for each technology.

5.2.1. Cost-benefit analysis

The criteria to be collected for the CBA include, on the one hand, the development and implementation costs of the selected innovations at the registration offices level. These will be weighed against the base costs that the registry offices and testing centres currently incur for the evaluation of those traits that can potentially be substituted through automation with the selected innovations. Both types of costs will be complemented with other indicators of interest, such as the use of resources (water, land, inputs, labour) at each stage of the process, which will help to translate economic and financial variables into environmental and/or societal-type of variables.





It will also be important to quantify the expected impacts, for which quantitative (e.g. monetary or resource savings) or qualitative (e.g. increased test accuracy or more information generated) valuations will be needed. This information will be collected through in-depth semi-structured interviews with technology developers, registration and post-registration offices, and testing centres. The data will be supplemented with secondary information obtained through literature review.

Expected impacts	Innovations	Indicator	Type of indicator	Data collection	Targeted stakeholders	
Automation of manual scoring procedures in variety testing	Improved variety testing networks Genotyping and phenotyping tools	Cost of maintaining a registration trial	Economic	In-depth survey and cost sheet (for wheat and apple in Switzerland and Spain)* Secondary data from literature review		
Reduction in the number of reference varieties in collections		Resource use (water, agrochemicals, fertilizers) on registration trials	Environmental		Registration offices, testing centres	
Reduction in the		Cost of assessing each trait of interest	Environmental			
number of reference varieties to be sown		Resource use for each trait of interest	Economic			
in the registration trials		Labour quantities and costs used for the measurement of traits of interest	Economic, social			
Improve efficiency		Cost of developing and implementing the technology	Economic		Developers of the	
(reduction in costs, labour and resources)		Quantification of expected impacts from the implementation of the technology	Economic, environmental, social		technology, research centres	
Reduce number of environments for variety testing		Economic valuation of environmental and social variables of interest	Economic, environmental, social		Not applicable	

Table 5. Selected indicators for the Cost-Benefit Analysis

*Might be extended to other crops and countries



5.2.2. The Analytical Hierarchical Process

The conduct of the AHP requires only one type of indicator, which is the degree of preference of the different stakeholders on the implementation of different scenarios to amend the variety registration system. These preferences will be expressed in terms of the Saaty scale of values that each stakeholder will answer in the online questionnaire.

Expected impacts	Innovations	Indicator	Type of indicator	Data collection	Targeted stakeholders
Improved accuracy in variety testing	Genotyping and phenotyping tools and models Integrate sustainability and resilience criteria in variety testing	Preferences regarding the implementati			Breeders, farmer
Improved and standardize protocols for variety testing Improve information and recommendations on variety performance Varieties more adapted to specific environments and more resistance to biotic and abiotic stresses	Integrate sustainability and resilience criteria in variety testing Improved variety testing networks	on of institutional arrangements and prioritization of factors for the development of new plant varieties	Social	AHP questionnaire (for all crops and countries)	organizations, registration offices and testing centres, CPVO, seed companies and nurseries, research organizations
Varieties better adapted to sustainable production systems	Integrate sustainability and resilience criteria in variety testing				

5.2.3. Discrete choice experiment

In the case of DCE, the necessary criteria are the willingness of producers to pay for varieties with different combinations of sustainability traits and subject to different evaluation techniques for registration. These will be collected through surveys with local producers and will be expressed in monetary terms.

Table 7. Selected indicators for the Discrete Choice Experiment

Expected impacts	Innovations	Indicator	Type of indicator	Data collection	Targeted stakeholders
Improved accuracy in variety testing	Genotyping and phenotyping tools and models	WTP for varieties registered under new	Economic, environmental	In-person DCE survey	Farmers



	Integrate sustainability and resilience criteria in variety testing	methods for variety testing
Varieties more adapted to specific	Improved variety testing networks	WTP for varieties better adapted to specific environments
environments and more resistance to biotic and abiotic stresses	ore resistance to fotic and abiotic of the models of the m	

5.3. Approach to data collection to feed the indicators/criteria

Data will be collected at different stages and in different ways depending on the methodology. For the CBA, in-depth interviews will be conducted with each WP leader to list and quantify the costs of implementing their innovations and to identify the potential benefits this may have on variety testing. More specifically, leaders and scientists from WP1, WP2, WP3 and WP5 will be contacted for this end. This is first stage of data collection will take place between Septembers and October of 2023.

A similar approach will be used with the registration offices, from which the baseline for conducting the analysis will be defined. A cost sheet will be developed to break down each of the costs associated with measuring the selected traits and maintaining the reference collection. This will be complemented by qualitative information to be obtained through interviews to gather perceptions on the potential for adoption of such technologies, the main limitations and other aspects to be considered for the CBA. In an initial phase, the CBA will be limited to the cases of wheat and apple in both study countries For wheat, we will work directly with the designated examination offices in Spain and Switzerland. For the specific case of apple, examination offices in France and Germany will be contacted, considering they are two of the three testing centres across EU conduct DUS assessments. In case of data constraints, interviews will be conducted with other examination offices in the EU. In addition, post-registration offices will also be interviewed following the same guidelines, with the main objective of collecting data on how the selected innovation could affect this set of agents if applied at this level. This second stage of data collection will be conducted simultaneously with the previous one.

For the AHP, an online survey that follows the methodological aspect of the instrument will be distributed to all types of stakeholders involved in variety testing across the European Union. The survey will be distributed online. As of the date of the last review of this deliverable, this phase has been completed and data is being analysed.





For the DCE, only apple and wheat farmers in Spain and Switzerland will be targeted. Data will be collected in person through a survey and in close collaboration with local partners. Throughout the process, literature reviews, expert consultations and stakeholder surveys will be carried out for the design of methodological tools, interpretation and review of results and policy formulation. A first stage in this process will consist in the design of the experiment, for which expert consultations with wheat and apple breeders in Switzerland and Spain will take place in the last trimester of 2023. Then, in-person surveys with more than 100 farmers in each country will be take place in the first trimester of 2024.

There are some risks involved in conducting the data collection. The most important is the availability of data and the willingness of local partners and other stakeholders to collaborate. Another limitation is that registration offices or other adopters may not consider the selected innovations relevant or may not foresee quantifiable benefits from the adoption of such tools. This could limit the relevance of our results. Finally, there are time and resource constraints that may limit the level of detail of the analysis.

To mitigate these risks, we will work closely with the project leader and key INVITE partners, who will be instrumental in facilitating contact with other WP leaders, and particularly, with the registration and post-registration offices. While the list of registration offices to be interviewed has initially been limited to those involved with the registration of the selected species in the study countries, in case of data collection constraints the scope of analysis will be expanded first to registration offices working with the same crops in other countries, and ultimately to similar crops within the study countries or other countries in the European Union. Interviews will be planned well in advance and, to the extent possible, will be conducted in-person or through online meetings following semi-structured guidelines, which will allow us to delve more deeply into the nature and extent of the data collection, and as far as the project regulations and dissemination strategy allow, the results will be shared with the interviewed parties.

The results of the analysis will be validated in detail with the WP6 leader and the Project leader. Collaboration and feedback from Task 6.4 will also be essential, as the results of the CBA will serve as input for the achievement of the objectives of this task (D6.5). Similarly, the results will be shared with WP8, with whom a strategy for their dissemination will be worked out in more detail, particularly to convey the message to policy makers (Task 8.4). Other WPs and task leaders (WP1, WP2, WP3 and WP5) will also receive the results in detail, as relevant insights from our analysis could help them improve or adjust their technologies to fulfil the needs of the final beneficiaries, (examination offices, post-registration offices and farmers).





5. Conclusion

In this document we focused on defining the approach to evaluate the impact of INVITE selected innovation to improve the process of registration of new plant varieties in the EU, highlighting the criteria necessary to carry it out. This first step is fundamental for conducting the assessment, since in addition to identifying the most appropriate methodologies for this purpose and the criteria they require, it also allowed us to map the main stakeholders to be contacted for data collection and to identify possible limitations that may arise in the process.

The focus of our analysis will be on the cost-benefit analysis of phenotyping and genotyping tools that aim to reduce costs and time in the evaluation of certain traits in registration tests. The methodology was selected because the impacts associated with these technologies are quantifiable from an economic point of view, although environmental impacts will also be quantified and monetized. To do this, we will need to conduct in-depth interviews with registration and post-registration offices, testing centres, and technology developers to gather information on the costs of implementing the selected technologies in the variety registry. This will help us define the baseline, as well as the different scenarios to be evaluated in terms of technology implementation.

Due to the difficulty of quantifying the impacts of innovations of an institutional nature that involve a series of amendments to the registration system at the European Union level, it was decided to use AHP as a tool for prioritizing these types of innovations. Beyond the prioritization exercise, which is expected to help outline different scenarios under which the CBA can be built, the results of this process are expected to be used to nurture eventual policy recommendations that may arise from the experiences and results obtained in the project.

The third methodology we selected was the DCE, which will be used to elicit the availability of producers for varieties with sustainability traits and registered under new techniques for the evaluation of varieties in the registration process. This methodology allows us to analyse the preferences of producers for factors that under normal circumstances do not have a market value, but that become important at the moment of quantifying variables of environmental and/or social interest to measure the impact of innovations focused on facilitating the production of varieties better adapted to more sustainable production systems.

The list of listed criteria selected for each methodology should be interpreted as a reference that should be subject to data availability and stakeholder perceptions of the potential adoption of the technologies in a variety testing. Therefore, it is important to consider risks such as the absence of data and the willingness of stakeholders to participate in the research for the success of the impact assessment. It is also important to consider other risks, such as time and budget constraints, which may affect the scope of the evaluation. Strategies such as the expansion of the scope of analysis to other crops and other countries and close collaboration with members and other project partners were devised to mitigate the occurrence of such risks.





This document will be the main guide to be used for the development of the tools to be used in the data collection, which corresponds to the next step to be followed for the conduct of the assessment. These tools will be discussed among the authors of this document and validated with project partners (WP leaders and registration and post-registration offices). Once validated, interviews will be conducted with the identified key stakeholders and a database will be built with the collected data. Once the data is analysed, it will be further reviewed and validated by WP6 members and the project leader, and shared with the key stakeholders who have been interviewed in the process. The final results will serve as input for the elaboration of other tasks (Task 6.4, Task 8.4), which will also imply the production of key tools and information for decision making by key stakeholders such as policymakers and the registry offices themselves.

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