PRO-GRACE

PROMOTING A PLANT GENETIC RESOURCE COMMUNITY FOR EUROPE

DELIVERABLE 5.6

Analysis of the ethical, social, and regulatory (ESR) aspects of the transition of the present PGR system to an integrated pan-European Research Infrastructure

This deliverable has been submitted and is currently pending approval by the European Commission.

Call identifier:
PRO-GRACE
Grant agreement no: 101094738

Promoting a plant genetic resource community for Europe

Deliverable No. D5.6

Analysis of the ethical, social, and regulatory (ESR) aspects of the transition of the present PGR system to an integrated pan-European Research Infrastructure

Contractual delivery date:
M28

Actual delivery date:
M28

Responsible partner:
CSIC

Contributing partners:
ENEA (IT), IPGRI (IT), RBGK (UK)

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101094738.

Grant agreement no.	Horizon Europe - 101094738
Project full title	PRO-GRACE – Promoting a Plant Genetic Resources Community for Europe

Deliverable number	D5.6
Deliverable tittle	Analysis of the ethical, social, and regulatory (ESR) aspects of the transition of the present PGR system to an integrated pan-European Research Infrastructure (v1)
Type	R
Dissemination level	PU
Work package number	5
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Keywords	Plant Genetic Resource Governance, Conservation of PGRFA, Multilateral and Bilateral ABS Systems, Regulatory Fragmentation and Legal Uncertainty, Stakeholders' Perceptions, Qualitative Sociological Research (In-depth Interviews)

The research leading to these results has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101094738**.**

Contents

List of acronyms

ABS: Access and Benefit Sharing

AEGIS: A European Genebank Integrated System

AI: Artificial Intelligence

BBMRI-ERIC: European Research Infrastructure for biobanking and biomolecular resources

BBMJ: United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction

BS: Bilateral System

CBD: Convention on Biological Diversity

CGRFA: Commission on Genetic Resources for Food and Agriculture

COP: Conference of the Parties

CPVO: Community Plant Variety Office

D: Deliverable

DSI: Digital Sequence Information

ECPGR: European Cooperative Programme for Plant Genetic Resources

ELSI: Ethical, Legal and Social Issues

ERIC: European Research Infrastructure Consortium

ESR: Ethical, Social, and Regulatory (aspects)

EU: European Union

EURISCO: European Search Catalogue for Plant Genetic Resources

FAO: The Food and Agriculture Organization of the United Nations

FRM: Forest reproductive material

GATT: General Agreement on Tariffs and Trade

GR: Genetic Resources

GRACE: European Research Infrastructure (RI) dedicated to Plant Genetic Resources (PGR), whose proposal addresses the PRO-GRACE project

ICJ: International Court of Justice of the United Nations

IP: Intellectual Property

ITPGRFA: The International Treaty on Plant Genetic Resources for Food and Agriculture

MLS: Multilateral System

MS: (EU) Member State(s)

MTA: Material Transfer Agreement

Nagoya Protocol: Nagoya Protocol on Access and Benefit-Sharing

OECD: Organisation for Economic Co-operation and Development

PGR: Plant Genetic Resources

PGRFA: Plant Genetic Resources for Food and Agriculture

PIC: Prior Informed Consent

PIP: WHO Pandemic Treaty

PRM: Plant reproductive material

SMTA: Standard Material Transfer Agreement

SSH: Social Sciences and Humanities

TRIPS agreement: The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994

ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture

UN: United Nations

UNCED: United Nations Conference on Environment and Development (UNCED), Earth Summit

UPOV: International Union for the Protection of New Varieties of Plants

WHO: World Health Organization

WIPO: World Intellectual Property Organization

WTO: World Trade Organization

Executive summary

1. We are at a time of significant transition from gene banks and related structures to more complex research infrastructures, with the aim of increasing their impact on the global challenges of food and nutrition, as well as on the objectives of strategic autonomy pursued by Europe in the field of food. Rather than a linear or homogenous transition, this is a complex transition that must overcome several obstacles, which implies significant changes in the way in which the current entities involved in the conservation and storage of PGR are managed, perceived, organised and financed.

2. The strategic importance of this transition for the EU and other EU countries is beyond doubt; however, it faces the insufficient construction of a common European political and regulatory space to enable the transition. To help European agriculture respond to the challenges of climate and strategic autonomy in the region, the EU would need to improve the framework affecting access to, conservation and use of PGR in all its forms. Pending such regulatory change, it is important to seek solutions within the current complex and fragmented framework.

3. PGR and the activities of access, conservation and use that are carried out on them are framed by an international, fragmented framework that is subject to complex dynamic processes. Without a global logic, various international instruments have gradually focused attention on the one hand on the protection of intellectual property associated with plant material and on the other on the protection of germplasm in the public domain (currently under state sovereignty).

4. It may appear, at first glance, that there is significant consensus on this issue, given the large number of countries that have signed the TRIPS agreement, in the field of intellectual property, and the CBD, in relation to sovereignty over PGR in the public domain. Nevertheless, even among EU Member States, different regulations and guidelines coexist, which results in a very different application of these instruments, especially with regard to germplasm under sovereignty. All this translates into legal uncertainty for many of the activities that, beyond conservation, involve the use of PGR under sovereignty. Two factors intensify this situation:

> First: EU Member States have not generated a common framework for action to overcome these limitations. Neither do they have a formalised space for political reflection for the generation of such a common space.
>
> Second: the lack of a shared vision means that the activities of the PGR in the EU are affected by the dynamics that are being generated in international arenas (especially around the FAO Treaty on Plant Genetic Resources and the Nagoya Protocol).

5. The PRO-GRACE Project, led by Giovanni Giuliano and funded under HORIZON-INFRA-2022-DEV-01, addresses the urgent need for a European Research Infrastructure (RI) dedicated to Plant Genetic Resources (PGR). Since 2022, the project has been developing the concept for a distributed RI to conserve, document, and utilize PGR, in response to fragmented data, threats from climate change and habitat loss, and a lack of dedicated infrastructure. With over 2 million ex situ accessions and significant in situ diversity at risk, PRO-GRACE supports European biodiversity, food security, and climate resilience, and aligns with existing ESFRI initiatives.

6. As regards legal and governance issues, and in comparison, with other relevant initiatives that contribute to collaboration between these types of entities (such as integrated systems of germplasm banks), **the creation of an ERIC-type PGR infrastructure in the EU has a very valuable distinguishing feature**: its international nature, its European legal status and its consideration as an international entity for all purposes.

7. Notwithstanding other services that the infrastructure may provide, **such European legal status**, which can also be complemented by specific actions of the European Commission, **confers strategic advantages in several ways**:

1) The infrastructure's international status can serve as a legal basis for hosting germplasm collections shared between EU countries associated with the infrastructure, whether germplasm originating in these countries or incorporated into those collections from countries with which specific agreements are negotiated.

2) The infrastructure itself can provide an international and stable legal basis for the realisation of activities that, at present and due to the high level of bureaucracy, cannot be carried out by European nation states.

3) By opening up the possibility of generating regulatory testing environments, this infrastructure can serve as a legal basis for generating a system of intensified and collaborative response in plant breeding to emergencies (climatic, phytosanitary) that the EU considers a priority for action.

4) Through ad hoc-generated regulatory sandboxes, this infrastructure can pave the way for the implementation in the EU of participatory plant breeding methods that in other regions of the world are finding their way to the commercialisation of agri-food products.

5) It can also help Member States to perceive in greater detail the potential of all activities related to germplasm and, based on that perception, move towards the progressive adoption of common positions that respond to the challenges of agriculture and food security in the European Union.

Content description

1. T5.6 addresses the analysis of the ethical, social and regulatory (ESR) issues arising from the transition from the current PGR system to an integrated pan-European research infrastructure.

2. The overall objective of the work undertaken is to identify, through the combination of methodologies used and from an ethical and legal perspective, the challenges, needs and opportunities to be considered in the transition towards a pan-European PGR infrastructure.

3. This report **presents the results of the research activities carried out for the purpose of this analysis**, obtained through different research modalities using two complementary methodologies.

a) On the one hand, initial oral interviews and subsequent in-depth dialogue interviews were conducted with various actors whose professional performance is closely linked to access, conservation and/or different types of use of plant genetic resources (PGR), both within and outside the ecosystem of the project. See detail in I.3.

b) On the other hand, and in parallel, an exhaustive documentary review of various specialised sources was carried out (see detail in I.3).

4. The report is structured in five sections. The first section, by way of introduction, sets out the context of the research and the framework of the analysis and describes the methodologies employed.

5. The next three sections present the results of the analysis undertaken. The first of these sections examines the state of the current regulatory framework (section II). The second (section III) addresses the perception of the challenges, needs and opportunities associated with this framework, from the perspective of the actors involved and considering the different activities related to access, conservation and use of PGR. The third (section IV) analyses the experience of the European BBMRI-ERIC infrastructure and highlights that, as far as the PRO-GRACE project is concerned, the transition towards a pan-European PGR infrastructure could lead to a substantial improvement in the management of ethical, social and legal issues.

6. Finally, the final section provides a list of ESR (Ethical, Social, Regulatory) and ELSI (Ethical, Legal and Social Issues) services that can be provided from GRACE-RI.

7. The report also includes an annex compiling the bibliographical and documentary references used.

I. Introduction to the analysis of the ethical, social and regulatory (ESR) aspects of the transition from the current PGR system to an integrated pan-European research infrastructure. Research context, objectives, methodologies and form of execution

I.1. The transition from the current PGR system to an integrated pan-European research infrastructure: ESR issues.

1. We are currently experiencing a significant transition phase, with gene banks and associated entities shifting towards more sophisticated research infrastructures. This strategic shift is aimed at enhancing their impact on global food and nutrition challenges, as well as on the strategic autonomy objectives pursued by the EU in the food sector. This transition is complex and must overcome various obstacles[1], including changes to the management, perception, organisation and financing of current organisations involved in the conservation and storage of PGR[2].

2. **The triple challenge for world and EU agriculture and the relevance of the PGR.** We are facing a global scenario in which, according to the OECD[3], world agriculture is facing a triple challenge: firstly, the need to increase productivity to contribute to food security and global well-being; secondly, the challenge of ensuring sustainability by significantly reducing the carbon footprint of agricultural systems; and finally, the need to increase resilience, in particular in the face of the challenges posed by climate change. Access to, conservation and sustainable use of PGR is a key element in addressing this triple challenge, not only in terms of adapting varieties to new climatic challenges, but also in the search for means to mitigate biotic and abiotic stresses, make more efficient use of resources and optimise the quality of different processes and products.

3. It is not overlooked that the transition to more complex research infrastructures, especially if they are to serve the whole of the EU and even beyond, has an important component **not only of ESR aspects, but also of techno-scientific, organisational and financial dimensions**. Among other things, it is necessary to explore the possibilities in terms of institutional forms and partnerships[4] or mechanisms for linking gene banks and seed systems[5]. Other work packages and tasks are dedicated to the technical-scientific, organisational and financial dimensions of the transition to a pan-European PGR infrastructure and, without ignoring related aspects, this work has focused its attention on the ESR aspects.

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[1] McCouch, S. et al (2020). Mobilizing Crop Biodiversity. Molecular Plant 13, 1341-1344.

[2] Wambugu PW, Ndjiondjop MN, Henry RJ. Role of genomics in promoting the utilization of plant genetic resources in genebanks. Brief Funct Genomics. 2018 May 1;17(3):198-206. doi: 10.1093/bfgp/ely014. PMID: 29688255; PMCID: PMC5967547.

[3] OECD (2023), Measuring the Environmental Performance of Agriculture Across OECD Countries, OECD Publishing, Paris, https://doi.org/10.1787/4edcd747-en.

[4] Halewood, M. et al. (2018). Plant genetic resources for food and agriculture: Opportunities and challenges emerging from the science and information technology revolution. New Phytologist, 217, 1407-1419.

[5] Westengen, O.T., Skarbø, K., Mulesa, T.H. *et al.* Access to genes: linkages between genebanks and farmers' seed systems. *Food Sec.* **10**, 9–25 (2018). https://doi.org/10.1007/s12571-017-0751-6.

4. **Significant efforts have been made to integrate germplasm bank systems in different regions of the world**, including Europe. In this sense, it is worth mentioning the European Cooperative Program for Plant Genetic Resources (ECPGR) and initiatives such as AEGIS, which, based on the existing organizational bodies of the ECPGR program, promotes the creation of an Integrated System of European Germplasm Banks for plant genetic resources for food and agriculture[6]. **The creation of an ERIC infrastructure with legal personality under European law** and, therefore, with international personality, **implies, as will be described, a qualitative leap** in the potential for transition for organizational and financial purposes.

5. According to the Plant Genetic Resources Strategy for Europe (ECPGR)[7], the ongoing transition aims to enhance the functionality of gene bank systems and related institutions. This includes achieving both efficient conservation and, crucially, promoting sustainable use of genetic resources within the context of the European Green Deal. However, **from an ethical, social, and regulatory (ESR) viewpoint, conservation and storage activities in germplasm banks generally present fewer challenges compared to the incorporation of new genetic materials and the active utilization of stored resources**[8]. Given the original mission and often limited financial resources allocated to these conservation institutions, it is unsurprising that overcoming ESR challenges—especially those impeding the mobilization and broader use of conserved genetic diversity—becomes a critical aspect of this transition. Therefore, developing effective strategies to address these ethical, social, and regulatory hurdles is essential to fully realize the potential of plant genetic resources.

6. Regarding *ex situ* plant genetic resources (PGR), there is currently no unified, comprehensive regulatory framework specifically promoted by the EU with the aim of harmonization across Member States. The most harmonized framework currently existing among EU countries concerns PGRFA of species listed in Annex 1 of the ITPGRFA, consistent with the treaty's objectives. Indeed, regulatory instruments are often subject to varying interpretations between countries and regions[9]. Multiple regulations and guidelines coexist, each applied differently depending on local contexts. A tangible example of this complexity is found within individual germplasm collections, where stored germplasm subgroups can possess differing legal statuses based on their historical context and geographical origin. This diversity of applicable legal frameworks and administrative procedures becomes even more intricate in *in situ* conservation activities, where territorial sovereignty significantly influences management practices. In addition to ABS-related rules, a range of other legal instruments—including phytosanitary regulations and seed laws—can affect the acquisition, conservation, and transfer of accessions, with differing levels of coordination and harmonization across Member States.

7. However, it is precisely the *in situ* access to and use of plant genetic resources (PGR) that are most affected by increasing regulatory complexity—especially when stakeholders involved in

[6] J. M. M: Engels/ L. Maggioni (2011) "AEGIS: a regionally based approach to PGR conservation", accessed at: https://www.ecpgr.org/fileadmin

[7] ECPGR. (2021). Plant Genetic Resources Strategy for Europe. European Cooperative Programme for Plant Genetic Resources, Rome.

[8] Brink, M., & Van Hintum, T. (2020). Genebank operation in the arena of access and benefit-sharing policies. Frontiers in Plant Science, 10, 1712. https://doi.org/10.3389/fpls.2019.01712.

[9] Arjjumend, H. (2018). Debate on genetic resources accessed ex situ in the Nagoya Protocol. Grassroots Journal of Natural Resources, 1(1), 5-12. https://doi.org/10.33002/nr2581.6853.01011

these activities are not all from the country under whose sovereignty the PGR fall. The historical evolution of ethical, social, and regulatory (ESR) dimensions associated with plant genetic resources, particularly those intended for food and agriculture (PGRFA), **can be traced historically**[10]. Nonetheless, recent developments in this area are primarily attributed to the **turning point represented by the United Nations Conference on Environment and Development** (UNCED), commonly known as the "Earth Summit," held in Rio de Janeiro, Brazil, from June 3 to 14, 1992. Since then, ethical, social, and political awareness has notably increased regarding the impacts that scientific and technological advancements and international trade dynamics have on various communities and regions around the world. Consequently, significant efforts are currently underway to establish a coherent regulatory framework aimed at the sustainable management of these resources, reducing fragmentation and ensuring their long-term conservation and use. This dynamic situation of the regulations is also part of the complex context of PGR.

I.2. Objectives of the analysis

1. The objective of task 5.6 was to map **the current legal status** of the PGR available in the PRO-GRACE consortium and the possibilities of creating links within and outside the consortium, in a process of transition towards a pan-European PGR infrastructure.

2. To carry out this task, an exhaustive analysis was made of a wide variety of documentary sources, as well as sociological research based on in-depth interviews, the design and execution of which required the collaboration of personnel from gene banks, seed systems or storage entities, as well as other actors participating in the consortium. For a pan-European infrastructure, it was considered strategic to know the legal status of existing resources, both with regard to storage and conservation activities and to the activities of use that agents can carry out with PGR or the possibilities of mobilisation to third parties.

I.3 Research methodology

1. The research carried out combined **two types of research methodologies**. On the one hand, an desk-based research and analysis of a wide variety of documentary sources (details in I.3.1), and on the other hand, sociological research based on in-depth interviews (I.3.2), for the design and execution of which the collaboration of gene banks, seed systems or storage entities was required, as well as other actors participating in the consortium, both in terms of the activities carried out by these agents and in terms of the activities for which PGR material is provided to third parties.

2. Both methodologies **were combined because** the legal status of PGR is highly fragmented and in a state of transition and, consequently, in addition to a rigorous interpretation of the regulations (in their current state), a complementary view of their inconsistencies and gaps, as well as the dynamic evolution in which they are immersed, is essential. The perception of very

[10] Maxted, N., Hunter, D., & Ortiz Ríos, R. (2020). Plant genetic conservation. Cambridge University Press. 45-46.

specific actors can also help to establish the challenges, needs and opportunities of this ESR framework.

3. Although not initially planned, an additional research block was added (see results in IV), aimed at extracting valuable elements from the experience of the BBMRI-ERIC infrastructure for the GRACE RI, specifically with regard to the handling of ESR/ELSI issues.

I.3.1. Desk-based research.

1. A comprehensive desk-based analysis was carried out, covering a wide range of elements and identifying those that are strategic with respect to the transition from the current European PGR system to a pan-European infrastructure.

2. Sources collected and analysed:

a) Current regulations affecting access to, conservation and use of PGR.

b) Peer-reviewed scientific publications on ethical and legal aspects of PGR (journal articles and monographs).

c) Documents from institutions involved in the conservation of PGR.

d) Documents from government offices on policy strategies, recommendations and guidelines.

e) Documents related to decision-making processes and legislative developments in the EU.

f) Materials reflecting discussions and developments in international negotiations on access and equitable sharing of benefits arising from the use of plant genetic resources.

These negotiations were analysed especially in the context of the International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter, ITPGRFA, approved on November 3, 2001, and entered into force on June 29, 2004) and the Nagoya Protocol on the fair and equitable sharing of benefits arising from the utilisation of genetic resources (hereinafter, the Nagoya Protocol, which entered into force in 2014 and implements the third objective of the Convention on Biological Diversity (hereinafter, the CBD, which entered into force on 29 December 1993).

g) Other documents suggested by interviewees and members of PRO-GRACE.

I.3.2. Sociological research (in-depth interviews)

1. Regarding the sociological research carried out, an approach and design was used that considered the results of various surveys conducted by other authors between 2015 and 2020 on different actors, including those involved in governance, on regulatory aspects related to plant genetic resources (PGR), especially those subject to the International Treaty on Plant

Genetic Resources for Food and Agriculture (ITPGRFA). Among others, the following are worth highlighting:

a) In 2015 a study was published that analysed the way in which current regulations affect collecting germplasm in Europe.

> Maggioni, López Noriega, Lapeña, Holubec and Engels (2015) 11 examined this issue by means of a survey addressed to those responsible for European germplasm banks, with the aim of finding out their perception of the national and international regulations applied to the collection of phytogenetic resources. By means of a questionnaire sent to 43 members of the European Plant Genetic Resources Programme, the study collected, as of 2015, both a description of national legal procedures and the practical experiences of these managers in trying to comply with the ABS regulations in force in Europe.

b) Separately, in 2017, **Kell, S., Marino, M. & Maxted**[12], published the results of a survey on "Bottlenecks in the PGRFA use system: stakeholders' perspectives". The research was conducted in 2015 using the SurveyMonkey platform (receiving 392 responses from a wide range of stakeholders, in different languages).

> Univariate descriptive analyses of the data (frequency and dispersion distributions) were performed on the responses to the mandatory questions in MS Access and MS Excel and the results were presented in bar and pie charts and/or in the narrative.

c) Concerning ABS and Nagoya, for its part, a voluntary survey, open to users, was carried out by T. Greiber (2019) in connection with the application in the EU of Regulation 511/2014[13].

> This paper shows that competent national authorities in the European Union, such as Germany, are currently facing a number of practical challenges, ranging from raising awareness of ABS in many and very diverse sectors, to clarifying the highly controversial scope of EU ABS legislation, and developing effective, proportionate and dissuasive compliance controls.

2. Likewise, it has been considered that the PRO-GRACE project also makes use of sociological research methods in other tasks in some of its sections (see PRO-GRACE deliverables D5.4 and D.5.5).

3**. The research designed,** with respect to others whose results have been published and with respect to those carried out in the execution of other PRO-GRACE tasks, **can be distinguished by the following features**:

[11] Collecting Plant Genetic Resources in Europe: A Survey of Legal Requirements and Practical Experiences. In: Coolsaet, B. et al. (eds.) Implementing the Nagoya Protocol: comparing Access and Benefit-Sharing regimes in Europe. Leiden/Boston: Brill Nijhoff. pp. 327-362 doi 10.1163/9789004293212_01.

[12] Kell, S., Marino, M. & Maxted, N. Bottlenecks in the PGRFA use system: stakeholders' perspectives. Euphytica 213, 170 (2017). https://doi.org/10.1007/s10681-017-1935-z

[13] T. Greiber, "Implementation of the Nagoya Protocol in the European Union and in Germany", Phytomedicine, Volume 53, 2019, pages 313-318.

I. The timeframe for conducting the interviews in relation to key elements in the evolution of/ negotiations within the main PGR regulatory frameworks (ITPGRFA and Nagoya Protocol). See details below, para. 4.
II. The format of the qualitative research carried out: in-depth oral interviews. See details below, para. 5.

4. **The chronological timing of the interviews with respect to key elements in the evolution of the regulatory frameworks.** The interviews and preliminary contacts were carried out in the second half of 2023, and the in-depth interviews were carried out in the first eight months of 2024. During this period, the regulatory framework that applies to PGR at international and European level underwent a series of changes that have been tracked in parallel with the interviews to be conducted. All the details about these dynamics in the political and regulatory frameworks are described in the corresponding section of the results (II). It is worth highlighting, among others:

i. Numerous working documents were generated in the EU in relation to the Green Deal and the Biodiversity Strategy, as well as specific legislative work related to PGR: (1) the draft regulation on Plant Reproductive Material presented by the Commission in July 2023, and the process of reflection to which it has subsequently given rise; (2) the EU's participation in the negotiations, in the context of the World Intellectual Property Organization for an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources.

ii. At the international level, the governing body of the ITPGRFA met in November 2023 in Rome, a meeting which the T5.6 working group attended as observers. Throughout the event, a multitude of actors and country representatives drew attention to the low mobilisation of PGRFA that had occurred since the adoption of the Treaty, highlighting the significant contributions to the ABS fund of the ITPGRFA by a limited number of actors and countries, as opposed to the indecision of others. Note was also taken of the diversity of interpretations of the factors and causes that have led to this timid quantitative progress in the two decades since the existence of the ITPGRFA. The evolution of the multilateral ABS system has been followed in detail, as have the discussions on linking access to DSI to that system.

iii. The preparatory work and the holding of COP 2024 in Cali (Colombia) were also followed, especially in relation to the use of digital sequence information (DSI). The CBD's post-2020 *Kunming-Montreal Global Biodiversity Framework*[14] explicitly mentioned DSI, reflecting the fact that the fair sharing of benefits from DSI is now considered part of the strategy to halt biodiversity loss. COP 15 (2022) had agreed to establish a multilateral mechanism for the distribution of benefits derived from the use of digital information on sequences of genetic resources. In 2024, the 'Cali Fund for the fair and equitable sharing of benefits arising from the use of DSI on genetic resources' was set up, although the suspension of the Cali Summit prevented the negotiation of all the details.

[14] The Kunming-Montreal Global Biodiversity Framework (GBF) was adopted during the fifteenth meeting of the Conference of the Parties (COP 15) following a four-year consultation and negotiation process (2022).

5. The format of the qualitative research carried out: in-depth oral interviews. An in-depth interview is a qualitative technique that consists of a direct and open conversation between the researcher and an interviewee, designed to explore a specific topic in depth. Unlike structured surveys, this type of interview uses open-ended and adaptive questions that allow the natural rhythm of the conversation to be followed, delving deeper into the perceptions and experiences of the participant.

i. This methodology is widely used in sociology and other social science disciplines because of its capacity to obtain detailed and meaningful testimonies that are difficult to achieve with quantitative methods or structured questionnaires. The in-depth interview is particularly useful when the researcher seeks to understand a phenomenon in depth, generating hypotheses or theories based directly on the narratives of the interviewees.

ii. Unlike other techniques, in-depth interviews require an empathetic and trusting relationship to be established between interviewer and interviewee, thus facilitating a comfortable and honest environment that allows the participant to share sensitive and authentic information.

iii. Among its main advantages is the obtaining of information rich in context and nuance, revealing the understandings, assumptions and meanings underlying the interviewees' responses. This was decisive in this case, as the aim was to obtain information on challenges, needs and opportunities beyond what is published in formal documents.

iv. However, this research methodology also has some inherent limitations. Compared to other types of research, the main limitations of in-depth interviews, especially on highly specialised topics, are: (1) the difficulty in recruiting people capable of providing meaningful information, the high consumption of time and resources, and the subsequent effort required for the organisation and analysis of the data obtained; and (2) the lower statistical representativeness. However, in this case, the participants —who came from an already limited group— were carefully selected for having characteristics relevant to the issues under investigation. In addition, the interviews were meticulously planned and designed. The logic behind the sampling consisted of selecting participants who could contribute as much information as possible about the questions posed by the research. Some participants were intentionally selected for their direct participation in the PRO-GRACE project, while others were included following references provided by the initial interviewees or thanks to searches undertaken in relation to bibliographic or documentary references provided by the interviewees.

v. This format was chosen because it is the most appropriate for studying a complex subject from a complementary perspective with respect to the desk-based research undertaken. We are dealing with stagnant regulations that generate bottlenecks and have an impact both on daily operations and, especially, on the planning of future activities in the medium and long term. The constraints of the in-depth interviews have been complemented with the results of a rigorous and extensive documentary (desk-based) investigation, integrated into a mixed research design that consistently reinforces the context and completes the qualitative data obtained.

6. Interviewers: the interviews and subsequent analysis were carried out by two academics from the University of the Basque Country, Leire Escajedo, Jurist (with a second doctorate in Biological Sciences), Professor of Law and Ethics in Biosciences; and Igor Filibi, expert in International Relations, Doctor in Sociology and Political Science.

7. Selection of participants and phases of the interview process. As mentioned above, he success of a study involving in-depth interviews depends largely on the correct strategy for recruiting participants. The selection was aimed at finding different stakeholders and agents who participate in the conservation and use of PGR, or access it for different purposes, as well as experts from different disciplines who address issues related to the conservation, access and sustainable use of PGR, with special attention to ABS**.**

i. Given the objectives of the interviews to be conducted, the selection had to be right in terms of choosing people who could offer valuable information and perspectives and, at the same time, who were sufficiently diverse to complement each other.

ii. Initial contact was made through the PRO-GRACE network. We provided a questionnaire (see ANNEX) that clearly showed the type of information we wanted to talk about. The aim was to find out in more detail how the different actors perceive the barriers and bottlenecks of the regulatory frameworks, as well as the gaps, both with respect to their main activity and, especially, with respect to project/work proposals that go beyond that sphere of activity and, ultimately, with respect to the construction of a pan-European PGR research infrastructure.

iii. The initial questionnaire was circulated among PRO-GRACE partners with the aim of identifying stakeholders who could provide us with an interesting perspective on the issues raised, ensuring a plurality of perspectives (background, origin, principal activity).

iv. Approaching contacts were also made with some people, not about the content, but about which people could enrich the plurality of perspectives that was being sought. In addition to the profile, we needed people who understood what the study involved and who were available to participate.

v. We received, on the one hand, proposals from people who could be good candidates for the interviews, as well as, alternatively, information on documentary sources of very diverse types from which some kind of answer to the questions raised could be obtained.

vi. Interviews actually carried out: 51 approach interviews and 23 in-depth interviews (8 out of the consortium), some of them with two participants from the same organisation in the same interview.

vii. The interviews were conducted in English with the exception of those very specific cases in which the interviewee was a native Spanish speaker (such as the interviewers).

vii. All of the interviews (both initial and in-depth) lasted a total of 187 hours, with the in-depth interviews lasting between 50 minutes and 1 hour 50 minutes.

8. Awareness of the potential for saturation in relation to actors with a similar profile who are closely related in their activity (especially professionals in European gene banks). The principle of saturation in qualitative research refers to the point at which the collection of new data no longer provides relevant additional information, indicating that a sufficiently deep understanding of the phenomenon under study has been reached.

i. As a result of their close collaboration on very prominent research and development projects at the European level (see other D5 deliverables), it was considered very likely that many of the

actors in the PRO-GRACE ecosystem would reflect a very similar view of the ESR challenges, needs and opportunities in the transition to a pan-European infrastructure.

ii. Some of the organisations contacted through the initial questionnaires, meanwhile, indicated that they did not have a person with a profile that could/would participate in the in-depth interviews, offering as an alternative document that had already been published (whether they were the results of the aforementioned surveys, documents published as the results of joint European projects or documents from different organisations).

iii. Demographics of the interviewees. Of the in-depth interviews carried out, practically one third were conducted with people outside the PRO-GRACE consortium and 15% with people whose professional activity with PGR is located outside the European Union (non-EU professionals), with the aim of obtaining different perspectives on the phenomenon studied. In terms of profile, 40% of the in-depth interviews were conducted with genebank managers (mostly national, including one collective life manager), and the remainder with other professionals involved in PGR-related activities outside the genebank environment (e.g. agri-science researchers and plant breeders of different types). In terms of geographical origin, and given the profile of the infrastructure, most of the professionals interviewed carry out most of their activity in the European Union, compared to those interviewed from other regions of the world. Given GRACE-RI's vocation to provide services to third parties, and the similarities of vision of some PRO-GRACE participants, it should be noted that a special effort has been made to interview actors not directly involved in the PRO-GRACE consortium, 34% in total, (although in some cases with indirect links).

9. Results analysis method for the interviews: a thematical content analysis was carried out, identifying the central themes in relation to the challenges and needs that the aspects of ESR currently pose to the PGR system. Attention was paid to the coincidences and divergences, as well as to the different narratives on coinciding elements and circumstances.

i. Thematic content analysis is a qualitative analysis method that consists of identifying, examining and interpreting recurring patterns of meaning (or themes) within a dataset, maintaining contextual richness.

ii. The data obtained were transcripts of interviews and field notes, as well as - in the case of authorised recordings (see paragraph 10, this section: ethical and confidentiality aspects) - the visualisation of the interviews carried out.

iii. Patterns in the discourse were sought, as well as repeated ideas or dominant concepts, which were then grouped into meaningful themes.

10. Ethical aspects of the research: informed consent, data protection and confidentiality. The selection of participants followed strict ethical and legal criteria to ensure, at all times, voluntariness, informational clarity and confidentiality.

All participants received full information about the objectives of the research and the characteristics of their participation (whether in brief or in-depth interviews). Before starting the interviews, it was made clear that participation would be completely confidential: n*either*

the individuals nor their institutions would be identified, and their contributions would not be quoted.

Likewise, for those interviewees who gave their consent, informed and expressed consent was obtained to record the in-depth interviews with the commitment to totally delete the recordings after processing the information. The sole purpose of the recordings was to allow for more natural conversations between the interviewees and the interviewers, without compromising the recording of information to be processed later. All recordings were deleted.

I.3.3. BBMRI-ERIC

During the WP5 work process, considerable interest emerged in different aspects of the BBMRI-ERIC operation. As part of T5.6, it was decided to dedicate time to researching those elements of the BBMRI-ERIC experience that may be valuable for the pan-European PGR infrastructure. This was done based on the analysis of different documentary sources (regulations, documents from the infrastructure itself and peer-reviewed publications).

III.- Block 1 of results (DESK BASED RESEARCH): Ethical, social and regulatory aspects affecting PGR in terms of its access and conservation, and the diversity of uses with a view to the construction of a pan-European research infrastructure

II.1 Ethical and social aspects arising from PGR, with special emphasis on PGRFA

1. Ethical and social reflection on PGR, with special reference to PGRFA, involves a series of fundamental dilemmas related to the access, ownership, use and distribution of plant genetic resources. Seeds are not just agricultural inputs; they represent cultural memory, ancestral practices, local knowledge and possible futures. Their control and regulation involve ethical decisions about who has the right to conserve, improve, exchange and benefit from them, as well as the impact that different decisions about conservation, improvement and use have on the environment and biodiversity

From a perspective of justice, the debate revolves around the equitable distribution of the benefits derived from the use of genetic resources, especially between industrialized countries — where plant breeding industries are usually located — and the agricultural communities of the Global South, which have historically been the main custodians of cultivated biodiversity[15]. This asymmetry is reflected in the commercial use of seeds improved from traditional varieties, without fair compensation to those who have kept them alive and adapted over time.

Issues such as appropriability, recognition of the contribution to knowledge (and/or innovation) and, for some decades now, the notion of sovereignty over resources and food sovereignty, which defends the right of peoples to define their own agricultural policies and to conserve, use and freely exchange their seeds, also come into play. In contrast to intellectual property regimes

[15] Fowler, C., & Mooney, P. (1990). Shattering: Food, politics and the loss of genetic diversity. Tucson: University of Arizona Press.

— such as patents or plant breeders' rights — that restrict these practices, seed ethics (with very diverse approaches) proposes alternative models based on the commons, recognizing the collective and cultural value of genetic resources[16]..

Finally, from an environmental perspective, it is necessary to conserve genetic diversity as a vital heritage for the resilience of agroecological systems in the face of the challenges of climate change, emerging diseases and the erosion of local varieties. In this sense, seed ethics promotes a responsible relationship with biodiversity, based on respect, care and reciprocity[17].

2. Balance between the theoretical and pragmatic orientations of environmental ethics, and their projection in relation to PGRFA. While more theoretical approaches to environmental ethics traditionally emphasize its fundamental questions of value (i.e., what has intrinsic value), more pragmatic approaches recommend focusing not only on the fundamental values underlying environmental decisions; instead, they seek consensus at the policy or management level[18]. It should be noted that, although it can be difficult to reach consensus at a fundamental level, at a practical level, and despite divergent fundamental values, it is possible to converge on some agreements.

In the case of genetic resources, this trend towards pragmatism is very visible around the CBD, which projects an almost universal consensus on a generic formulation of certain fundamental values and in whose evolution, since 1992, it has sought to accommodate the divergent ways in which different countries interpret this fundamental minimum.

3. Ethical reflections on cultivated biodiversity have a longer and more documented history than those concerning wild resources, specifically when considering the latter in the context of plant genetic resources (PGR). In this regard, it is important to clarify that we are referring to the perspective of the ethics of plant genetic resources, which focuses on the human use of useful plants — such as agricultural crops or wild species with potential value. Within this framework, nature is viewed as a resource, something that humans use, manage, conserve, or exploit.

Since at least the 1940s, governmental and non-governmental organizations have been debating the recognition — and its possible forms — of the custodians of genetic resources for food and agriculture (PGRFA), by virtue of their work in the conservation and management of this stored biodiversity[19]. This debate intensified especially after the approval of the Plant Patent Act in the United States in the 1930s, which protected varieties that reproduce asexually, and later, with the enactment of the Plant Variety Protection Act of 1970. The latter granted plant breeder's rights to those who developed new varieties, but also included a key exception for farmers: the right to save and exchange their own seeds, although this right would be significantly limited in 1994 with respect to biotechnologically improved seeds[20].

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[16] Kloppenburg, J. (2010). Seed Sovereignty: The Promise of Open Source Biology. In *The Wealth of the Commons*.Shiva, V. (2000). *Stolen Harvest: The Hijacking of the Global Food Supply*. South End Press.

[17] Altieri, M. A., & Nicholls, C. I. (2005). Agroecology and the Search for a Truly Sustainable Agriculture. UNEP.

[18] Marion HOURDEQUIN (2015), *Environmental Ethics. From theory to practice*, Bloomsbury, 117-118.

[19] Cummings, C. H. (2009). *Uncertain peril: Genetic engineering and the future of seeds*. Boston: Beacon Press; Fowler, C., & Mooney, P. (1990). *Shattering: Food, politics and the loss of genetic diversity*. Tucson: University of Arizona Press.

[20] Kloppenburg, J. R. (2005). *First the seed: The political economy of plant biotechnology*. Madison: University of Wisconsin Press.

Around the same time, in the 1970s, the member countries of the (current) European Union[21] generated a series of agreements aimed at organizing the standardized seed trade[22],, based on a very significant element: the Common Catalogue, which compiled the national seed catalogues. The situation of local varieties and less standardized forms of seed exchange with respect to the evolution of this commercial scenario will increasingly be, and has been until now, the subject of ethical and political debate — with no room for common and holistic dialogue — between different conceptions of what seeds represent and even models of agriculture[23].

4. Bearing in mind that a large part of plant breeding still depends on access to genetic material as raw material, fundamental questions arise: how much of the value comes from the resources themselves and how much from the plant breeding activity? And what kind of value is at stake: economic, social, cultural and/or ethical?

All these questions are still on the table, although with a particularity that sharpens the questions to be debated. On the one hand, at least apparently, almost all the governments of the world (except the USA) agreed in 1992 on the same interpretation of the values represented by biodiversity, as well as a series of key principles on human responsibility for its conservation and the equitable sharing of the benefits derived from it. On the other hand, and at the same time, the scenarios for the implementation of the CBD, and the bifurcation that will be explained between the ITPGRFA and the Nagoya Protocol, have incorporated into the ethical and social reflection on PGR elements that transcend the latter and that, ultimately, connect with the notable socioeconomic inequalities across the planet.

5. When it comes to biodiversity, including wild biodiversity, we can identify at least four areas of discourse in which the concept of biodiversity, coined in 1986, is integrated: conceptual, ethical, methodological and sociopolitical[24]; that is to say: what biodiversity is; why it deserves to be preserved; how it should be measured; and, finally, how the meaning, value and measurement of biodiversity are or should be a sociopolitical concern. Michael Soulé was one of the first voices to proclaim the intrinsic value of biodiversity and the need to consider this value as one of the central normative postulates in the field of conservation biology[25], but this type of proclamation[26] and, in particular, the consequences that should derive from such a normative premise with respect to conservation have not ended up forging a consensus. When

[21] In January 1973, Denmark, Ireland, and the United Kingdom joined the six founding countries of the European Communities (the Federal Republic of Germany, France, Italy, the Netherlands, Belgium, and Luxembourg).

[22]A set of standards aimed at ensuring that seed in trade meets uniform, consistent, reliable and predictable product characteristics. Cohen, S. (2014). Seed Banking, Seed Saving, and Cultivating Local Varieties. In: Thompson, P.B., Kaplan, D.M. (eds) Encyclopedia of Food and Agricultural Ethics. Springer, Dordrecht. https://doi.org/10.1007/978-94-007-0929-4_487

[23] Standards-based value chains and Geographical Indication (GI) labelling as market schemes. They are recognised as having some utility, although they also tend to specialise or reinforce certain local breeds to the exclusion of others. Larson, J. (2007). *Relevance of geographical indications and designations of origin for the sustainable use of genetic resources*. Rome: Global Facilitation Unit for Underutilized Species.

[24] Katie McSchane (2017) "Is Biodiversity Intrinsically Valuable? (And What Might That Mean?", in: The Routledge Handbook of Philosophy of Biodiversity, edited By Justin Garson, Anya Plutynski, Sahotra Sarkar, 155-158.

[25] Michael E. Soulé (1985), "What is conservation Biology", BioScience 35:727-734, 731.

[26] Thus, some scholars interpret intrinsic value as equivalent to moral standing—a status typically recognized only in moral agents, according to biocentric ethical theories (see Taylor, 1980). Others refer to the objective value of biodiversity as a factual condition, to a value that exists independently of its instrumental utility (O'Neill, 1992), or to the notion that biodiversity holds unconditional value, regardless of the context in which it exists (Rolston, 1988).

there is a lack of minimal consensus on the interpretation of a concept, in this case, on what exactly intrinsic value is and what the intrinsic value of biodiversity is, these different meanings of a key term mean that the debate cannot go well[27]. In fact, some voices in the literature have argued that assertions of intrinsic value, in general, have not been useful and may even be counterproductive with respect to conservation[28].

In what sense does biodiversity matter? According to the literature[29], biodiversity has direct use value (food, biomedical, contribution to biological control, obtaining raw materials, recreational gathering, ecotourism), indirect use value (of the services it provides to ecosystems) and value regardless of any use (existential, value of its transmission to future generations, intrinsic value).

6. The complexity of resolving the multitude of conflicting values and interests involved in PGR decision-making is evident in the remarkable transformation of the status of non-commercial PGR over a relatively short period. For a brief time, it appeared that PGRFA were moving towards being recognised as part of the "commons" — that is, as resources collectively managed for the benefit of all, under shared access and stewardship principles rather than individual ownership. However, this trend was later challenged by evolving regulatory frameworks and proprietary claims. The clause recognizing PGRFA as the common heritage of humanity (1983), included in the *International Undertaking on Plant Genetic Resources for Food and Agriculture*[30]. The International Undertaking, a non-legally binding resolution adopted by the FAO Conference[31], was intended to be an open-access regime under which PGRFA should be made available without restriction and for the benefit of humanity at large[32]. Between 1989 and 1991, the Undertaking was amended, as the parties adopted amendments on plant variety rights, breeders' rights and the sovereignty of nation states over their PGRFA. All this, before starting the negotiations that led to the adoption of the ITPGRFA in 2001.

The international compromise adopted an open-access approach to plant genetic resources, considering them the common heritage of humanity. This implied that they were available without restrictions and that their use was considered beneficial for current and future generations. This international compromise was a reaction of the countries of the global south, concerned about the flow of genetic resources to the global north and their subsequent transformation into private property[33]. Many industrialized states (such as the United States, Germany, France or the United Kingdom) did not adhere to the commitment or did so with reservations, because the scope of the Commitment was not limited to raw genetic resources,

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[27] McShane, K. (2007), "Why Envinronmental Ethics Shouldm't Give Up on Intrinsic Value", *Environmental Ethics* 4: 101-114.

[28] L. A. Maguire/ J. Justus (2008), "Why Intrinsic Value Is a Poor Basis for Conservation Decisions", Bioscience 58: 910-911.

[29] Kevin J. Gaston/ John I. Spicer (2004), "Does biodiversity matter?", *Biodiversity. An Introduction*, 2ª ed, Blackwell, 91-2; Jan Bengtsson, Hefin Jones, Heikki Setälä (1997) "The value of biodiversity", Trends in Ecology & Evolution, Volume 12, Issue 9, Pages 334-336; Burch-Brown J, Archer A. In defence of biodiversity. Biol Philos. 2017;32(6):969-997.

[30] F. Rabitz (2021), The Global Governance of Genetic Resources, Routledge, 65-69.

[31] J. Esquinas Alcazar e. al. (2013), "A brief history of the negotiations on the International Treaty og Plant Genetic Resources for food and Agriculture", in M. Halewood/ I. López Noriega/ S. Louafi (eds), Crop Genetic Resources as a Global Commons, Routledge, 138-139.

[32] F. Rabitz (2021), The Global Governance of Genetic Resources, Routledge, 58-59.

[33] P. R. Mooney (1983), The law of the seed. Another development and plant genetic resources, *Development Dialogue*, 1983, No. No. 1/2, 1-172.

but it also included special genetic reserves, such as elite breeding lines. The incompatibility of open access with the property rights recognized by the mechanisms for the protection of digital varieties was notable.

This clause, in practice, made it difficult to recognize producers and custodians, since its most notable effect, within the borders, was the impossibility of a resource being considered private property[34] and/or public domain, and it had no clear impact on the possibility of recognizing intellectual property rights with respect to improved varieties, which was advancing through different mechanisms.

7. For its part, the Convention on Biological Diversity (CBD) quickly became an international instrument with almost universal adherence — with the notable exception of the United States — and achieved accelerated entry into force. The CBD proposes a collective commitment based on three fundamental pillars: the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from its use. These pillars reflect values shared worldwide, although there is no clear consensus on how to implement them in practice, which has generated extensive debate and tension among the signatory countries.

The application of the principles of the CBD is constantly strained by the coexistence of other regulatory frameworks and divergent points of view on agri-food innovation, international trade models and intellectual property systems. Conflicts also arise between dominant cultural hegemonies and efforts to preserve cultural diversity and collective memory. These tensions are exacerbated when variables such as gender or the differential recognition of the various actors involved are introduced, making the design of coherent and equitable policies for the governance of biodiversity even more complex[35].

8. The “two” developments of the CBD with respect to PGR: the ITPGRFA and the Nagoya Protocol. The institutional bifurcation in the development of the Convention on Biological Diversity (CBD), specifically with regard to plant genetic resources for food and agriculture (GRFA), cannot be understood without taking into account the prior existence of the *International Undertaking on Plant Genetic Resources for Food and Agriculture* (1981)[36]. This instrument reflected a logic based on the principle of the common heritage of humanity, while the CBD subsequently introduced the principle of national sovereignty over biological resources. The two approaches respond to different logics, which generates conceptual tensions between collective management and state control.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) can be interpreted as an attempt to update and adapt that initial commitment, incorporating new

[34] Fowler, C., & Mooney, P. (1990). Shattering: Food, politics and the loss of genetic diversity. Tucson: University of Arizona Press.
[35] Cummings, C. H. (2009). *Uncertain peril: Genetic engineering and the future of seeds*. Boston: Beacon Press; Fowler, C., & Mooney, P. (1990). *Shattering: Food, politics and the loss of genetic diversity*. Tucson: University of Arizona Press.
[36] The International Treaty on Plant Genetic Resources for Food and Agriculture, referred to as the Plant Treaty, was approved on 3 November 2001 by Members of the Food and Agriculture Organization (FAO), headquartered in Rome, Italy.

political and legal values, but limiting its scope to a defined number of food and forage crops of global importance.

At the same time, the normative development regarding how to implement the CBD in key areas such as access and benefit-sharing (ABS) for plant genetic resources (PGR) remained uneven following the adoption of the ITPGRFA. While the ITPGRFA established a detailed regulatory framework, as previously discussed, with respect to other PGR—those in the public domain or under the sovereignty of States not party to the Treaty—the text of the CBD appeared to rely primarily on bilateral agreements. To some extent, the Nagoya Protocol subsequently opened a clearer space for international cooperation concerning PGR not covered by the ITPGRFA.

Although the Nagoya Protocol adopts a broader approach, encompassing all genetic resources and not only PGR, from the specific perspective of plant genetic resources, the regulatory status of sovereign PGR not covered by the ITPGRFA was developed—particularly with regard to access and benefit-sharing (ABS)—through the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits in 2010, which entered into force in 2014.

In order to properly articulate the relationship between the Nagoya Protocol and earlier international instruments, such as the ITPGRFA, the Protocol expressly includes Article 4. This provision regulates the interaction between the Nagoya Protocol and other international agreements. Essentially, the Protocol seeks to complement and strengthen the Convention on Biological Diversity (CBD), without replacing or conflicting with other compatible instruments that support the objectives of the Convention. Furthermore, the Protocol does not apply where a specialized international instrument exists that is both compatible with the CBD and governs the same subject matter.

[37]. Currently, new ethical challenges for genetic Resources stem from advances in DNA sequencing and synthetic biology, which may lead to a "dematerialization" of genetic material, with the potential to allow researchers and corporate entities to circumvent the obligations to obtain permits to access and share the benefits of use with the providers of genetic resources

II.2 Current regulatory status of PGR: A fragmented PGR regulatory framework, pending implementation in some key aspects and which does not provide sufficient legal certainty to some of the actors involved

1. In the transition from the current Plant Genetic Resources (PGR) system to an integrated pan-European research infrastructure, one of the most critical elements from an ethical-social and legal point of view is the status (or, more precisely, the plurality of statuses) to which plant reproductive material is currently subject.

[37] M. A. Bagley (2018), "De-materializing genetic resources. Synthetic biology, intelectual property and the ABS bypass", in C. R. McManis/ B. Ong (eds), Routledge Handbook of Biodiversity and the Law, Oxfordshire-NewYork, 219-224.

The regulatory framework that applies to PGR and to the activities of access, conservation and use that are carried out on them is an international framework, fragmented and subject to complex dynamic processes. Various international instruments have been paying increasing attention, without an overall logic, on one hand to the protection of intellectual property associated with plant material and on the other to the protection of germplasm in the public domain (currently under state sovereignty).

It may appear, at first glance, that there is significant consensus on this issue, given the significant number of countries that have signed the TRIPS agreement[38], with regard to intellectual property, and the CBD, in relation to sovereignty over PGRFA in the public domain. However, even among EU Member States, different regulations and guidelines coexist, resulting in very different applications of these instruments, especially with regard to germplasm under sovereignty. All this translates into legal uncertainty for many of the activities that, beyond conservation, involve the use of PGR under sovereignty.

Two factors aggravate this situation:

- First: Member States have not generated a common framework for action to overcome these limitations. Nor do they have a formalized space for political reflection for the generation of such a common space.

- Second: this absence of a shared vision means that PGR activities in the EU are affected by the dynamics that are being generated in international spaces (especially around the FAO Plant Treaty and the Nagoya Protocol).

2. The *Strategy for Plant Genetic Resources in Europe* (ECPGR)[39] refers to these obstacles as "gaps and needs in the policy and legislative landscape and in related or relevant instruments for the conservation and sustainable use of genetic resources". The lack of a holistic approach has a simple explanation, but a difficult solution[40]. Since the 1980s, the EU has addressed specific aspects of the legal and policy space related to seeds, sometimes at the EU level and sometimes through transnational strategies in different governance forums (UN, WTO, UPOV). The specific tensions and circumstances, together with the particular ways in which political majorities are constituted in each of these arenas, can help explain, if not always understand, how the current situation has been reached. A situation in which unwanted frictions arise and administrative and regulatory obstacles are created[41] that impede progress towards collaborative science.

3. On a global scale, this complexity and fragmentation in the EU can be attributed to several factors, such as:

[38] World Trade Organization. (1994). Agreement on Trade-Related Aspects of Intellectual Property Rights. Retrieved from https://www.wto.org/english/docs_e/legal_e/27-trips.pdf
[39] ECPGR. (2021). Plant Genetic Resources Strategy for Europe. European Cooperative Programme for Plant Genetic Resources. Rome: ECPGR. URL: www.ecpgr.org/pgrstrategy21
[40] Escajedo San-Epifanio, L. (2022). The (un)protection of agri-biotechnological innovation in the EU: When regulations collide with reality. En IP in Agriculture: Contemporary IP issues in the Field of Agriculture. Thomson Aranzadi.
[41] Prip, C. and Fauchald O. K. (2016) Securing Crop Genetic Diversity: Reconciling EU Seed Legislation and Biodiversity Treaties. Review of European, Comparative and International Environmental Law. Vol 25, issue 3, p363-377.

a. **Diversity of international frameworks**. The existence of international regimes of different origins, which cover different sets of genetic resources in a fragmented manner. There is no single unified regime, but rather several agreements that partially or sectorally overlap. The CBD and its development instruments represent a global trend, but they do not apply to all resources under state sovereignty. Of the 196 countries that have signed the CBD[42], 152 are parties to the ITPGRFA, which does not fully coincide with the 142 parties that have ratified the Nagoya Protocol.

Parties of the CDB (and Nagoya Protocol)	Parties of the ITPGRA
196 parties (Nagoya: 142 Parties). USA is not party of the CBD. Among other, Chile, Australia, Canada, USA, Rusia and Poland are not part of the Nagoya Protocol	As of 1 April 2025, the International Treaty has 154 Contracting Parties including one member organization. Among other, China, Rusia, South Africa, New Zealand, and Mexico are not part of the ITPGRFA.

In addition, some countries have opted for national regulations to implement some aspects of the CBD and are inclined to formalise bilateral agreements (between their state and potential users) as a mechanism for access to plant genetic resources and the articulation of benefit-sharing.

b. Lack of coherence. Although the mission, vision and objectives of these international agreements are similar, the way in which they are implemented is not harmonised. Each legal framework follows its own procedures, resulting in inconsistent approaches.

c. Unequal participation of countries. Not all countries participate in these international agreements in the same way or implement them in the same way. Some countries are party to some treaties but not to others, or apply obligations with varying degrees of rigour, which hinders global regulatory harmonisation.

d. Proliferation of national legislation. Many countries have chosen to develop national ABS legislation (either in addition to, or in some cases as an alternative to, international agreements). The diversity of national laws reflects different approaches to the issue, but there is an international consensus on ensuring that local communities and countries that are custodians of biodiversity receive fair benefits for its conservation and sustainable use. In general, these national legal frameworks aim to prevent misappropriation (biopiracy) and promote balanced cooperation between providers and users of genetic resources, and include common elements such as the requirement for prior informed consent from the country or community of origin, the signing of agreements with mutually agreed terms for the sharing of benefits (both economic and non-economic), the creation of registers of traditional knowledge to prevent the misappropriation of indigenous and local knowledge, and the establishment of trust funds to ensure that financial benefits are appropriately used for conservation, local development and support to indigenous communities.

[42] The Convention on Biological Diversity (CBD) was negotiated and signed by nations at the Earth Summit at Rio de Janeiro in Brazil on June 5, 1992. The convention came into force on December 29, 1993. At the present, there are 196 Parties to this Convention.

e. Key aspects are yet to be implemented. Some of the key rules governing PGR at the international level are still in a dynamic process of negotiation and development. In particular, aspects related to Access and Benefit Sharing (ABS) and Digital Sequence Information (DSI), as well as - with particular nuances - the issue of farmers' and local communities' rights, are still under discussion and have not been fully specified, adding uncertainty to the legal framework.

f. Unresolved tensions in relation to state sovereignty over plant genetic resources, intellectual property regimes and international trade. The recognition of state sovereignty over a large part of plant genetic resources has been implemented within the international system of the United Nations. However, intellectual property regimes for plants revolve around two instruments that do not belong to the United Nations system: the international trade system, whose reference institution is the World Trade Organization (WTO) and within which the TRIPS agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights)[43] was signed, and the system around WIPO, which has substantial agreements with the WTO. Some countries have recently promoted an international instrument to better articulate the elements of the CBD and the international intellectual property regime. The European Union participated in the negotiation of this instrument in 2024[44], which is now open for signature (not yet into force), but no EU Member State is currently a signatory.

4. Similarly, in the context of the European Union (EU), **it is essential to acknowledge the impact of EU legislation**, including regulations concerning the marketing of seeds and other plant reproductive materials, plant variety rights, and patents, on the conservation and sustainable use of genetic resources[45]. Currently, the marketing and exchange of genetic resource materials (GRM) in the EU are regulated through ten Council Directives, the earliest dating back to 1966. The EU aims to consolidate these directives into a single, unified regulation. On 5 July 2023, the European Commission adopted two legislative proposals: one concerning the production and marketing of plant reproductive material in the Union (the 'Plant Reproductive Material Regulation') and another regarding the production and marketing of forest reproductive material in the Union (the 'Forest Reproductive Material Regulation'). The European Parliament adopted its position on these proposals, with amendments, on 24 April 2024, and Council's position was adopted in May 2025[46]. Discussions within the Council are progressing through the Working Party on Genetic Resources and Innovation in Agriculture, with the latest progress report issued on 29 November 2024[47].

5. The implications arising from the current coexistence of multiple regulatory frameworks, which emerged concurrently in distinct contexts and now govern different categories of germplasm, are examined in detail below.

[43] The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.
[44] WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge.
[45] ECPGR (2021). Plant Genetic Resources Strategy for Europe. European Cooperative Programme for Plant Genetic Resources.
[46] See: https://data.consilium.europa.eu/doc/document/ST-7448-2025-INIT/en/pdf
[47] See: https://data.consilium.europa.eu/doc/document/CM-2163-2025-INIT/en/pdf

II. 2. UNCED and the 1992 CBD as turning points: main changes with respect to pre-existing collections

II.2.1. The PGR regime derived from UNCED and the CBD

1. The **Declaration of the UN Conference on Environment and Development UNCED** – known as the 'Earth Summit' (1992)[48] - recognised among its principles that '*human beings are at the centre of concerns for sustainable development*', and are entitled to a healthy and productive life in harmony with nature (principle 1). Along with this, recognition is given to the sovereign right of states to exploit their own resources (principle 2) and they are invited to cooperate in a spirit of global partnership to conserve, protect and restore the health and integrity of the Earth's ecosystem (principle 7).

2. Unlike other environmental agreements negotiated prior to that date at the United Nations headquarters, **the UNCED Declaration is noteworthy because it also contains important economic objectives**. Thus, Principle 12 reads as follows: '*States should cooperate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries*'.

3. These principles of the Rio Declaration are projected in the different international agreements developed from UNCED, part of the international system of the United Nations, but from the outset they **raised some doubts about their coexistence with the rules governing the international economic system**. As is well known, the UN is an international organisation founded in 1945, whose main objective is to maintain international peace and security, protect human rights, foster cooperation between nations and promote social and economic development, while the WTO, founded in 1995 to replace the GATT (General Agreement on Tariffs and Trade, established in 1947), aims to regulate international trade by reducing trade barriers. Both institutions seek to strengthen international cooperation, but each has very different objectives, functions and structures, and the WTO's dispute resolution system has more forceful mechanisms.

4. Materialising this combination of environmental and human development objectives, **the CBD was articulated as a legally binding international treaty with three fundamental objectives** (art.1): (1) the conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits arising from the utilisation of genetic resources.

5. Biodiversity conservation, sustainable use and fair and equitable sharing of the benefits arising from the utilisation of genetic resources **are projected at a global level as a kind of mission that involves and, at the same time, benefits humanity as a whole**. In this sense, the CBD promotes cooperation between countries through information exchange, safe environmental technology transfer and scientific collaboration, recognising the global interdependence of biodiversity.

[48] Rio Declaration (1992). Rio Declaration on Environment and Development, in the Report of the United Nations Conference on Environment and Development. UN Doc. A/CONF.151/26 (Vol. 1), 12 August 1992.

6. **This notwithstanding, the CBD clearly establishes that biological resources are subject to the sovereign right of each State** (art, 3 CDB). As a result, it is up to each country to decide how to regulate access to its genetic resources (including traditional PGR) and it is also free to decide whether to establish cooperation instruments with other parties and on what terms.

7. Although they do not coincide in all their practical elements, **the legal instruments based on the CBD are characterised by the following elements**: 1) state sovereignty over their genetic resources, 2) facilitation of access to genetic resources, 3) recognition of the rights of the country of origin of genetic resources, 4) requirement for prior informed consent, 5) recognition of mutually agreed terms, 6) fair and equitable sharing of benefits, and 7) acknowledgement of the rights of indigenous peoples and local communities.

8. **This principle of national sovereignty replaced the previous interpretation**, held by some and outlined in the International Undertaking mentioned above, that plant genetic resources formed part of a kind of 'common heritage'. However, in principle, the CBD does not have retroactive application. This means that genetic resources that were accessed, conserved and utilised before 1993, the date of entry into force of the CBD, may be subject to different legal regimes. However, this must be verified on a case-by-case basis.

9. The important values and interests that have to do with the intersection between biodiversity, agriculture and the agri-food trade are intertwined in a very marked way in PGR. These interests are not always compatible with each other. Furthermore, on the one hand, the mechanisms within the orbit of the CBD (such as the ITPGRFA and the Nagoya Protocol) and, on the other hand, the WTO system and the TRIPS Agreement[49], manage the resolution of disputes generated by this intersectionality in very different ways.

10. **The CBD envisages a global commitment** to the fair and equitable sharing of benefits arising from genetic resources and, consequently, both the ITPGRFA and the Nagoya Protocol are evolving in that direction.

11. Under the WTO system, however, the TRIPS agreements were adopted, which seek to harmonise and strengthen intellectual property protection for innovations obtained by companies or plant breeders. Article 27.3(b) of the TRIPS Agreement requires countries to grant intellectual property protection to plant varieties, either through patents, an effective sui generis system (such as UPOV-type plant variety laws) or a combination of both. This requirement led to a drastic change for many developing countries, which until then had excluded plants and seeds from patentability or did not have IPR schemes for varieties, and at the same time were experiencing how international trade rules were extended to many sectors, but agreements on agricultural matters were not progressing.

12. A significant number of countries opposed the application of Article 27.3 (b)of the TRIPS Agreement, and **called for a transition period** in which to assess whether or not such agreements were compatible with the United Nations frameworks, in particular the CBD. But

[49] See reference above.

the WTO system and the United Nations system are, as has been said, autonomous systems and such a demand was not answered within the WTO.

13. Added to these difficulties is the way in which the new techniques of genetic improvement are leading to the questioning of the intellectual property protection regimes that have been applied to plants (whether patents or the plant variety system). Since conventional breeding processes are relatively long and economically costly, the aim is to speed up breeding by accumulating desirable traits or events in a single variety, with the aim of promoting rapid developments in the market in a short period of time. This **accumulation of traits** from multiple sources can cause tensions between different systems (plant breeders' rights, patents, rights over traditional varieties) and there is concern about the uncertainty of not knowing which rules would prevail in each case.

14. Digitisation, especially with the boost from AI, is expected to contribute to improving the efficiency and timelines of plant breeding processes, but at the same time, if there is an increase in patents on native characteristics, this can generate other problems: such as making it difficult to identify the relevant patents and efficiently negotiate the corresponding licences, or colliding with the rights corresponding to traditional varieties.

15. Schematically, by way of summary, **five categories or groups of genetic resources can be distinguished according to the legal framework that governs** them, considering the key moment of the entry into force of the CBD in 1993. The status of each specific PGR has to be determined on a case-by-case basis, complying as appropriate with the provisions of the regulations that affect it. The five groups are as follows:

1) **Genetic resources with status dating from before 1992/3**: Genetic material collected or conserved prior to the adoption of the CBD, which generally remained outside the scope of the new ABS obligations.
2) **Genetic resources under bilateral agreements subsequent to the CBD**: Resources accessed subsequent to 1992 managed mainly through bilateral access agreements between provider and user countries, supported by the national ABS legislation of each country.
3) **Genetic resources under state regulations subsequent to the CBD** (countries that have not ratified or have not fully adhered to the instruments developed from the CBD, such as the ITPGRFA or the Nagoya Protocol).
4) **Plant genetic resources under the multilateral system of the ITPGRFA** (2001, 2004): Certain genetic resources for food and agriculture that are subject to a specialised multilateral regime established by the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).
5) **Genetic resources under the Nagoya Protocol** (2010, 2014): The broad set of genetic resources (of any kind, beyond the agricultural sector) and associated traditional knowledge that since 2014 are managed under the binding global framework of the Nagoya Protocol on ABS, complementary to the CBD. Since 2014, a wide range of genetic resources (of any kind, beyond the agricultural sector) and associated traditional knowledge may be subject to national access and benefit-sharing (ABS) regulations adopted by countries in line with the Nagoya Protocol.

II.2.2. Resources with statutes dated prior to 1992 and resources under national regimes after 1992

1. **Before the CBD came into force** (in December 1993), there was no legally binding international framework to regulate access to genetic resources or the sharing of benefits. During that period, the prevailing notion in the international community was that plant genetic resources constituted the common heritage of humanity. Under the auspices of the FAO, for example, an International Undertaking on Plant Genetic Resources was promoted from the 1980s onwards, encouraging the free availability of seeds and other materials in international germplasm banks. Consequently, numerous plant genetic resources were collected, stored and shared before 1992 without formal ABS mechanisms.

2. **These pre-CBD materials were largely left out of the new access and benefit-sharing regime established after 1992**. Their use continues to be governed by previous agreements (for example, conventions between international centres and countries of origin) or simply by informal practices based on good faith and scientific cooperation. This historical legacy has created challenges, as the CBD rules do not apply retroactively: genetic resources obtained before 1992 are not subject to the prior consent requirements and benefit-sharing agreements that do apply to new acquisitions.

3. After 1992, **following the paradigm shift introduced by the CBD** and prior to the approval of the ITPGRFA and the Nagoya Protocol, countries began to develop mechanisms to regulate access to genetic resources within their jurisdictions and to ensure the sharing of benefits. The CBD laid the legal foundations for this approach by establishing that access to genetic resources is subject to the prior informed consent of the country of origin and the negotiation of mutually agreed terms for benefit sharing. On this basis, many countries enacted national laws on access to genetic resources that define the procedures for granting permits, the requirements for material transfer agreements, the modalities of benefit sharing (which may include payments, technology transfer, training, co-authorship in research, etc.) and sanctions in case of non-compliance. **The implementation of these national ABS legislations varies considerably**: some countries have detailed regulations and dedicated administrative authorities, while others still lack specific regulations, creating legal loopholes.

4. An issue of importance within national frameworks (and closely linked to bilateral ABS agreements) is the recognition of the rights of indigenous and local communities over their traditional knowledge associated with genetic resources. In practical terms, it is increasingly common for national ABS laws to require **not only authorisation from the State, but also the prior informed consent of the indigenous or local communities** concerned for access to traditional knowledge associated with genetic resources, as well as the negotiation of benefit sharing with them on mutually agreed terms. It even promotes the creation of community protocols based on the customary laws of each indigenous people or local community, to guide how the process of consent and benefit sharing should be carried out according to their traditions and customs. In this way, **the bilateral ABS regime in some countries is evolving to incorporate a community dimension:** it is no longer just about agreements between states and users, but also directly involves native communities in decision-making and in obtaining fair benefits for the use of their resources and knowledge.

II.2.3. International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2001)

1. The **International Treaty on Plant Genetic Resources for Food and Agriculture** (ITPGRFA), adopted in 2001 under the auspices of the FAO, is a specialised multilateral agreement that addresses the management of plant genetic resources (i.e. plant genetic resources) of importance for food and agriculture.

2. Its objectives include the **conservation and sustainable use of these resources**, as well as the **fair and equitable sharing** of the benefits derived from their utilisation, all in harmony with the general framework of the CBD. 154 countries have signed up to it, virtually maintaining a kind common gene pool of 64 key crops[50] (around 1.2 million accessions of 64 crops[51]). Although the resources are not physically gathered together (they are kept in different centers of origin), in a way they are considered part of a virtual common fund, given that: on the one hand, there are common access regulations and, on the other, a multilateral system of benefit distribution was articulated (art. 10 ITPGRFA).

3. One element that clearly distinguishes the ITPGRFA from the dynamic of bilateral agreements that the CBD seemed to encourage in its Article 15, is the aim for the system of access, conservation and use of PGRFA to be more cooperative and predictable, due to the relevance of these resources for global food security. It thus proposed a multilateral system (MLS) applicable to a defined set of basic and forage crops, described as PGRFA (art. 3) and listed in its Annex I. It is important to note that access to these resources (art. 12.3.b of the ITPGRFA) is granted exclusively for the purpose of utilisation and conservation for research, breeding and training for food and agriculture, on the condition that such purpose does not include chemical, pharmaceutical or other industrial uses not related to food and feed.

4. Signatories **are encouraged to make the genetic resources of these species collectively available to all others**, facilitating access to seeds and other *ex situ* materials for research, plant breeding and conservation purposes, under standard conditions. In effect, access to any MLS resource is granted through a Standard Material Transfer Agreement (SMTA)[52], the text of which is standardised for all users. This standardised agreement defines the rights and obligations of both the supplier of the genetic material (for example, a germplasm bank) and the recipient (the researcher or plant breeder requesting the resource), including clauses on how the benefits derived from its use will be shared.

5. Nearly two decades after ITPGRFA came into force, **the pool of resources shared by the signatory states has not achieved its initial objectives**. A very significant percentage of the resources accessed through this system come from the CGIAR international centres and other specific providers. Theoretically, according to Article 11.4, the governing body, after evaluating

[50] Art. 3 of ITPGRFA, together with its Annex I.

[51] The notification of material available is made through the registration of the material in the Global Information System. As of 20 July 2022, PGRFA holders have reported the availability of 1 103 814 accessions in the MLS through the Global Information System

[52] SMTA model, FAO. Access at https://openknowledge.fao.org/server/api/core/bitstreams/e0521161-1b06-4107-8f0f-70b838da908a/content

the progress made in including PGRFA in the multilateral system, may adopt some kind of measure, but the path taken has been to work in favour of voluntary collaboration.

6. Regarding **local and indigenous communities**, the ITPGRFA sets out a series of provisions whose implementation, however, is left to national governments. Thus, it is up to national governments to adopt appropriate measures to protect:

a) Traditional knowledge relevant to plant genetic resources.

b) The right to participate equitably in the benefits arising from the use of these resources.

c) The right to intervene in decision-making at the national level on the conservation and sustainable use of plant genetic resources.

7. The treaty also places any **farmer's rights to save**, use, exchange and sell farm-saved seed or propagating material under national jurisdiction (art. 9), while specifying that nothing in the ITPGRFA may be interpreted as limiting these rights (art. 9.3).

8. Apart from this, and in line with the objective of contributing to the global food system promoted by the ITPGRFA, art. 12.3 also establishes that **recipients shall not claim any intellectual property right or other right that may limit access to the PGRFA provided to them under this treaty** (art. 12.3.d), nor any similar rights over the genetic parts or components of said PGRFA.

II.2.4. Nagoya Protocol on Access and Benefit Sharing

1. The **Nagoya Protocol** (see details above) is the main international instrument that develops the third objective of the CBD — the fair and equitable sharing of benefits. In principle, it applies **to all** genetic resources (not only agricultural ones) and the traditional knowledge associated with them, although Article 4 of the protocol provides for the possibility that ABS relating to some genetic resources may be addressed in more specialised instruments (such as the ITPGRFA, see II. 2.3, and the Treaty on Marine Resources Beyond Jurisdiction or the WHO Pandemic Treaty, which we will refer to later).

2. The Protocol came into force in October 2014 and represents the consolidation of a globally binding legal framework to regulate ABS. Nagoya complements the CBD, providing more clarity and enforceability: it obliges the countries that are party to it to establish internal regulations on how access to their genetic resources is permitted and how the benefits derived from them should be shared, thus creating more homogeneous conditions at the international level.

3. Initially, the Nagoya Protocol was interpreted as **transferring the general principle of the CBD (Article 15, on access)** to specific obligations with respect to provider countries and potential users.

4. **Strengthening compliance** with ABS regulations is an important contribution of the Nagoya Protocol. It obliges the Parties to take legal, administrative or political measures to ensure that, within their jurisdiction, the genetic resources used have been accessed in accordance with the laws of the country of origin. Thus, among other things, Nagoya requires the establishment of ***'checkpoints'*** along the research and development chain — for example, offices that provide scientific funding, patent offices, or customs authorities — to verify that those who use genetic resources have the documentation that demonstrates legal access (for example, an international certificate of compliance issued by the provider country). In the European Union, this reinforcement of compliance was materialised through **Regulation (EU) 511/2014**[53], which imposes the obligation to exercise **due diligence** on users of genetic resources (for example, researchers or companies within the EU). This means that they must ensure that they have the consents and benefit-sharing agreements required by the country of origin of the resources they use, and they must declare such compliance to the competent authorities; otherwise, they expose themselves to sanctions.

5. The Protocol also establishes that each provider country must have **procedures for access** to its genetic resources — normally requiring the prior informed consent of the State and/or the local communities involved — and must establish **conditions for the sharing of benefits** through terms mutually agreed between the provider and the user.

6. Practically speaking, one key difference between this Protocol and the provisions of the ITPGRFA lies in **the treatment of traditional knowledge and the participation of indigenous and local communities**. Both legal texts recognize a right to equitable participation, but it should be emphasized that while the ITPGRFA essentially leaves the management of this participation to States (without specifying how), the Nagoya Protocol explicitly encourages obtaining prior informed consent from indigenous and local communities for access to their traditional knowledge. It also promotes the creation of protocols that define rules for interaction with users, tailored to the practices and expectations of each community, and respectful of their culture.

7. Although it is not a legally binding text and does not strictly belong to the acquis of the CBD, these provisions are considered to reflect the United Nations Declaration on the Rights of Indigenous Peoples (2007). This Declaration recognises, among other, the right of these peoples to maintain, control, protect and develop their cultural heritage and their traditional knowledge and practices, which include the plants and seeds they have preserved and the knowledge associated with them (Art. 31).

II.3. ABS regimes affecting PGR: a challenge for the pan-European research infrastructure

[53] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol. https://eur-lex.europa.eu/eli/reg/2014/511/oj/eng

II.3.1. The assumptions linked to the concept of ABS and the challenges for their materialisation

1. As indicated in III.2.1, the CBD was articulated as a legally binding international treaty with three fundamental objectives: (1) the conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits arising from the utilisation of genetic resources. In view of the literal wording of the text, **the objective of fair and equitable sharing is not presented strictly in the CBD as a distribution of specific benefits obtained by providers in return for allowing access**. Article 15, which refers to bilateral access agreements and establishes a series of guidelines for carrying out the MTA (including references to financial dimensions), does not strictly identify participation or benefit sharing as a specific action of sharing with the provider the precise benefits that a user has obtained from the access and use of a PGR.

2. The truth is, however, that in the negotiations of the States party to the implementation of the CBD, 'access and equitable sharing of benefits', identified by the acronym ABS, were progressively formulated as interrelated components that are difficult to separate. Moreover, in the literature and in the narratives coming out of some regions of the world, ABS has come to be seen as a promise[54] sustained on three pillars (national sovereignty, development purposes, environmental goals). Note, however, that these types of interpretations go beyond the terms agreed by the parties and venture into interpretations based on something the CBD ought to have said[55]. Summarising the whole concept of equity in a single definition seems impossible[56], although the idea or commitment it evokes when used in international agreements is interpreted as meaning justice between the different parties to an agreement or process. But at the international level it is possible to adopt the reference developed by the International Court of Justice of the United Nations (ICJ) has addressed its use in disputes over cultural heritage or environmental law, investment arbitrations or cross-border disputes, but the most prominent role of equity has been in disputes over the definition of marine boundaries.

4. Although not explicitly stated, it has been assumed in the context of the CBD that this idea of equity is transactional in nature. For example, the infographics produced by the CBD Secretariat to explain the concept of ABS present it as an agreement between two parties shaking hands, one of them as the provider and the other, the user, as the party that shares the benefits. From this narrative it is clear that the ABS principle has a transactional nature (as an exercise in exchange or commutative justice[57]), and not as a mechanism of distributive justice[58].

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[54] Tsioumani, E. (2017) "Beyond Access and Benefit-Sharing: Lessons from the Law and Governance of Agricultural Biodiversity" by Elsa Tsioumani, published in the Journal of World Intellectual Property in 2017.

[55] L. Parks, E. Tsioumani Transforming biodiversity governance? Indigenous peoples' contributions to the Convention on Biological Diversity, *Biol. Conserv*., 280 (2023), Article 109933, 10.1016/j.biocon.2023.109933

[56] Titi, C, The Function of Equity in International Law (OUP 2021) 18.

[57] B Dauda and K Dierickx, 'Benefit Sharing: An Exploration on the Contextual Discourse of a Changing Concept' (2013) 14 BMCMedEthics 36, 36. See also P Andanda et al, 'Legal Frameworks for Benefit Sharing: From Biodiversity to Human Genomics' in D Schroeder and J Cook Lucas (eds), Benefit Sharing (Springer 2013).

[58] Hampton A-R, Eccleston-Turner M, Rourke M, Switzer S. 'EQUITY' IN THE PANDEMIC TREATY: THE FALSE HOPE OF 'ACCESS AND BENEFIT-SHARING.' International and Comparative Law Quarterly. 2023;72(4):909-943. doi:10.1017/S0020589323000350

5. This inspiration seems consistent with the fact that States are recognised as having sovereignty over their resources, something that invites us to think of a transactional connotation, close to the market. However, it does not harmonise well with the claim to distributive justice that both the UNCED Declaration and the CBD seem to aspire to: that all human beings, that is, whether they are providers or not, participate in these benefits.

6. The concept of ABS and this transactional allusion, close to buying and selling, are so ingrained in the current perception of the CBD that it no longer seems possible to separate one objective from the other, accepting, for example, that the distribution of benefits is not strictly dependent on the provision of access[59] or that a tangible benefit to be shared is not obtained in all cases, as may be the case in which the result of the use of a PGR translates into a contribution to scientific knowledge[60].

7. This transactional characterisation is ascribed to the fact that it was created at a time, in the late 1980s, when the belief that market-based solutions could solve global problems was widespread[61]. Recognising sovereign rights over genetic resources and proposing ABS as the result of a bilateral contractual agreement between the provider country and the recipient user implied that bilateral contracts would generate sufficient tangible benefits (whatever their nature) to incentivise potential providers to conserve their resources and guarantee access to potential users[62]. What's more, in a way, although it does not fit in well with the idea of a transactional mechanism, a certain hope was generated that beyond the exchange, space would be opened up for a kind of distributive justice or solidarity at a global level.

8. However, the passage of time has revealed that the bilateral ABS contractual mechanism provided for in Article 15 of the CBD, partly due to the lack of tangible benefits[63], is not suitable for mobilising PGR. Among the difficulties in specifying the real benefit attributable to access to a PGR is the fact that plant breeding processes take a long time, making it difficult to trace and value the original contributions[64].

9. Without fully overcoming this last limitation, **the parties to the ITPGRFA opted for a different model to that of bilateral agreements**: the creation of a multilateral system (MLS) containing, on the one hand, a pool of PGR shared among the parties under common MTA terms; and, on the other hand, a Benefit Sharing Fund, administered by the Governing Body of the Treaty, which

[59] Morgera, E, Tsioumani, E and Buck, M, 'Introduction' in Morgera, E, Tsioumani, E and Buck, M, Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity (Brill, Nijhoff 2014)

[60] Morgera, 'Fair and Equitable Benefit-Sharing at the Cross-Roads of the Human Right to Science and International Biodiversity Law' (2015) 4 Laws 803; E Morgera, 'Fair and Equitable Benefit-Sharing in a New International Instrument on Marine Biodiversity: A Principled Approach towards Partnership Building?' (2018) 5 MarSafetySecLJ 48

[61] H Mayrand, 'From Classical Liberalism to Neoliberalism: Explaining the Contradictions in the International Environmental Law Project' (2020) 50 RGDIP 57; C Corson and KI MacDonald, 'Enclosing the Global Commons: The Convention on Biological Diversity and Green Grabbing' (2012) 39(2) JPeasantStud 263.

[62] K Fuentes-George, 'Neoliberalism, Environmental Justice, and the Convention on Biological Diversity: How Problematizing the Commodification of Nature Affects Regime Effectiveness' (2013) 13 GlobEnvironPolit 144.

[63] S Laird and R Wynberg, Connecting the Dots… Biodiversity Conservation, Sustainable Use and Access and Benefit Sharing (BioInnovation Africa 2021) <https://bio-economy.org.za/wp-content/uploads/2021/08/Laird-and-Wynberg-2021-Connecting-the-Dots.pdf>.

[64] NordGen (2023). Access and Rights to Genetic Resources: A Nordic Approach (II). Accessed at: https://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1744186&dswid=-4121

finances conservation and agricultural development projects in developing countries. It should be emphasised that universal access for the States party is encouraged and, although ABS continues to be presented as a kind of transaction between those who provide and those who share benefits in return[65], it promotes an equity that is more akin to distributive justice (giving more to those who have less) than to transactional equity (or equilibrium in the quid pro quo). Some details of this multilateral system (MLS) are addressed in III.3.2.

10. The Nagoya Protocol, for its part, in line with the provisions of Article 15 of the CBD, in principle keeps the path of bilateral agreements open, although the conferences of the parties have been working towards a MLS.

II.3.2. Bilateral and multilateral ABS systems

1. In the comparative presentation of, on the one hand, the bilateral agreements promoted in application of Article 15 of the CBD and, on the other, the MLS model included in the ITPGRFA, **reference is often made to two alternative ABS models**. The bilateral model is simple to explain, given that in each specific case the provider and user negotiate the terms of the MTA. The novelty, with respect to the bilateral scheme, is the proposal included in the ITPGRFA which, despite being presented as part of the acquis of the CBD, acquires (or aims to acquire) a character more of distributive justice than of transactional justice.

2. Although it is an agreement that belongs to and is in harmony with the acquis of the CBD, the ITPGRFA emerged as a multilateral response to promote the conservation of and shared access to the seeds that are key to the world's food supply. Its central objectives are the conservation and sustainable use of crop diversity and the fair and equitable sharing of the benefits arising from its use, all with a view to achieving food security and sustainable agriculture. It did not, therefore, seem consistent to rely on bilateral agreements to achieve access and the fair and equitable sharing of benefits.

3. It should be borne in mind that **it is the States parties of the ITPGRFA (and not specific user entities, e.g. companies) that are legally bound by the MLS**. Therefore, it does not seem that the MLS can offer the transactional justice that some States Parties expect and, understandably, it is perceived negatively by those parties. In reality, MLS models, without expressly formulating it, try to recover a broader idea, close to distributive justice, although they continue to present themselves as congruent with the same idea of ABS as bilateral agreements.

4. As a result, a Multilateral System of Access and Benefit Sharing was established, whereby 64 essential crops (listed in the Annex I of the ITPGRFA) are placed in a global pool that is freely accessible for food and agricultural purposes. The way it is expected to work is as follows. On the one hand, the member countries provide samples of these seeds to researchers, plant breeders or farmers in other countries under a standard agreement (SMTA) that guarantees facilitated access. On the other hand, there is a Benefit Sharing Fund that is sustained by voluntary contributions and, if applicable, by payments that users who develop commercial

[65] Winands-Kalkuhl and K Holm-Müller, 'Bilateral vs. Multilateral? On the Economics and Politics of a Global Mechanism for Genetic Resource Use' (2015) 7 JNatResourcesPolRes 305; Muller, M Ruiz, Genetic Resources as Natural Information: Implications for the Convention on Biological Diversity and Nagoya Protocol (1st edn, Routledge 2015); S Laird et al, 'Rethink the Expansion of Access and Benefit Sharing' (2020) 367(6483) Science 1200.

products must make to the fund. 5. Regarding user payments, the forecast is as follows. If the recipient develops a commercial product using a resource obtained through the MLS**, and** that product cannot be obtained freely (that is, it is not available without restrictions for further research and improvement by third parties, for example, due to intellectual property protection), then the user must make a **payment obligation** — a fixed proportion of their sales — to an international common fund. By contrast, if the derivative product **does remain** available for new research and improvement work (i.e. it is not completely privatised), payment to the fund is voluntary.

5. Besides monetary contributions, the ITPGRFA emphasises the importance of **non-monetary benefits**, which include the exchange of scientific information, access to and transfer of relevant technologies, capacity building (training, research networks) in the field of plant genetic resources, among others. All these forms of cooperation contribute to a sharing of benefits beyond money, strengthening the capacities of the countries and communities that contribute germplasm.

6. By these means, the ITPGRFA attempts to balance open access with intellectual property: research and free improvement with shared materials is permitted, but if a patented or protected variety is generated that cannot return to the free pool, then compensation is required. However, as has already been pointed out elsewhere, it is prohibited to patent PGR, parts of these or their genetic material in the form in which they were received through the system

7. Maybe because of the transactional perception referred to above, the specialised mechanism of the ITPGRFA has not generated a perception of benefit that encourages participation in them[66], while at the same time resulting in high costs[67]. In the case of the ITPGRFA, in 2019 an agreement was almost reached on a possible subscription system, which would bind parties to payment obligations and users to the payment of fees to access all or part of the resources, but it was not achieved[68]. For the time being, transactional inspiration is still somehow present in the expectations of some parties.

8. A different case is that of the WHO Pandemic Influenza Preparedness Framework (PIP)[69], also a specialised convention of the CBD acquis, in which ABS has not been established in such transactional terms. The objective of the PIP Framework is to create a '*fair, transparent, equitable, efficient and effective system*' for sharing influenza viruses with human pandemic potential, and '*access to vaccines and the distribution of other benefits'*. It is basically a system

[66] M Walløe Tvedt, 'A Contract-law Analyses of the SMTA of the Plant Treaty: Can It Work as a Binding Contract?' (2021) 24 JWIP 83, 84: 'As yet, the [Plant Treaty's Multilateral] Fund has not received substantial payments through the mandatory "benefit-sharing" provisions of the [Plant] Treaty.' See also E Tsioumani, Fair and Equitable Benefit-Sharing in Agriculture: Reinventing Agrarian Justice (Routledge 2021).

[67] S Laird et al, 'Rethink the Expansion of Access and Benefit Sharing' (2020) 367(6483) Science 1200.

[68] NordGen (2023). Access and Rights to Genetic Resources: A Nordic Approach (II). Accessed at: https://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1744186&dswid=-4121

[69] Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, WHO, 2023. El documento describe tres opciones de benefit sharing, categorías A, B, C muy detalladas en relación con las vacunas y antivirales, los productos de diagnóstico y las contribuciones a la academia e institutos de investigación.

in which potential accessors contribute through an annual payment, a subscription, and is therefore closer to associative participation in a common purpose[70], than to quid pro quo. The contributions of all parties, whether they be access to GR (through the exchange of pathogens) or the sharing of the products obtained (percentages of pharmaceutical products distributed to disadvantaged countries), are all presented as contributions to the common goal: public health.

II.3.3. Linkages emerging between DSI and ABS models

1. The CBD does not explicitly mention digital sequence information (DSI), but the term 'genetic resources' has been considered to leave some ambiguity as to whether or not genetic sequence data is covered.

2. Much of the concern about the application of the PGR regulatory framework to DSI is due to the fact that there are some publicly accessible databases in which, without accessing the physical samples or obtaining permission from the countries from which they originate, it is possible to obtain information on the sequences, thus creating a loophole in the traditional ABS regimes. It is estimated that advances in genetic synthesis will significantly reduce, or even eliminate, the need to access physical samples[71].

3. Both at various meetings of the governing body of the ITPGRFA and at the CBD COPs, **there has been intense debate as to whether access to DSI**, even in the case of public access formats, should be subject to the obligations imposed by the CBD, including access and benefit sharing (ABS).

4. While discussions are ongoing in the governing bodies of the ITPGRFA and the CBD, two international agreements considered specialised ABS conventions in the sense of Article 4 of the Nagoya Protocol, have explicitly advanced in the sense of understanding that the ISD should be considered part of genetic resources. One of the agreements is the United Nations Convention on the Use of Marine Diversity beyond national jurisdiction (BBNJ, 2023)[72], which includes provisions on the distribution of benefits from marine genetic resources collected on the high seas. The other scenario is that of the WHO PIP Framework. In the context of a new Pandemic Treaty that is being negotiated, the WHO is explicitly discussing the DSI of pathogens, with the aim of ensuring that, if countries share genomic data of outbreak strains, they also share benefits such as vaccines.

5. **Regarding the DSI of PGR, the work at the Nagoya Protocol forum has been somewhat faster than the governing body of the ITPGRFA**. The governing bodies of the CBD have been discussing

[70] Sedyaningsih, E et al, 'Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia' (2008) 37 Ann Acad Med Singap 482Google Scholar; M Rourke, 'Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark it Left on the World' in M Eccleston-Turner and I Brassington (eds), Infectious Diseases in the New Millennium, vol 82 (Springer International Publishing 2020).

[71] A Hampton, 'Pathogen Dematerialization and the ABS Loophole' (2023) 10 JLB lsad002.

[72] The Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ Agreement) was adopted on 19 June 2023 by the Intergovernmental Conference on Marine Biodiversity of Areas Beyond National Jurisdiction convened under the auspices of the United Nations. The BBNJ Agreement becomes the third implementing agreement to the United Nations Convention on the Law of the Sea.

this issue since 2016. At CBD COP14 (2018) and COP15 (2022), a consensus was reached that some form of solution for IDS was necessary, but opinions differed on the form it should take. During 2022, the CBD COP15 took a significant step forward by agreeing to 'establish a multilateral mechanism for the distribution of benefits arising from the use of DSI'. The parties also agreed on a set of guiding criteria for any DSI solution: it must be practical, not excessively costly, must not impede research, should provide legal clarity, and must be compatible with open access to data.

6. **Between 2022 and 2024, several proposals for generating income from the access to DSI were put forward**, from subscriptions or fees for the use of databases to taxes on the sale of products or patents involving DSI. The post-2020 Kunming-Montreal Global Biodiversity Framework of the CBD explicitly includes access to DSI as an element that must be reflected with regard to the fair sharing of benefits, as a means of combatting the loss of diversity[73].

7. Disagreements remained, however, among the parties to the CBD as to whether a different ABS mechanism should (or should not) be generated with regard to DSI[74] and physical resources. Given that there is no transfer of material, a multilateral system with fewer elements would be possible, consisting even of mechanisms such as payment of a fee, although provider countries have been expressing concern that separating DSI from physical resources could mean that the DSI system would be based on less sound obligations[75]. Consequently, some countries have adopted national regulations in which DSI, sometimes referred to as 'intangible genetic resources', is considered part of the ABS system[76]. For the time being, the way in which the EU and some countries that have signed up to the Nagoya Protocol (such as Canada and Australia) implement this regulation only covers the physical extraction of genetic resources.

8. On this matter, in 2022 the Conference of the Parties (COP 15) agreed that 'the distribution of digital information on sequences of genetic resources and the distinctive practices in their use require a distinctive solution for the distribution of benefits'[77]. Notwithstanding, the 'deposit of more digital sequence information on genetic resources, with appropriate information on geographical origin and other relevant metadata, in public databases' is encouraged[78]. It was also recognised that '*the monitoring and tracking of all digital sequence information on genetic resources is not practical*'[79]. Consequently, COP15 agreed to establish 'a multilateral mechanism

[73] Decision 15/4 from the 15th meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD). You can also use the formal title, "Kunming-Montreal Global Biodiversity Framework" followed by the year of adoption (2022).

[74] Charles Lawson, Fran Humphries, Michelle Rourke, Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources, Journal of Intellectual Property Law & Practice, Volume 19, Issue 4, April 2024, Pages 337–357, https://doi.org/10.1093/jiplp/jpad129

[75] G. Qin, H. Yu, C. Wu Global governance for digital sequence information on genetic resources: demand, progress and reforming paths. Global Pol., 14 (2023), pp. 403-415, 10.1111/1758-5899.13202; R. Nehring
Digitising biopiracy? The global governance of plant genetic resources in the age of digital sequencing information Third World Q., 43 (2022), pp. 1970-1987, 10.1080/01436597.2022.2079489

[76] Countries such as Namibia, Bhutan and Malaysia have legislation in this regard, as well as Brazil (since 2015 it extends ABS obligations to digital information about sequences of Brazilian origin), India and South Africa. Vid. Margo A. Bagley et al., Fact-Finding Study on DSI in Domestic Measures (CBD Study 4, 2020) .

[77] UN Convention on Biological Diversity, 'Digital Sequence Information on Genetic Resources' (18 December 2022) UN Doc CBD/COP/15/L.30, para 3.

[78] UN Convention on Biological Diversity, 'Digital Sequence Information on Genetic Resources', para 4.

[79] UN Convention on Biological Diversity, 'Digital Sequence Information on Genetic Resources', para 5.

for the distribution of benefits arising from the use of digital sequence information on genetic resources', a mechanism that would include a global fund[80].

9. Attention should be drawn to the fact that the schemes based on subscriptions, taxes, levies, etc. that feed a multilateral fund are no longer consistent with the transactional idea, but rather move towards a principle of distributive justice or, according to some, a kind of system to which different actors associate in good faith. In any case, it is still key that there is no mechanism to oblige private parties to participate in ABS systems.

10. During the 2024 CBD COP 16 in Cali (Colombia) [81], the decision was made to create the '*Cali Fund for the fair and equitable sharing of benefits arising from the use of DSI on genetic resources*'. The fund is expected to be financed by contributions from DSI users, particularly large commercial actors. So as to provide legal security to the companies involved, it was proposed that a certificate be issued according to whether a company contributes as required, it will be 'considered to have shared the benefits in a fair and equitable manner' for their use of DSI, and will not be subject to further claims, not even national ones (avoiding the double penalty of also facing bilateral claims). Non-commercial users (e.g. academic institutions, public research organisations and others who use DSI but do not benefit directly) will, in principle, be exempt from mandatory contributions, applying the principle of not creating obstacles to research.

11. Just as with the ITPGRFA Fund, the resources of the Cali Fund are expected to be used in developing countries, either in biodiversity conservation programmes (directly or through training, technology transfer, etc.), or through programmes to support indigenous peoples and local communities.

12. There are still many aspects of the Cali Fund that have yet to be finalised in order to become a reality. These include, among other points to be specified, the methods of calculating fees, the way of differentiating between small and large companies, the collection mechanisms and the way of linking companies from countries that are not party to the Nagoya Protocol (such as US companies) to this fund.

13. Last but not least, there is one fact that should not be overlooked. Even if the Cali Fund is activated, as is the case with the ITPGRFA, it cannot be ruled out that many potential provider states will also prefer, with regard to access to DSI under their sovereignty, models of agreement that guarantee them a sufficient economic return.

II.4. PGR and rules on the protection of plant innovations in the EU

1. As noted above, new techniques of genetic improvement are leading to the questioning of the intellectual property protection regimes that have been applied to plants (whether patents

[80] UN Convention on Biological Diversity, 'Digital Sequence Information on Genetic Resources', para 16.
[81] COP16 Decision 16/2, "Cali Fund for DSI Benefit-Sharing" (2024); David R. Curry, *COP16 DSI Mechanism Summary* (2025).

or the plant variety system). Given that conventional breeding processes are relatively long and economically costly, the aim is to accelerate improvement by combining desirable traits or events in a single variety, with the aim of promoting rapid developments in the market in a short period of time. Such stacking of traits from multiple sources can cause tensions between different systems (plant breeders' rights, patents, rights over traditional varieties) and there is concern about the uncertainty of not knowing which rules would prevail in each case.

2. At the present, the protection of plant varieties in the EU is mainly implemented through **plant breeders' rights** (UPOV Convention).

3. For its part, European patent law **explicitly excludes plant varieties from patentability**. Both the European Patent Convention (art. 53(b) EPC) and EU Directive 98/44/EC (on biotechnological inventions)[82] stipulate that plant varieties and essentially biological processes for the production of plants are not patentable. Note that this means that it is not possible to obtain a patent covering an individual plant variety (variety protection is channelled via the aforementioned breeder's rights). However, Directive 98/44/EC itself clarifies that biotechnological inventions relating to plants can be patented when the technical feasibility of the invention is not limited to a specific plant variety.

4. Regarding plant breeders' rights, at the community level there is a unified system, established by Regulation (EC) No. 2100/94[83], which creates the Community Plant Variety Rights as the sole and exclusive form of industrial property protection for plant varieties within the EU. In other words, a single application to the Community Plant Variety Office (CPVO) can be used to obtain a breeder's certificate valid in all Member States. To obtain this protection, the variety must meet the classic criteria of being new, distinct, uniform and stable (DUS – Distinct, Uniform, Stable – in addition to commercial novelty). Once granted, the breeder's right confers on the holder the exclusive right to authorise the production or reproduction, the sale, the commercialisation, the export, the import and the storage for these purposes of the reproductive material of the protected variety. The duration of the protection is 25 years for most species, and extends to 30 years in the case of varieties of woody plants. After that time, the variety passes into the public domain. It should be noted that community protection coexists with national plant variety rights systems (several EU countries have their own national breeders' rights); however, the community title offers uniform coverage throughout the Union and facilitates management at the multinational level.

5. Plant variety rights balance the exclusive rights of the breeder with certain **exceptions in the public interest**. In particular, Regulation 2100/94 recognises the so-called **breeder's exemption** (*breeder's exemption*), whereby a protected variety may be freely used for the **obtaining of new varieties**. Consistent with international rules (UPOV Act of 1991), this regulation guarantees **free access to germplasm** for plant breeding purposes, thus fostering innovation: any breeder can use an existing protected variety to create a new one (and eventually obtain a new right over the latter) without the need for permission from the original owner. In addition, another important exception is the **farmer's privilege** (*farmer's privilege*), which authorises **farmers** to reuse part of the harvest obtained from a protected variety on their

[82] See: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[83] See: https://eur-lex.europa.eu/eli/reg/1994/2100/oj/eng

own farm in order to use it as seed for the next sowing (i.e. to use *farmer's seed*). Such use is subject to certain **restrictions on** use – for example, it only applies to certain crops (generally *self-pollinating* crops such as cereals, legumes, potatoes, etc., excluding horticultural crops) and may require the payment of a reduced remuneration to the breeder, with the exception of small farmers. Through these safeguards, the legislation seeks to **encourage plant breeding** while taking into account considerations of genetic diversity and traditional agricultural practices.

6. Discussions are taking place on the future of plant innovation protection mechanisms, both in the management bodies of the UPOV convention and in the EU in relation to the European Directive on Biotechnological Innovations (following the exception to patentability that the European Parliament has proposed to include in the proposed regulation on genome-edited plants). It has also been mentioned that at the WIPO headquarters some countries have promoted a treaty (2024) that more adequately balances the provisions contained, on the one hand, in the CBD acquis and, on the other, in the TRIPS. The EU has participated in the negotiations, but, for the moment, it is not among the signatories of the treaty.

7. It is an issue to which it is undoubtedly advisable to pay attention.

III.- Block 2 of results: Challenges, needs and opportunities to be taken into account in the transition of the PGR system towards a pan-European infrastructure. Stakeholders' perception of the ESR context as expressed in in-depth interviews.

III.1. General considerations expressed by the people interviewed

The objective of the exploratory dialogues and in-depth interviews (see I.3.2 on the methodology used), together with documentary evidence and attention to the forums that the interviewees recommended we access, was to gain a more detailed understanding, beyond the literal meaning of the legal texts, of how the barriers and bottlenecks of the regulatory frameworks are addressed in the activity of different actors, as well as the gaps, both with respect to their main activity and, especially, with regard to project proposals/work that goes beyond that comfort zone. The ultimate goal was to obtain a complete overview of the challenges, needs and opportunities that the construction of a pan-European PGR infrastructure has in terms of ESR.

1. Awareness and means of dealing with the difficulties associated with PGR's ESR. The perception of regulatory complexity with respect to the global panorama is high, especially with regard to PGR that have been under national sovereignty since 1992. Access through bilateral agreements is seen as highly complex, the resources (mostly wild, but also PGRFA excluded from the ITPGRFA because they are not in the Annex I or are not from signatory countries) under the Nagoya Protocol are in a situation pending clarification and in the case of the resources covered by the ITPGRFA, the shared pool is pending an increase.

- In the case of the most highly organised actors, such as national gene banks, the decision has been made to organise standardised MTAs (in some cases following the model proposed by the ITPGRFA) to transfer the resources they hold with legal certainty[84].
- It is perceived, however, that some other actors, including some of them custodians of valuable materials in the EU or users (both researchers and especially farmers), do not have sufficient technical or organisational means and/or capacities to deal with the complex regulatory framework. They focus their activity on safe activities.

A pan-European infrastructure may help all the actors to know how far they can go in accordance with the current regulatory framework, and establish mediation mechanisms for those resources for which access requires a more complex legal-administrative process.

2. **Particular difficulty in aggregating new material.** From the ESR point of view, the legal situation regarding conservation and storage is more defined than the possibility of aggregating new materials or of using them in ways that go beyond storage or basic research on the conserved materials. However, with a view to planning a pan-European structure, the perception of the following challenges was very high among all the people interviewed**:**

- Regulations are imprecise, fragmented and also in the process of evolution. Rather than activating projects that may involve plant breeding efforts without legal certainty, this encourages more waiting (with no specific date).

- Until certain elements of ABS or the interconnection of DSI with ABS are clarified, Exchange of PGR and collaborative activities with plant breeders presents many difficulties.

3. Throughout the interviews there has been insistent mention of the good practices of those germplasm banks in the PRO-GRACE ecosystem that have established a policy of access to PGR, standardized MTAs and mechanisms for compliance with ethical and legal aspects. In some cases, the information is contained on each genebank's website. Particular importance is given to the prevention of the aggregation of resources without a clear legal status or without a consistent possibility of traceability, with a view to compliance with EU Regulation 511/2014 by banks and the users who access them.

4. On several occasions, in relation to the ESR and their management in Europe, the NordGen model[85] and the effort made by the participating countries in the maintenance and evolution of the infrastructure has been highlighted[86]. With regard to the ESR, the work carried out in the successive versions of the explanatory documents on access to the resources and the rights involved[87] is very useful. It deals with the legal status of Nordic genetic resources and how the

[84] Note: ECPGR is promoting the use of SMITA for all European Collection material (including PGR out of Annex I of TIRFAA), though only EU germplasm bank interviewees referred to that initiative.
[85] The Nordic Genetic Resource Center (NordGen) serves the Nordic countries of Denmark, Finland, Iceland, Norway, and Sweden.
[86] NordGen (2023). Access and Rights to Genetic Resources: A Nordic Approach (II). Accessed at: https://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1744186&dswid=-4121
[87] "Access and Rights to Genetic Resources – A Nordic Approach (2023 updated version), in light of the developments that have taken place within the international framework since the adoption of the 2003 Nordic Ministerial Declaration on Access and Rights to Genetic Resources (Kalmar Declaration, 2003) and the subsequent 2013 Declaration. These

benefits derived from their use will be distributed. NordGen has opted, and explains why, for a system aimed at public domain access for all PGRFA (not only those included in the ITPGRFA), and recommendations have been proposed on the legal status of wild genetic resources, including those of the sea.

5. Concern about legal uncertainty that affects some actors more than others (small and medium-sized plant breeders, and farmers who wish to participate in conservation and plant breeding). It is perceived that the ESR framework and its fragmentation make it difficult for certain actors to operate with legal certainty regarding the use of certain PGR. It should be remembered that the EU recognises the fundamental right to good administration (art. 41 CDFUE) and the principle of legal certainty, which is a guarantee that emanates from the rule of law set out in art. 2 TEU (Treaty of the European Union), which, among other things, implies that the rules must be clear and predictable, so that citizens and businesses know what their rights and obligations are, allowing them to act accordingly[88].

6. **Access to germplasm from non-European countries,** with the exception of the channels offered by the CGIAR international centres or the resources of the ITPGRFA pool, is perceived as practically impossible for most stakeholders. This is the case even in the case of supplier countries that have organised an administrative model to manage exploration agreements and subsequent MTAs. The practical application of these administrative systems tends to be inefficient, due to bureaucratic difficulties, silences, excessive deadlines, lack of guarantees or the impossibility of dealing with the terms in which possible bilateral ABS agreements are propose.

A pan-European infrastructure, especially with the recognition of international organisation that gives it ERIC infrastructure status, has a position from which it can explore support or even a certain involvement as a structure in obtaining materials not included in the MLS.

7. Proof of compliance with the regulatory framework. Institutions that safeguard plant genetic resources (germplasm banks, botanical gardens, research centres and on-farm) shall apply *in situ* and *ex situ* conservation techniques in accordance with scientific and ethical standards, **as well as the corresponding regulatory requirements**. In order to translate principles and standards into concrete actions, best practices and guidelines for ethical compliance in the conservation, use and access to plant genetic resources have been developed. These practices ensure that researchers, gene banks, companies and governments act responsibly.

> On this matter, it has been a recurring theme that a pan-European infrastructure for PGR can serve as a support in the execution and accreditation/certification of the following activities:
> - Quality and phytosanitary compliance.
> - Transparency in operations with PGR and monitoring to ensure compliance with any restrictions that may have been agreed with suppliers (in ABS) or that are imposed by applicable ABS regulations (ITPGRFA, NP).

developments include the implementation experience of the ITPGRFA, the adoption of the Nagoya Protocol, and the emergence of new issues such as the digitalisation of genetic information.

[88] Paunio E. Beyond Predictability – Reflections on Legal Certainty and the Discourse Theory of Law in the EU Legal Order. German Law Journal. 2009;10(11):1469-1493. doi:10.1017/S2071832200018332-

- Training of personnel on ABS requirements
- Adoption of codes of conduct and good practices.

III.2. Perception of the ethical-legal aspects relating to the activities of OBTAINING and CONSERVATION of PGR, both through formal systems and in the case of seed systems managed by farmers.

The signatory countries of the CBD are committed to conserving these resources both in situ and ex situ (through germplasm banks, seed collections and other means), and to promoting the sustainable use of agrobiodiversity in which conservation is integrated with agriculture. In other words, supporting practices such as participatory plant breeding, the maintenance of traditional crops and diversification, so that the use of genetic resources does not undermine its own long-term basis. This approach reflects Article 1 of the Convention on Biological Diversity, which emphasizes not only the conservation of biological diversity but also the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of genetic resources—highlighting that access and availability are as crucial as conservation itself. Connected to this, **the Kunming-Montreal Global Biodiversity Framework**, adopted at COP15 in December 2022 (see above, note 73), establishes a vision for 2050 and specific objectives for 2030, aiming to halt and reverse biodiversity loss. Its Goal 4, closely related to the CBD, focuses on the sustainable management of natural resources, including the legal, sustainable, and safe exploitation of wild species and the promotion of biodiversity conservation and sustainable use in sectors such as agriculture, forestry, and fishing.

1. The driver of conservation actions is to ensure the greatest possible level of conservation (whether *in situ* or *ex situ*), and in the case of *ex situ*, within parameters of quality and good practice that guarantee adequate conservation. Beyond being considered an 'international obligation', conservation is subject to very little explicit international regulation. Compliance with it rests with each sovereign state and, within it, on the existence or not of specific conservation activities or infrastructures that house valuable material, as well as on the resources available to each of these infrastructures (equipment, support databases, etc.). Things are the same in the EU. Each country deals with this issue independently, either through specific national regulations - especially with regard to wildlife - or through political strategies or programmes.

2. A European effort to achieve a minimum level of harmonisation of these strategies is seen as something distant. In some interviews in particular, the interviewees were asked whether they thought this might be due to the intersectionality that we have noted in the PGR (see above, III.2.1 para.9), that is, to the fact that they combine competences on biodiversity, agriculture and seed markets, distributed in a complex way even within each Member State. Instead of focusing on the dispersion of competences in a static sense, **responses have pointed to the discrepancy between,** on the one hand, the interest shown by the EU in the Green Deal, the Biodiversity Strategy and other documents, and, on the other hand, the work undertaken in the EU to ensure that Member States fulfil their commitments to facilitate access to their PGR to other Member States.

3. **The need for a coherent European legal framework, at least for EU stakeholders**. European countries have established national programmes for the management of their PGR and there is a cooperative ECPGR programme to coordinate conservation initiatives, although several

interviewees recall, as stated in the document Plant Genetic Resources Strategy for Europe (2021) that political support for conservation is weak and uneven and that the EU lacks a governance framework to reinforce conservation activities and, especially, to guarantee and facilitate sustainable access and use of resources. Even though the EU has a group of highly qualified and recognised actors and stakeholders in the use of PGR, the governance framework on conservation and use is limiting. It is necessary to review the governance framework (political and legislative elements of the EU with respect to PGR) and move towards a coherent legal framework within the EU, despite the limitations that may arise with third countries.

4. Occasionally, the issue of the role that seed systems (in their different forms) should be given in the EU has arisen. It has not been a recurring theme. In percentage terms compared to other countries, the US farmer-managed seed systems (FMSS) are in an inferior situation with respect to formal systems. Globally, FMSS account for an average of 70% of seed use and are widely recognised for their contribution to biodiversity protection and, crucially, to food security. In the EU context, however, these systems are perceived primarily through the lens of biodiversity conservation. Several factors contribute to this limited recognition, including the Common Agricultural Policy and its provisions, the prevailing PRM commercialisation model, and the lack of dedicated European programmes to support FMSS. As a result, these actors face barriers to professional collaboration in the characterisation and conservation of plant genetic resources, except in the context of specific multi-actor research projects.

A pan-European infrastructure can make a decisive contribution to improving the position of farmers in variety conservation in the EU, not only offering technical services (see D5.4 and D.5.5 of this project), but also generating a stable bridge of communication between farmers and germplasm banks, helping farmers to find out who to contact and how, or what kind of support they can receive to collaborate in the characterisation and conservation of PGR in the EU.

III.3. Perception of the ethical-legal aspects of ACCESS to PGR and equitable benefit sharing (ABS)

1. Access to PGR, especially for the purposes of research, development and/or commercialisation, is the area that currently poses the greatest difficulties. Those interviewed not only insist on this, but also refer to published peer-reviewed works or institutional documents in which this circumstance is emphasised (e.g. the ones issued by ECPGR and NordGen, as well as the Secretariats of the CBD and the ITPGRFA, as well as papers and papers that were incorporated into the desk-based research).

A convergence of opinion has been observed on the following: (1) the paradigm shift that occurred after the entry into force of the CBD was a turning point; (2) and that this paradigm, especially with regard to ABS, is not easily articulated.

With regard to ex situ access, a pan-European infrastructure for plant genetic resources (PGR)—particularly in its close connection with the FAO system and the CGIAR centres—may contribute, among other things, to identifying and strengthening the common interests of EU Member States, both among themselves and in their collaboration with other countries worldwide. This applies particularly in matters concerning the conservation, access, and

sustainable use of biodiversity, as well as in the development and implementation of access and benefit-sharing (ABS) strategies.

2. Difficulty of access also extends to resources outside genebanks in MS, both *ex situ* (hosted in other types of institutions) and especially in situ.

As far as the EU is concerned 80% of the respondents active in the EU confirmed that currently access to EU country resources is necessarily on a country-by-country basis, where appropriate through ministerial-level information mechanisms, although the separation of agriculture and biodiversity portfolios at national level, as well as the federal reality of some EU countries, makes it difficult for non-national experts to have easy and comprehensive access to what they need.

A PGR infrastructure can be a common access gateway to guide access within EU diversity, and can also serve as an aid to increase the genetic base of varieties, as a support for participatory breeding, as a space for innovation, as a provider of scientific-technical services and organisational and legal-ethical guidance.

3. There is a perception of significant difficulty in accessing germplasm and/or the necessary information, especially by some (not all) actors, and for research and crop improvement purposes. Bottlenecks are particularly concentrated around certain activities, such as those involving plant breeding processes.

> Several interviewees also agree that correctly identifying the legal steps to follow and proceed is complex and generally time-consuming (beyond specific organisations providing this information, such as CGIAR or NordGen with respect to their resources, international organisations such as FAO, MLS; or knowledge networks such as ECPGR or inventories), and unlikely in some cases.
>
> An ERIC infrastructure on PGR can serve as a dedicated portal.

4. The EU has not yet adapted its Regulation EU 511/ 2014 to **the developments taking place at the COP on digital sequence information** (see in detail on this ESR issue above, at III.3.3). There is awareness, however, that these regulatory developments will come sooner rather than later. Some interviewees have pointed to the realisation that digital data exchange has in some areas of use reduced the demand for physical genetic material, in some cases pointing to the NordGen 2023 report as a source. A pan-European infrastructure can contribute to the EU's reflection and position in this respect.

5. On 5 July 2023, the Commission adopted **a legislative proposal on the production and marketing of plant reproductive material in the EU** ('Plant reproductive material Regulation') and a legislative proposal on the production and marketing of forest reproductive material in the EU ('Forest reproductive material Regulation'). Current EU legislation on plant and forest reproductive material has proven to be effective in ensuring the identity, performance, quality and health of all plant and forest reproductive material. Additionally, it has contributed to fostering an internationally competitive plant and forest reproductive material industry. However, as some of the legislation dates back to the 1960s, the Commission has revised the legislation with the aim of ensuring a level playing field for operators across the EU, supporting innovation and competitiveness of the EU PRM/FRM industry and contributing to addressing

challenges related to sustainability, biodiversity and climate. **The Commission's proposed draft regulation maintains the basic principles of the current legislation**, according to which varieties must be registered and PRM must be certified before they can be marketed. Pending the evolution of the legislative process, the draft regulation has raised concerns among some of the actors involved in PGR. Issues with the status of conservation varieties, or the exchange of PGR from genebanks, organisations and networks (or between them).

Apart from participating in the legislative process, the infrastructure can provide important services to enable some entities to meet the requirements (especially plant health, registration and/or traceability) that are expected to be requested by these regulations in relation to: operators involved in conservation; farmers exchanging seeds; and handling exceptions on varieties that have not yet been definitively certified or have temporary authorisations, experimental processes, etc.

III. 4. Perception of the incongruence among the regulatory frameworks of the ethical-legal aspects of ABS and those that address the protection of plant innovation

The interviewees have referred on numerous occasions to whether or not the MLS system contributes to overcoming the limitations of bilateral agreements, both from the perspective of the countries of origin and from the perspective of the recipients of PGRFA. The reference has been to the MLS of the ITPGRFA in most cases, given that within the scope of the Nagoya Protocol an MLS as such has not yet been activated. A high percentage of those interviewed consider that, to a certain extent, there are doubts about the possible conflicts that may arise between respect for the right of sovereignty that has been recognised for States in the CBD and the possibility that some users may claim rights over new derived varieties or, where appropriate, over some traits. Some interviewees understandably expressed concern about how to ensure that native traits and traditional plants are not patented. In this sense, the infrastructure could provide several valuable elements, expanding the good

In this sense, the infrastructure could provide several valuable elements, expanding the good practices already employed by national gene banks (in terms of MTA and compliance monitoring), as well as establishing, where appropriate, other compliance verification mechanisms.

IV. Block 3 of results: what can be learnt from the EU's efforts to create an infrastructure of biobanks of biological samples and tissues of human origin for research purposes?

The BBMRI-ERIC (European Research Infrastructure Consortium) is a pan-European platform that brings together the main actors involved in the field of biobanks, including researchers, medical professionals, biobank managers, industry representatives, patients and citizens. Its main objective is to enhance biomedical research through cooperation and coordination of efforts among participants. It is headquartered in Graz, Austria, and was established by

European legislation[89]. The name 'ERIC' refers to a special legal form recognised by European law, which confers certain administrative and fiscal advantages[90]. In particular, this legal status means that, for specific purposes such as value added tax (VAT) and certain taxes, ERICs are treated as equivalent to certain international bodies.

What lessons can the BBMRI-ERIC experience bring to the development of a pan-European plant genetic resources (PGR) infrastructure? The significant growth of biobanks over the last decades was driven by an increased recognition of the strategic value of human biological samples for research. The generation of transnational collaborations has become increasingly central to genetic and genomic research. This momentum has been particularly reflected in areas such as personalised medicine and advanced biomedical research, highlighting the importance of integrating multiple ethical, social and regulatory perspectives (Bossert et al., 2018; Domaradzki and Pawlikowski, 2019).

Setting up these infrastructures has had to face multiple ethical and legal challenges, especially when crossing borders. On the one hand, and as with PGR, it is important to consider that, except for biobanks established after the European regulation on harmonisation of human biological samples[91], each previous biobank was formed in particular geographical, social and historical contexts, with very different objectives, designs and collection conditions (Hoeyer, 2010). On the other hand, although some have proposed considering these samples as a *commons*[92], the governance of biobanks remains mainly national, with frequent overlaps between national, regional and international rules. General challenges, regardless of tissue type, include the protection of participants' privacy, the return of information, and the fair sharing of benefits derived from research, which are essential to strengthen public trust. In addition, there are specific challenges associated with the use of human embryos and embryonic cells.

From the ESR perspective, an additional interesting dimension of the BBMRI-ERIC infrastructure is the coordinated effort it has undertaken, in collaboration with the associated entities, to comply with the regulations governing the creation of such consortia within the EU. Specifically, it has actively worked on establishing a harmonized common minimum for the application of the EU Tissue Directive, along with other relevant regulations and standards. This common minimum goes beyond technical and legal aspects and also covers essential conditions to ensure the quality, safety, and traceability of biological materials, including key elements such as risk management, data protection, and operational interoperability between biobanks across

[89] COUNCIL REGULATION (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC).
[90] Council Regulation (EC) No. 723/2009.
[91] EU regulations governing human biological samples in biomedicine emphasize safety, quality, and patient rights. The SoHO Regulation (2024/1938) sets standards for substances of human origin, including blood, tissues, and cells, used in biomedical research and applications. This regulation aims to improve the safety and quality of these substances, ensuring they are fit for human use. Additionally, the EU Tissue Directive (2004/23/EC) provides standards for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells, including cross-border exchange within the EU. See: https://eur-lex.europa.eu/eli/dir/2004/23/oj/eng
[92] Haidan Chen and others, 'A Call for Global Governance of Biobanks' (2015) 93 Bulletin of the World Health Organization 113. See also the Bartha M Knoppers, 'International Ethics Harmonization and the Global Alliance for Genomics and Health' (2014) 6 Genome Medicine 13. Edward S Dove, 'Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework' (2015) 43 The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics 675, 679.

different countries. This approach facilitates transnational collaboration and strengthens trust among partners, which is essential for large-scale biomedical research.

In this context, the European Commission's decision on the creation of BBMRI-ERIC establishes the obligation for each member to guarantee access to biological and biomolecular resources and related data, complying with common standards and conditions defined in the BBMRI-ERIC Members' Charter and approved by the Assembly of Members. These standards explicitly include compliance with the applicable ethical and legal framework. Drawing from its own experience, BBMRI-ERIC not only acts as a reference model in this field but also actively contributes to the training and capacity-building of other biobanking entities and users, both within the EU and internationally.

V. Block 3: Recommendations on how to manage ESR aspects in the generation of a pan-European PGR infrastructure, in light of the results of blocks 1 and 2.

V.1. Specific potential of an ERIC PGR infrastructure, compared to other approaches

1. As previously mentioned, an ERIC is a special legal entity recognised under European law, which confers certain administrative and fiscal advantages[93]. In particular, this legal status means that, for specific purposes such as value added tax (VAT) and certain excise duties, ERICs are treated as international organisations. Together with other operational and funding advantages, in some cases this type of infrastructure has helped to address the cross-border ethical and legal challenges of some research areas more efficiently.

2. Although BBMRI-ERIC and GRACE-RI focus on different types of biological resources and engage with distinct groups of stakeholders, they nevertheless face a series of common scientific, technical, and organisational challenges. The significant expansion of biobanks in recent decades has been driven by the growing recognition of the strategic value of human biological samples for research purposes. The development of transnational collaborations has progressively become a cornerstone of genetic and genomic research. This momentum has been particularly evident in fields such as personalised medicine and advanced biomedical research, underscoring the importance of incorporating multiple ethical, social, and regulatory perspectives[94].

Much of the biobanks that form part of BBMRI-ERIC and many of their collections existed before the harmonisation of European regulations on human biological samples, as will be seen with the PROGRACE ERIC infrastructure. Each pre-existing biobank was formed in particular geographical, social and historical contexts, with very diverse objectives, designs and collection conditions[95]. Moreover, and although some voices have proposed considering these samples as

[93] Council Regulation (EC) No. 723/2009.

[94] Bossert, S., Kahras, H., & Strech, D. (2018). The public's awareness of and attitude toward research biobanks: A regional German survey. Frontiers in Genetics, 9. https://doi.org/10.3389/fgene.2018.00190; Domaradzki, J. & Pawlikowski, J. (2019). Public attitudes toward biobanking of human biological material for research purposes: A literature review. International Journal of Environmental Research and Public Health, 16(12), 2209. https://doi.org/10.3390/ijerph16122209.

[95] Hoeyer, K. (2010). Donors' perceptions of consent to and feedback from biobank research: Time to acknowledge diversity? Public Health Genomics, 13, 345–352. https://doi.org/10.1159/000262329

a common good[96], the governance of biobanks remains mainly at the national level, with frequent overlaps between national, regional and international regulations. Among the general challenges, regardless of the type of tissue, the protection of participants' privacy, the return of information, and the fair distribution of the benefits derived from research, essential aspects for strengthening public trust, stand out. In addition, there are specific challenges associated with the use of human embryos and embryonic cells.

3. Regarding GRACE-RI, many of these statements are reiterated, with one key distinction: the EU does not foresee regulatory harmonization (or approximation) of the Member States' PGR (Plant Genetic Resources) regulatory frameworks and policies in the short term. As previously noted, the Member States have not developed a common framework to address these limitations. Additionally, there is no formalized platform for political dialogue aimed at creating such a common framework. As mentioned earlier, this lack of a shared vision results in PGR activities in the EU being influenced by dynamics unfolding in international forums, particularly those surrounding the FAO Plant Treaty and the Nagoya Protocol.

4. This particularity of the regulatory situation of PGR, however, makes an ERIC infrastructure in this field especially valuable. From a legal and governance point of view, and with respect to other relevant initiatives that contribute to collaboration between this type of entity (such as integrated germplasm bank systems), **the generation of an ERIC-type infrastructure for PGR in the EU presents a very valuable differential element**: its supranational, European legal status and its consideration as an international entity for all purposes.

V.2. Specific strategic advantages

Notwithstanding other services that may be provided by the infrastructure, the ERIC status under European law, which can also be complemented by specific actions of the European Commission, offers strategic advantages in several ways:

1) It can serve as a **legal basis for hosting PGR shared between EU countries associated with the infrastructure** (ex situ and in situ, and their associated networks), whether it be germplasm of origin from those countries or germplasm incorporated into those collections from countries with which specific agreements are negotiated.

2) The infrastructure can offer **an international and stable legal basis for the realisation of activities** that, at present and due to the high level of bureaucracy, cannot be carried out by European nation states.

3) By opening up the possibility of **generating regulatory sandboxes**, this infrastructure can serve as a legal basis for generating a system of intensified collaborative plant breeding response to emergencies (climatic, phytosanitary) that the EU considers a priority for action. A regulatory sandbox is a controlled and flexible space where companies or entities can test new innovations

[96] H. Chen and others, 'A Call for Global Governance of Biobanks' (2015) 93 Bulletin of the World Health Organization 113. See also B. M. Knoppers, 'International Ethics Harmonization and the Global Alliance for Genomics and Health' (2014) 6 Genome Medicine 13; E. S. Dove, 'Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework' (2015) 43 *The Journal of Law, Medicine & Ethics*: A Journal of the American Society of Law, Medicine & Ethics 675, 679.

or approaches under a temporarily relaxed or adapted regulatory framework, without being subject to the standard regulations. This approach allows experimentation in a real-world but supervised environment to assess risks and benefits before large-scale implementation. In the context of PGR (Plant Genetic Resources), a regulatory sandbox could be used to test new practices for managing, sharing, and conserving genetic resources, temporarily adjusting regulations to encourage innovation and collaboration among countries and international actors while assessing impacts in terms of sustainability, legality, and equity.

4) Through regulatory sandboxes, this infrastructure can pave the way for the application in the EU of participatory plant breeding methods that in other regions of the world find their way to the commercialisation of agri-food products.

5) It can help Member States to perceive in greater detail the potential of all activities concerning germplasm and, based on that perception, move towards the progressive adoption of common positions that respond to the challenges of agriculture and food security in the European Union.

V.2. Details of services that a pan-European PGR infrastructure for research can offer in relation to ethical and legal aspects

1. Provision of ELSI services, along the lines of those offered by the BBMRI-ERIC infrastructure with respect to the resources it hosts. Conducting research related to ethical, social and legal aspects of PGR (in European projects and publication), and support in the elaboration of codes of conduct for research with PGR. Contributing to the knowledge of PGR not only in their scientific-technical dimensions, but also in the SSH aspects related to agri-food innovation, together with other actors.

2. **Providing legal services to the various stakeholders within the EU PGR system and for collaborations between the EU and actors from other countries.** A European infrastructure on PGR that supports the conservation, documentation and sustainable use of genetic resources can provide not only technical scientific support (see other deliverables of this WP) but also support in the management of the legal-ethical dimensions. That is, support to different actors and potential users, facilitating compliance with legal and regulatory requirements and best practice standards. And contributing to capacity building for compliance with the ethical-legal aspects associated with PGR (through training and workshops).

These services include, among others, the following:

- Facilitating discovery and access (optimised access to genebank resources, collections and additional services across the EU). A permanent legal helpdesk could be established as well as linkages to other interesting services (such as AEGIS).

- Building bridges with third countries (assisting with permit applications, facilitating stakeholder collaboration) and with international forums such as the FAO, CG, and regional groups. The EU's analysis of compliance with the EU ABS Regulation (2020) highlighted the challenges faced by users in accessing information on the obligations and procedures to follow with provider countries in each case, leading to anticipated increased costs and delays in obtaining materials.

- Possibility of implementing compliance monitoring mechanisms at the European level. Currently, compliance monitoring mechanisms focus primarily on PGR incorporated into research funded by public grants, and to some extent on PGR used in the development of plant varieties intended for registration under UPOV or those involved in inventions seeking patent protection. Other aspects of compliance are not externally monitored.

- And an intermediation service to streamline processes, to facilitate communication and access between PGR custodians and interested users.

3. **Contribution to third party compliance (in application of the Bonn Declaration).** In line with the Nordic countries (NordGen, 2023:53), the infrastructure can reinforce the compliance of accessing users with legal obligations towards provider countries, for example:

- Through **the designation of control points** for the receipt and dissemination of coordinate information for the EU on the exploitation of genetic material from other countries (reinforcement of compliance with ABS Regulation 511/ 2014 ABS, the Commission Implementing Regulation on that Regulation as regards monitoring of user compliance and good practices; and the guidance document issued by the European Commission in 2021 on the implementation of that Regulation[97]), which contribute to ensuring that the use of accessed PGR and associated traditional knowledge is employed in accordance with mutually agreed terms.

- By issuing certificates of compliance with international obligations to the appropriate body.

- Providing Member States with traceability mechanisms to ensure compliance with the corresponding obligations in terms of benefit sharing (according to the applicable system).

4. An ERIC infrastructure is also a space for the creation of synergies that will enable us to work more effectively and with a medium- and long-term perspective with a view to improving European governance in this area.

From its role as a European reference centre for the promotion of the sustainable management of plant genetic resources, and thanks to its cooperation at a global level, the pan-European infrastructure is in a position to offer advice to those responsible for governance and legislators on:

- Up-to-date mapping of the regulatory landscape: Continuously tracking and updating the regulatory framework related to plant genetic resources, identifying emerging

[97] Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2021/C 13/01).

trends, and ensuring that each section is regularly revised and updated to reflect changes in legislation, policies, and international agreements.

- Managing legislative heterogeneity: Addressing the challenges posed by varying national regulations and supporting the implementation of legal frameworks that, despite being approved, are still in the process of being enacted. This includes facilitating the negotiation of international regulations and agreements with third countries to align policies across borders.
- - Identifying shared interests among Member States: Mapping common priorities and areas of interest related to plant genetic resources, and helping Member States to coordinate and promote joint strategies. This task includes fostering collaboration for the development of collective policies or actions that can enhance the sustainable use and conservation of PGR at the EU level.

5. An ERIC PGR infrastructure can be an EU platform for regulatory sandboxes on strategical uses of PGR. For example,

- sandboxes to generate a system of intensified collaborative plant breeding response to emergencies (climatic, phytosanitary) that the EU considers a priority for action;

- and sandboxes for participatory plant breeding opportunities (specially the ones involving *in situ* PGR) that are currently bureaucratically unfeasible in the EU.

Annex

I. - Initial Questionnaire for Identifying Candidates for In-Depth Interviews (Qualitative Research)

Individuals and entities capable of providing information or insights related to all or some of the questions listed below are being sought. This includes professionals from organizations involved in the conservation of germplasm (such as genebanks or similar institutions), organizations that supply germplasm to others, and organizations that use germplasm for research or plant breeding purposes, in a broad sense.

The objective of this recruitment is to conduct in-depth interviews aimed at capturing perceptions regarding the ethical, social, and legal aspects associated with Plant Genetic Resources (PGR), which must be considered when designing a European PGR infrastructure.

The questionnaire is organized into thematic blocks:

BLOCK 1: Professional Relationship with PGR

- What is/has been your professional relationship with PGR (e.g., conservation, research, plant breeding)?
- Whether your work involves a germplasm conservation entity or a major user of PGR obtained from others, please specify the origin of the PGR managed. Are/were the PGR classified as PGRFA under the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty), or do they fall under other legal categories?

Explanation: This section aims to identify the participant's involvement with PGR, whether through conservation, research, or use for plant breeding. Clarifying the legal classification helps to understand the regulatory framework governing these resources.

BLOCK 2: Concerning PGRFA Resources

- What percentage of the PGRFA resources under your management were fully owned by your entity, and what percentage are subject to limited or conditional assignments?
- If applicable, clarify the differences between resources under full ownership and those under limited or conditional assignment (e.g., sourced from third countries, before or after the ITPGRFA's entry into force, under intellectual property (IP) rights, or involving traditional knowledge, etc.).

Explanation: This block seeks to differentiate between resources fully owned by the entity and those that are subject to restrictions, as these distinctions have important implications for their management, access, and distribution.

BLOCK 3: Concerning Non-PGRFA Resources

Similar to the questions in Block 2, but adapted for non-PGRFA resources. The legal status may include details about transfer regimes (e.g., sourced under bioprospecting agreements or in the context of the Nagoya Protocol).

Explanation: This block explores the management of non-PGRFA resources and seeks to understand how they are treated in terms of legal frameworks, especially regarding international agreements such as the Nagoya Protocol.

BLOCK 4: Organizational Frameworks and Agreements

- Does your organization have specific European Strategic Research (ESR) frameworks or agreements with particular entities, and can examples of these be shared? Alternatively, does your organization interact with organizations that have such frameworks in place?
- Any reference to relevant documentation would be greatly appreciated, where possible.

Explanation: This section investigates the existence of formal agreements and frameworks, particularly related to the exchange and management of PGR, which can provide important insights into existing operational and legal structures.

BLOCK 5: Additional Relevant Information

- Which other individuals or institutions could provide valuable insights on these matters?
- Are there any other stakeholders that should be contacted for this study?

Explanation: This block aims to identify other key individuals or organizations that might offer perspectives on the ethical, social, or legal considerations related to PGR, thus broadening the scope of the research. In your opinion, **which person or persons, and from which institutions, do you believe could provide us with an interesting perspective on these issues? Are there any other stakeholders you would recommend we contact for this study?**

II.- In-Depth Interviews: Approach and Guiding Questionnaire

In-depth interviews were a key method in the qualitative research conducted for the Grace-RI project. These interviews, characterized by their open-ended and flexible structure, were designed to capture detailed and nuanced insights from participants. Unlike structured surveys or questionnaires, in-depth interviews allow participants to express their perspectives in depth, providing richer, more comprehensive information. This method enabled us to explore underlying motivations, attitudes, and perceptions, offering a deeper understanding of the complex challenges faced by European Plant Genetic Resources (PGR).

The interviews began by outlining the objective of the Grace-RI project. Based on the European Strategy for Plant Genetic Resources, developed with a wide range of stakeholders by the European Cooperative Programme for Plant Genetic Resources (ECPGR) and various EU initiatives, the PRO-GRACE project aimed to address the challenges faced by European PGR. The project sought to establish systems, processes, standards, and methods, while developing the concept, regulatory framework, and governance for a functional and efficient research GRACE infrastructure.

However, the construction of such an infrastructure faced significant ethical, social, and legal challenges. **The interviews were designed to capture the ESR perspectives of individuals working with PGR, whether within the EU or internationally, to gain insights into how these challenges were perceived from their positions**. The information gathered was invaluable in enriching the understanding of these issues.

The guiding questionnaire for the in-depth interviews was organized into thematic blocks, each addressing a key aspect of PGR management, from conservation and research to ethical and legal considerations. The approach allowed us to go beyond technical details and explore broader concerns, such as the ethical dilemmas, social impacts, and legal frameworks that influence decision-making and practices in the field. The insights gathered during the interviews were critical in identifying the key issues that must be addressed when building an effective and ethically sound PGR infrastructure.

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