

Access to genetic resources between biodiversity protection and intra-generational solidarity

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ABSTRACT: In Italy, even before the recent Constitution amendment of article 9, biodiversity protection was at the centre of the national strategy adopted with the ratification law of the Convention on Biological Diversity (CBD). The CBD establishes the sovereign rights of nations to control access to their biological diversity to safeguard an equitable sharing of the benefits arising out of the utilization of genetic resources. The Nagoya Protocol, a supplementary agreement to the CBD implemented in Europe with two Regulations, sets out the general framework for access and benefit-sharing (ABS legal instruments). EU States have recently implemented these regulations and the author suggests endorsing a study on ABS in order to make the system for exchanging genetic resources more effective in the interests of the community. A sustainable use of biological diversity, preserved through the ABS mechanism, is fundamental to cope with climate change and achieve food security: this key objective requires solidarity between present and future generations.

KEYWORDS: Biodiversity Protection; Access and Benefit Sharing; Nagoya Protocol; Genetic Resources; ABS Regulation

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1. Introduction

Even before 2022 with the amendment of article 9, Italian Constitution, biodiversity protection was at the centre of the national strategy adopted by Italy with the national law which ratified the Convention on Biological Biodiversity.¹

Genetic resources, understood by the Convention on Biological Diversity (CBD) as genetic material of “plant, animal, microbial or other origin containing functional units of heredity”,² play significant

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¹ Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, 1760 UNTS 79.

² Art. 2, Convention on Biological Diversity.



roles in different economic sectors and in meeting societal challenges ranging from safeguarding food security to developing new medicines or adapting to climate change.³

Today the main issue is the correct use of genetic resources, in order to increase productivity (especially in this period of climate variation⁴ and the contraction in agricultural raw materials) and to grant food security.⁵

In this context, germplasm exchanges are a fundamental input for agricultural research and development. Moreover, no country is self-sufficient in plant genetic resources and all depend on the genetic diversity of crops from other countries and regions. International cooperation and exchange of genetic resources are therefore essential for food security and biodiversity protection.

The scope of this essay is the analysis of the regulatory frame and status for germplasm exchanges through Material Transfer Agreements (MTAs), and of their implementation under the national and international legal framework. At present, germplasm exchanges must be performed in compliance with the current regulations on the background of constitutional and domestic principles.

The paper will point out the procedures that should be promoted to make the system of genetic resources' exchanges more efficient in the interest of safeguarding future generations.

2. The biodiversity strategy protection framework

On the global scale, three main international treaties regulate biodiversity protection: the Convention on Biological Diversity (CBD), the EU Biodiversity Strategy, and the Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Firstly, the CBD⁶ entered into force on 29 December 1993 and has three main objectives: the conservation of biological diversity, the sustainable use of the components of biological diversity and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.⁷ At the Conference of the Parties in October 2010 in Nagoya, Japan, the 193 Parties to the Convention agreed on a ten-year global Strategic Plan for Biodiversity, 2011-2020, to combat biodiversity loss and defined 20 concrete targets⁸ in order to achieve this overall objective. Furthermore, during the Nagoya conference, the CBD Parties adopted a new international Protocol on Access to Genetic Re-

³ This essay is inspired by the author's study carried out for the University of Turin as part of the project VEG-ADAPT (Adapting Mediterranean Vegetable Crops to Climate Change-induced Multiple Stress), an international research project approved under the PRIMA and launched 1 October 2019. It is supported by the National Funding Agencies of the participating countries and the project coordinator is Professor Andrea Schubert (DISAFA, University of Turin) who authorizes the publication of the data collected during the research: see www.veg-adapt.unito.it (last visited 23/07/2022). The author acknowledges financial support by PRIMA (project VEG-ADAPT), a programme supported by the European Union.

⁴ FAO. 2020. *Climate change: Unpacking the burden on food safety*, in *Food Safety and Quality Serie*, 8, Rome. <https://doi.org/10.4060/ca8185en> (last visited 15/07/2022).

⁵ FAO. 2021. *Strategic Framework 2022-31*, Rome. www.fao.org/3/cb7099en/cb7099en.pdf (last visited 15/07/2022).

⁶ See www.cbd.int (last visited 15/05/2022).

⁷ E. MORGERA, *The Need for an International Legal Concept of Fair and Equitable Benefit Sharing*, in *The European Journal of International Law*, 2016, 353-383.

⁸ Known as Aichi Biodiversity Targets: see www.cbd.int/sp/targets (last visited 15/05/2022).

sources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (the ABS agreement or Nagoya Protocol).⁹

Secondly, the EU Biodiversity Strategy aims to halt the loss of biodiversity and ecosystem services in the EU and help stop global biodiversity loss.¹⁰ It reflects the commitments taken by the EU in 2010, within the international Convention on Biological Diversity.

The EU biodiversity strategy has also led to the strengthening of knowledge about ecosystems and ecosystem services within the EU, improved action for themes such as invasive alien species, and an increased contribution to combating biodiversity loss at international level.¹¹ Future decision-making, both public and private, needs to reflect the natural wealth of biodiversity and its contribution to the wellbeing of the EU's economy and society of the EU. These issues have been adequately addressed in the post-2020 biodiversity frameworks.¹² The commitments of the Nagoya Protocol are reflected in the EU ABS Regulation No 511/2014 adopted by the European Parliament and the Council on 16 April 2014.

Finally, the United Nations Food and Agriculture Organization (FAO) Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)¹³ entered into force on 29 June 2004. Its objectives are the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA) and the fair and equitable sharing of the benefits arising out of their use in harmony with the Convention on Biological Diversity (CBD), for sustainable agriculture and food security. These objectives have to be closely coordinated with all activities under this Treaty with other work done by the Food and Agriculture Organization of the United Nations, the Convention on Biological Diversity, and with national initiatives.¹⁴

2.1. The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)¹⁵ to the Convention on Biological Diversity (CBD) is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of the CBD.

⁹ E. MORGERA, E. TSIOUNAMI, M. BUCK, *Unraveling the Nagoya Protocol. A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, Leiden, Boston, 2, 2014.

¹⁰ F. RABITZ, *The Global Governance of Genetic Resources: Institutional Change and Structural Constraints*, London, 2021, 101 seq.

¹¹ N. SCHRIJVER, *Sovereignty Over Natural Resources: Balancing Rights and Duties*, Cambridge, 2008, 369 seq.

¹² See https://ec.europa.eu/environment/nature/biodiversity/international/cbd/index_en.htm (last visited 15/07/2022).

¹³ See www.fao.org/plant-treaty/en (last visited 15/07/2022).

¹⁴ M.A. MEKOUAR, *A Global Instrument on Agrobiodiversity: The International Treaty on Plant Genetic Resources for Food and Agriculture*, *FAO Legal Papers Online*, 2002, <https://www.fao.org/3/bb057e/bb057e.pdf> (last visited 23/07/2022).

¹⁵ Acronym for "Access and Benefit-Sharing" used to refer to the way in which genetic resources or traditional knowledge associated with such resources is accessed and how the benefits that result from the utilisation of such resources and associated traditional knowledge are shared with the countries and/or indigenous and local communities providing them. E. MORGERA, *The Need for an International Legal Concept of Fair and Equitable Benefit Sharing*, cit., 358.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan, and entered into force on 12 October 2014. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. Therefore, the Nagoya Protocol offers legal certainty and transparency for both providers and users of genetic resources by establishing more predictable conditions for access to genetic resources and aims to ensure benefit-sharing when genetic resources leave the country providing them. By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives¹⁶ to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. In particular, the Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources,¹⁷ benefit-sharing¹⁸ and compliance.¹⁹

The Protocol also contains significant provisions relating to Traditional Knowledge associated with genetic resources that are covered by the CBD and held by indigenous and local communities, where the rights of these communities over these resources have been recognized.²⁰

The Protocol also addresses genetic resources where indigenous and local communities have the established right to grant access to them. Contracting Parties are to take measures to ensure prior informed consent of these communities, and fair and equitable benefit-sharing, while taking into ac-

¹⁶ The Protocol will open the way for more access deals. Improved access to quality samples of genetic resources with high legal certainty and at the lowest possible transaction costs will maximize research and development opportunities on genetic resources.

¹⁷ Domestic-level access measures are to: create legal certainty, clarity and transparency; provide fair and non-arbitrary rules and procedures; establish clear rules and procedures for prior informed consent (PIC) and mutually agreed terms (MAT); provide for issuance of a permit or equivalent when access is granted; create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use; pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health; consider the importance of genetic resources for food and agriculture for food security.

¹⁸ Domestic-level benefit-sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources with the contracting party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources, as well as subsequent applications and commercialization. Sharing is subject to mutually agreed terms. Benefits may be monetary or non-monetary such as royalties and the sharing of research results.

¹⁹ Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting party providing genetic resources, and contractual obligations reflected in mutually agreed terms, are a significant innovation of the Nagoya Protocol. Contracting Parties have to: take measures providing that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting party; cooperate in cases of alleged violation of another contracting party's requirements; encourage contractual provisions on dispute resolution in mutually agreed terms; ensure an opportunity is available to seek recourse under their legal systems when disputes arise from mutually agreed terms; take measures regarding access to justice; take measures to monitor the utilization of genetic resources after they leave a country including by designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialization or commercialization.

²⁰ L. PAOLONI, *I "diritti degli agricoltori" sulle risorse genetiche e le conoscenze locali: un nuovo modello di proprietà collettiva?*, *Annali Università degli Studi del Molise*, 2010, 93-102.

count community laws and procedures as well as customary use and exchange in accordance with domestic legislation. Benefit sharing must be based on mutually agreed terms (MAT). More information on the Nagoya Protocol and traditional knowledge can be found in the Traditional Knowledge programme of work.²¹ In addition, Parties to the Protocol must ensure that their nationals comply with the domestic legislation and regulatory requirements of provider countries related to the access and benefit-sharing of traditional knowledge associated with genetic resources.

It should be noted that the Decision of the Conference of the Parties contains a review clause related to developments in the World Intellectual Property Organization (WIPO). Eight years after the entry into force of the Protocol, the Conference of the Parties serving as the Meeting of the Parties to the Protocol undertook an evaluation of the effectiveness of the Protocol. In this context, the Conference of the Parties decided that the implementation of the article related to compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources should be reviewed in light of developments in other relevant international organizations, including the World Intellectual Property Organization.

As a final point, the article of the Protocol addressing the relationship with international agreements and instruments may also be of interest. It refers to the possibility for Parties to develop and implement further relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention or the Protocol. It also refers to the need to pay due regard to ongoing work under relevant international organizations.

Thereafter, in order to be successful, the Nagoya Protocol requires effective implementation at a domestic level. A range of tools and mechanisms included in the Nagoya Protocol assist contracting Parties including: establishing national focal points (NFPs) and competent national authorities (CNAs) to serve as contact points for information, grant access or cooperate on issues of compliance; and also an Access and Benefit-sharing Clearing-House to share information, such as domestic regulatory ABS requirements or information on NFPs and CNAs.

Moreover, capacity building to support key aspects of implementation is the touchstone of the regulation and it can include capacity to develop domestic ABS legislation to implement the Nagoya Protocol and to negotiate MAT (mutually agreed terms). Consequently, Parties need targeted financial support for capacity-building and development initiatives through the Nagoya Protocol's financial mechanism, the Global Environment Facility (GEF).²²

2.2. International Treaty on Plant Genetic Resources

The Treaty is a key instrument for ensuring agricultural plant diversity on which farmers and breeders depend in order to be able to meet global challenges such as the growing world population and climate change, which make it necessary to breed tolerant varieties. Within the ITGRFA, access to genetic resources and fair distribution of the benefits resulting from their use are regulated under the

²¹ See <https://www.cbd.int/traditional/Protocol.shtml> (last visited 15.05.2022).

²² The GEF is an international partnership of 184 countries, international institutions, civil society organizations and the private sector that addresses global environmental issues. See <https://www.thegef.org> (last visited 29/08/2022).

Multilateral System (MLS) established by the Treaty. Transactions between suppliers and users of material are carried out on the basis of Standard Material Transfer Agreements (SMTA). Every year several thousand SMTA are concluded, the majority by the Centers of the Consultative Group on International Agricultural Research (CGIAR).

The key elements of the ITPGRFA are the conservation, exploration, collection, characterization, evaluation and documentation of PGRFA; the sustainable use of plant genetic resources; the rights of farmers; a Multilateral System of Access and Benefit-sharing (MLS) and a Funding Strategy. It should be mentioned that a multilateral international agreement for the fair and equitable sharing of benefits arising from the use of these resources has been practically implemented through the Treaty and its Multilateral System (MLS).²³

The ITPGRFA Funding Strategy is composed of several elements, including: allocation of predictable and adequate resources by international bodies for the implementation of plans and programs promoted under the Treaty; national funding for national activities; the Global Crop Diversity Trust²⁴, established in 2004; financial resources provided on a voluntary basis through bilateral, regional and multilateral channels; and the Treaty's Benefit-sharing Fund²⁵ which receives contributions from governments, industry, foundations and non-governmental organizations, and monetary benefits arising from the use of genetic resources obtained using the Standard Material Transfer Agreement when accessing germplasm from the MLS. The Benefit-sharing Fund invests directly in projects supporting farmers in developing countries to conserve crop diversity in their fields and assisting farmers and breeders to adapt crops to changing needs and demands.

The Treaty has been signed by the European Union and by most of its Member States.²⁶

It should be noted that the access and use of specific plant genetic resources may be governed by the provisions of the ITPGRFA, which can be considered a specialized instrument according to the Nagoya Protocol.²⁷

In accordance with Article 4(4) of the Nagoya Protocol, specialized ABS instruments prevail in respect of the specific genetic resource covered by the specialized instrument and for the purpose of that instrument, if it is consistent with and does not run counter to the objectives of the CBD and the Protocol. Accordingly, Article 2(2) of the EU ABS Regulation – see next paragraph 3 – makes it clear that

²³ In fact article 1 sets out the objectives of the Treaty in harmony with the Convention on Biological Diversity for sustainable agriculture and food security.

²⁴ See <https://www.croptrust.org> (last visited 14/06/2022). It is the only international organization dedicated solely to conserving and making available crop diversity: particularly Crop Trust supports and funds the world's most important crop collections via the CGIAR Gene bank Platform and provides support to key national collections of crop diversity most important for future global food security.

²⁵ The Benefit-sharing Fund operates under the International Treaty on Plant Genetic Resources for Food and Agriculture. Therefore, the genetic resources of our most important food crops – the “life insurance” for our food production – are managed by governments according to the provisions of the International Treaty. The Benefit-sharing Fund provides funding to conserve and develop crops genetic resources in cooperation with farmers, assisting farming communities in developing countries improve food security by helping them cope with climate change and other threats to food production. In fact, UN reports on climate change show that crop genetic resources can play a vital role in creating a more climate-resilient agriculture.

²⁶ In Italy, see law of ratification, 6th of April 2004, n. 101.

²⁷ E. MORGERA, E. TSIOUNAMI, M. BUCK, *Unraveling the Nagoya Protocol. A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity*, cit., 97-102.

the Regulation does not apply to genetic resources for which access and benefit-sharing is governed by such specialized international instruments. This currently includes material covered by the ITPGRFA.

However, the EU ABS Regulation does apply to genetic resources covered by the ITPGRFA if they are accessed in a country that is not Party to those agreements but is Party to the Nagoya Protocol. The EU Regulation also applies where resources covered by such specialized instruments are utilized for purposes other than those of the specialized instrument in question (e.g. if a food crop covered by the ITPGRFA is utilized for pharmaceutical purposes).

When germplasm exchanges fall within the legislative scope of Nagoya, the use of the SMTA²⁸ under the Treaty is one more important tool that can be used for exchanges of plant genetic resources. The Treaty does not provide for sanctions for violations, but does provide for an arbitration settlement of any disputes²⁹ and provides for a conciliation commission within the FAO.³⁰

3. Genetic resources transfer among EU States

The Nagoya Protocol, aimed at providing a transparent legal framework for ABS,³¹ entered into force on 12 October 2014. It is implemented in the European Union through Regulation (EU) 511/2014, which entered into force on the same date, and through Regulation (EU) 2015/1866 (often just referred to as “the Implementing Regulation”).

On 27 August 2016, a Guidance document was published by the European Commission on the scope of application and the core obligations of Regulation (EU) 511/2014. On 12 January 2021, a revised Guidance document was published by the EU Commission, providing more detailed information and practical examples on the scope of application and the core user obligations of Regulation (EU) 511/2014.

The EU Guidance documents are not legally binding. Nevertheless, the competent authority in the Member States use this document to orientate themselves when making relevant decisions about compliance.

EU ABS Regulation 511/2014 covers all genetic resources and traditional knowledge associated with genetic resources accessed at the entry into force of the Protocol for the EU. The ABS rules apply to the utilization of genetic resources and traditional knowledge associated with genetic resources. Utilization means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. In any case, genetic resources are used in research and development for many different purposes.

²⁸ As a mandatory model, the Standard Material Transfer Agreement is the result of lengthy negotiation among the Contracting Parties to the Treaty and may not be varied or abbreviated in any way.

²⁹ See Part I, Annex II, ITPGRFA.

³⁰ See Part II, Annex II, ITPGRFA.

³¹ I.R. PAVONE, *Il Protocollo di Nagoya e l'attuazione del principio di Access and Benefit Sharing con particolare riferimento all' user compliance pillar*, in *BioLaw Journal – Rivista di BioDiritto*, 1, 2018, 251-273.

The key element of EU ABS is what we can call a “due diligence approach” (article 4, Regulation 511/2014).³² In fact, users will have to exercise “due diligence” to ascertain that the genetic resources and the associated traditional knowledge they use have been accessed in accordance with applicable legal requirements and ensure that, where relevant, benefits are shared. Users will also be obliged to declare at specific check points (*Considerando* 25 and articles 9 and 10) that the correct procedure has been followed.

The due diligence obligation should ensure that the information relevant to ABS is available throughout the whole genetic resources value chain. This enables all users to know and respect related rights and obligations. At the same time, the due diligence approach does not prescribe details of the measures to be taken by users, but leaves users some flexibility to take measures that work best for their respective context, and also to develop sectoral best practices.

Therefore, users need to seek, keep and transfer to subsequent users information on the date and place of access to genetic resources or traditional knowledge associated with genetic resources and the description of the genetic resources or traditional knowledge associated with the genetic resources utilized. Moreover users have to transfer information on the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as the presence or absence of rights and obligations relating to access and benefit sharing, including rights and obligations regarding subsequent applications and commercialization. Finally, mutually agreed terms, including benefit-sharing arrangements, where applicable, are transferred to subsequent users.

In addition, users need to analyse if the information in their possession is sufficient and be certain to comply with applicable legal requirements in the provider country. Otherwise, users must either obtain the missing information or discontinue utilizing the genetic resources and/or the traditional knowledge associated with genetic resources. Users are obliged to retain any information relevant for access and benefit-sharing for a 20-year period after the end of the period of use.

The EU ABS Regulation foresees that specific choice taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs.

The Regulation (EU) 1866/2015 lays down detailed rules concerning the implementation of Articles 5, 7 and 8 of Regulation (EU) 511/2014 which refer to the register of collections, the monitoring of user compliance, and best practices. In particular, the EU Commission can recognize best practices in accordance with Regulation EU 1866/2015.

Articles 5 and 8 of Regulation 511/2014 provide for voluntary tools, namely registered collections and best practices, to assist users in complying with their due diligence obligation. Identifying and registering collections which effectively apply measures that result in supplying genetic resources

³² The transposition of due diligence obligation in a binding EU Regulation transforms the standard of care into an objective one, leaning towards the standard established by due diligence in international business law. See C. GODT, M. BURCHARDI, *Due Diligence and the Regulation of Transnational Economic Activity: Regulation (EU) No 511/2014 Compared to Other EU Diligence Schemes*, in E. CHEGE KAMAU (ed.), *Global Transformations in the Use of Biodiversity for Research and Development*, Berlin, 2022, 547-586.

and related information only with documentation providing evidence of legal access and ensuring the establishment of mutually agreed terms, where required, is expected to assist users in complying with that obligation.

In order to ensure uniform conditions for the implementation of provisions on monitoring user compliance, detailed rules are required. They regard the declarations to be made by recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources, as well as the declarations to be made by users at the stage of final development of a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources.

When monitoring user compliance at the stage of research funding, it is important to ensure that the recipients of the funding understand their obligations under Regulation (EU) No 511/2014 and that they exercise due diligence. It is equally important to provide information to the Access and Benefit-Sharing Clearing House (“ABS Clearing House”), and to ensure that such information is useful for the functioning and implementation of the Nagoya Protocol.

However, the unnecessary multiplication of due diligence declarations should be avoided. Therefore, a declaration made by recipients of research funding may cover more than one genetic resource or any traditional knowledge associated with genetic resources. A single declaration may also be made by several users jointly conducting research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources funded by one grant. In this context, a special role should be given to the project co-ordinator, who should be responsible for submitting the declarations on behalf of the users concerned.

The information provided in the due diligence declarations is to be submitted by the competent authorities to the ABS Clearing House pursuant to Article 7(3) of Regulation 511/2014. Where an internationally recognised certificate of compliance is not available, other relevant information should be submitted in accordance with Article 17(4) of the Nagoya Protocol, as specified in Article 4 (3) (b) of Regulation 511/2014.³³

4. EU collection register and the due diligence declaration. Breeders’ rights

The Regulation 1866/2015 has four Annexes that establish the detailed rules for the implementation of EU regulation 511/2014 relating to two main items, EU collection Register, and due diligence declaration.

The EU collection register (Annex 1) has to contain mandatory information: a registration code assigned by the Commission; the name given to the collection or part thereof and its contact details; name and contact details of the holder; category and short description of the collection or part thereof. Moreover, it is mandatory to provide the link to database, if this exists, and the competent authority of the Member State that verified the capacity of the collection to comply with Article 5(3) of Regulation No 511/2014.

³³ For a casistic analysis, see C. GODT, *Enforcement of Benefit-Sharing Duties in User Countries*, in E. CHEGE KAMAU, G. WINTER (eds.), *Genetic Resources, Traditional Knowledge & the Law: Solutions for Access and Benefit Sharing*, London, 2009, 419-438.

Therefore, the request for inclusion in the register of collections has to contain detailed information on the holder of the collection and a brief description of the collection or the relevant part thereof.

Holders of collections included in the EU Register of Collections have the obligation to supply genetic resources and related information only with appropriate documentation (PIC and MAT where applicable) and to keep records of all samples of genetic resources and related information supplied to third persons for their utilisation.

Non-mandatory information can also be presented in the request for inclusion: particularly, codes of conduct, guidelines or standards, whether national or international, developed by associations or organisations, and adhered to by the collection, and information relating to the collection's instruments for the application of those codes of conduct, guidelines or standards.

The second main item of the Regulation is the due diligence declaration. Two alternative protocols can be followed to complete this step.

In the first one, at the stage of research funding, the diligence declaration shall be made to the competent authority of the Member State in which the research is carried out.

The due diligence declaration shall be made by submitting the completed template set out in Annex II, Regulation 1866/2015. It shall be made after the first instalment of funding has been received and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded research have been obtained, but no later than at the time of the final report, or in absence of such report, at the project end. National authorities specify the time of submission for such declarations.

Where the same research project is funded by more than one source or involves more than one recipient, the recipients may decide to make only one declaration. As correctly done in the VEG-ADAPT project, that declaration shall be submitted by the project co-ordinator to the competent authority of the Member State in which the project co-ordinator is established.³⁴ If the project co-ordinator is not established in the Union and the research is carried out in the Union, the due diligence declaration shall be made to the competent authority of one of the Member States in which the research is carried out.³⁵

In the second one, the due diligence declaration is performed at the final development stage of a product. For the utilisation of genetic resources and traditional knowledge associated with genetic resources users shall make the due diligence declaration pursuant to Article 7(2) of Regulation (EU) No 511/2014 to the competent authority of the Member State in which the user is established. That declaration shall be made by submitting the completed template set out in Annex III to Regulation under discussion.

³⁴ This is one of the case studies in the VEG-ADAPT project: in compliance with the regulations above, a National Gene Bank replies to the declaration with the permission to send tomato seed samples abroad, which show performance in accordance with stress conditions caused by climate change, to VEG-ADAPT project partners.

³⁵ In Italy the national authorities responsible for the application of Regulation are the Ministry of the Environment and the Land and Sea Protection, the Ministry of Economic Development, the Ministry of University and Research, the Ministry of Agricultural, Food and Forestry Policies and the Ministry of Health, each within its own competence, as well as the Regions in relation to research activities financed through own funds and EU Structural and Investment Funds. In Italy the ABS National Focal Point is the Officer Directorate General for Natural Heritage, Ministry for Ecological Transition.

Therefore, it is important to know which is the information transmission method.

In accordance with Regulation 511/2014, and unless the information is confidential according to Regulation 511/2014, the competent authorities shall transmit the information received to the ABS Clearing House on the basis of Part A of Annexes II and III to this Regulation. This needs to be done without undue delay and, at the latest, one month after the information has been received.

Where essential information is confidential, the competent authorities shall, instead, consider transmitting that essential information directly to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol.

Another central question is how to demonstrate due diligence. First, due diligence can be demonstrated with reference to an internationally recognised certificate of compliance (IRCC) which is either issued for the user in question, or the user can rely on it because the particular utilisation is covered by the terms of the IRCC (in accordance with Regulation 511/2014). Parties to the Nagoya Protocol, that have regulated access to their genetic resources, have the obligation to provide an access permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, and if they notify that permit to the ABS Clearing House, it becomes an IRCC. Thus a national permit of access granted by a Party to the Protocol becomes an internationally recognised certificate when it is notified by that Party to the ABS Clearing House (see Article 17(2) of the Protocol). The reference to an IRCC also needs to have complementary information on the content of the MAT relevant for subsequent users, where applicable.

The duty to apply due diligence is not in conflict with the ongoing use of material protected under the UPOV plant breeders' rights regime and which comes from Parties to The International Union for the Protection of New Varieties of Plants.

The International Union for the Protection of New Varieties of Plants (UPOV) and the Council Regulation (EC) No 2100/94 on Community Plant Variety Rights provide for the possibility to obtain plant variety rights. These are a special type of intellectual property rights in the context of plant breeding.³⁶ There are some limitations to the effects of plant variety rights, inter alia, they do not extend to acts carried out privately and for non-commercial purposes. Moreover they do not extend to acts carried out for experimental purposes and to acts carried out for the purpose of breeding, or discovering and developing other varieties (Article 15 of Regulation (EC) No 2100/94, corresponding to Article 15(1) of the UPOV Convention).³⁷ The UPOV Convention does not constitute a specialised ABS instrument in the meaning of Article 4(4) of the Protocol. However, the Nagoya Protocol makes it clear – and the EU ABS Regulation confirms this (see Recital 14) – that it should be implemented in a manner which is mutually supportive with other international agreements,³⁸ provided they are supportive of and do not run counter the objectives of the Convention on Biological Diversity and the Nagoya Protocol. Furthermore, Article 4(1) of the Protocol provides that it does not affect the rights and obligations derived from existing international agreements (if they do not pose a serious damage or

³⁶ K. R. SRINIVAS, *Intellectual property rights and bio commons: open source and beyond*, in *International Social Science Journal (ISSI)*, 58, 188, 2006, 319-334, at 323, <https://bit.ly/3dJzHOR> (last visited 23/07/2022).

³⁷ This is known as the "breeders' exemption". See G. WÜRTEMBERGER, P. VAN DER KOIJ, B. KIEWIET, M. EKVAD, *European Union Plant Variety Protection*, Third Edition, London, 2021, 148-163, at 161.

³⁸ A. K. GUPTA, *Study on the role of intellectual property rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge*, UNEP-WIPO, 2005.

threat to biological diversity). The EU ABS Regulation is respectful of UPOV obligations: the compliance with the duties stemming from the Regulation is not in conflict with the UPOV obligation to provide for the breeders exemption. In other words, the duty to apply due diligence is not in conflict with the ongoing use of material protected under the UPOV plant breeders' rights regime and coming from Parties to UPOV (see Guidelines 2021 on application of core obligations of EU Regulation).³⁹

Usually, varieties of plant are used in research and development for non-commercial use. It is noted above that crossing and selection (including cases of unintentional mutation) are considered to involve research, and development of either parental materials or offspring, or alternatively of the source and selected microbiological stocks. Where genetic resources falling within the scope of the EU ABS Regulation are introduced for the purpose of crossing and selection, the resulting research and development falls within the scope of the EU ABS Regulation, which triggers due diligence obligations. Such obligations may concern activities undertaken by many actors, including private breeding companies, public research institutions, farmer-breeders and hobby breeders.

It is also important to know how the use of commercial plant varieties is regulated.

A commercial plant variety refers to any plant variety that has been (legally) placed on the market, whether still available on the market or not. Plant varieties developed for agriculture and horticulture commonly require registration in the EU Common Catalogues or in the national or regional catalogues/registers of Member States prior to their commercialisation. For plant varieties subject to intellectual plant variety protection or commonly known, there is a requirement for a denomination and description in these catalogues/registers. For some varieties, such as for ornamental species, registration of varieties prior to their commercialisation is not required. Suppliers nevertheless have to keep lists with the denomination and a detailed description of all plant varieties they place on the market. Such lists need to describe how a particular variety differs from the other varieties most closely resembling it. When a variety is subject to plant variety protection (PVP), or is commonly known, there is no requirement for an additional denomination and detailed variety description, as this already was part of the PVP registration process.

Many plant varieties are also subject to intellectual property protection under the Community Plant Variety Rights regime or by a national plant variety rights system, both based on the international UPOV Convention (including ornamental species). Some varieties may also have traits that are patent-protected or have been bred using processes protected by patents. Both forms of intellectual property rights protection (patent and plant variety system) involve a detailed registration of the protected plants or varieties, and their properties. When a variety is subject to compulsory registration prior to market access official tests are performed by, or under control of, Member States authorities to verify its characteristics as distinct, uniform and stable.⁴⁰ Such tests are carried out as one of the preconditions for registration. The same type of tests take place when a variety is subject to intellectual property protection under Community or national Plant Variety Rights scheme based on

³⁹ OFFICIAL JOURNAL OF THE EUROPEAN UNION, 12 January 2021, C 13.

⁴⁰ For interesting input, see T. HENNINGER, *Disclosure requirements in patent law and related measures: a comparative overview of existing national and regional legislation on IP and biodiversity*, in *Triggering the Synergies between Intellectual Property Rights and Biodiversity*, Eschborn, Germany, *Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ)*, 2010.

the UPOV Convention. Major field crops also require additional testing in the context of Variety Cultivation and Use. For agricultural landraces and varieties which have naturally adapted to local and regional conditions, and for vegetable landraces and varieties which have been traditionally grown in particular localities and regions, with no intrinsic value for commercial crop production, specific EU directives apply (Commission Directives 2008/62/EC and 2009/145/EC respectively).

A commercial plant variety should thus be understood as a plant variety made available on the market, with systems in place for its identification and characterisation, if legally protected by a plant variety right in accordance with the provisions of Council Regulation (EC) No 2100/94 or in accordance with national provisions. We have the same result when the variety has been registered in a national or common catalogue of varieties of agricultural plant and vegetable species, or in a list or register of forest reproductive material, fruit or vine varieties. A user (plant breeder) developing a new variety using material in the scope of the EU ABS Regulation (i.e. material from a Nagoya Protocol country with enacted ABS legislation, accessed after its entry into force etc.) is subject to due diligence obligations in line with Article 4 of the EU ABS Regulation. Likewise, the user needs to submit a due diligence declaration under Article 7(2) of the Regulation prior to the registration of such a variety or it being placed on the market.

Further use of a commercial variety that has been legally placed on the EU market for subsequent breeding programmes does not fall within the scope of the EU ABS Regulation, as the subsequent breeder relies on a new and different genetic resource, different from the initial genetic resource (accessed under the Nagoya Protocol and in scope of the EU ABS Regulation).⁴¹ When a variety is entered in one of the European Catalogues or in a national catalogue or a register of Member States, or when it is indicated on a list of varieties with an official or officially recognised denomination and description, it is considered to be a new variety different from existing varieties of common knowledge. Moreover, when a new variety is protected by a plant variety right according to the UPOV Convention, including under Regulation (EC) No 2100/94 on Community Plant Variety Rights, it is considered to be novel and distinct from existing commercial varieties or varieties of common knowledge. Further use in subsequent breeding programmes of varieties that have been protected by a plant variety right according to the UPOV Convention, including varieties having obtained protection by a plant variety right according to the UPOV Convention also in a country outside of the EU, is thus considered to be out of scope of the EU ABS Regulation, as the breeder who uses a plant variety that has been protected by a plant variety right relies on a new and different genetic resource, which is sufficiently different from parental genetic resources used to create the protected variety according to UPOV requirements.

Consequently, no due diligence obligation applies, and no due diligence declaration is required with regard to breeding activities involving the use of varieties that have been legally commercialised in the EU and/or protected by a plant variety right according to the UPOV Convention inside or outside of the EU.

It should be noted, however, that benefit-sharing obligations may apply to further use of a commercial plant variety depending on the contractual obligations made with a provider country by the initial user and passed on to subsequent users and such obligations, where they exist, need to be re-

⁴¹ G. WÜRTEMBERGER, P. VAN DER KOOIJ, B. KIEWIET, M. EKVAD, *op.cit.*, at 15.

spected.⁴² All registered conservation varieties are included in the national catalogues of varieties in accordance with the provisions of Commission Directive 2009/145/EC and Commission Directive 2008/62/EC. In line with the definition of a commercial plant variety (see above), the use of such varieties included in the national catalogues for further breeding activities is not covered by the scope of the EU ABS Regulation.

5. Implementation of the regulatory framework in user countries

It is known that the European Regulations become enforceable immediately as law in the UE Member States, as do the ABS legal instruments.⁴³ Regarding several non-EU States, VEG-ADAPT project partners, with an extraordinary variety of ecosystems, it should be noted that Jordan and Morocco are parties of Nagoya, but Turkey is not a party.⁴⁴ Nevertheless Turkey has ratified the International Treaty on Plant Genetic Resources, as have Morocco and Jordan. Regarding EU States, VEG-ADAPT project partners, they confirm the declaration made at adoption concerning the interpretation of Article 12.3.d of the International Treaty on Plant Genetic Resources as recognising that plant genetic resources for food and agriculture or their genetic parts or components which have undergone innovation may be the subject of intellectual property rights provided that the criteria relating to such rights are met.

In Italy the decree no. 179 of 2019 reorganized the Ministry of Agricultural, Food and Forestry Policies in three departments: the European and International Policies and Rural Development Department is competent for the enforcement of EU Regulation 511/2014 and, consequently, for the Nagoya Protocol.

Subsequently to the infringement procedure, Italian legislative Decree 153/2020 contains the sanctions pursuant to Article 11 of EU Regulation 511/2014.⁴⁵

The decree identifies the authorities in charge of supervising, ascertaining and imposing sanctions, which correspond to the competent national authorities responsible for the application of the regulation itself. Namely, these are the Ministry of the Environment, Land and Sea Protection, the Ministry of Economic Development, the Ministry of University and Research, the Ministry of Agricultural,

⁴² Recently see M.E. DULLOO (ed.), *Plant genetic resources. A review of current research and future needs*, Cambridge, 2021, 3 seq.

⁴³ B. COOLSAET, F. BATUR, J. PITSEYS, T. DEDEURWAERDERE, *Implementing the Nagoya Protocol. Comparing Access and Benefit-sharing Regimes in Europe*, 3, Leiden, Boston, 2015.

⁴⁴ F. BATUR, *The Legal Regime of Genetic Resources in Turkey: Opportunities for Access and Benefit-Sharing*, in B. COOLSAET, F. BATUR, J. PITSEYS, T. DEDEURWAERDERE, *op cit.*, 227-242, at 240.

⁴⁵ The decree provides for penalties for subjects who: in the absence of an internationally recognized certificate of compliance, or similar documentation, use or transfer to subsequent users genetic resources or traditional knowledge associated with these resources; do not fulfil the obligation to stop using genetic resources, in the event that the information in their possession is insufficient or uncertainties persist about the legality of access and use; acquire a genetic resource that is or can be a pathogenic cause of an international health emergency, without fulfilling the obligation to interrupt the activities following the exceeding of the terms indicated in the regulation. Moreover, penalties have been provided for subject who do not fulfil the obligations to keep information and documents on the access and use of genetic resources; in the final development phase of a product made through the use of genetic resources or traditional knowledge associated with them, they do not fulfil the obligations of declaration and transmission of documentation required by the regulation.

Food and Forestry Policies and the Ministry of Health, each within its own competence. As well as the Regions in relation to research activities financed through their own funds and European Structural and Investment Funds.

The administrative penalties for breach of due diligence obligations (articles 4 and 7 of EU Regulation 511/2014) are established by article 2 of the Regulation with a minimum penalty of five thousand euro up to fifteen thousand euros.

By Ministerial Decree of 19 February 2021, the Directorate General for Ministry of Universities and Research was divided into seven offices. Office VII of Agreements and financing programs of consortia, foundations and private research bodies is the competent national authority, responsible for the application of the compliance measures for users resulting from Nagoya Protocol and EU Regulation 511/2014 in research. It keeps relations with other national competent authorities and carries out the supervision and monitoring of user compliance activities, as a control point. It also imposes the administrative sanctions provided for by the legislative decree 26 October 2020, n. 153, in cases of violation of the provisions of EU Regulation 511/2014.

Greece signed the Nagoya Protocol on September 2011.⁴⁶ The EU Regulation 511/2014 was issued on 16 April 2014 and became immediately enforceable as law. Greece is currently in the process of issuing the necessary legal acts to implement the Nagoya Protocol and EU Regulation.

Spain also has ratified the Nagoya Protocol on 2011 and it defined the National local points provided by the ABS Regulation. However, already fifteen years ago, it adopted an important law on biodiversity, that is law no. 42/2007 *del Patrimonio Natural y de la Biodiversidad*.⁴⁷

Germany signed the Nagoya Protocol on June 2011. The Länder play an important role in preserving biological diversity because of their responsibility for nature conservation and landscape management.⁴⁸ Several Länder have developed their own biodiversity strategies or action plans and programmes relating to biodiversity.⁴⁹ A municipal alliance for biodiversity was founded at the start of 2012.

France stands out for its effective adaptation since 2016 when it adopted a virtuous set of regulations for compliance to Nagoya and for environmental protection.⁵⁰

⁴⁶ E. A. MARIA, G.P. LIMNIOU, *Legal Framework in Greece Regarding the ABS Regime, Implementation Gaps and Issues Requiring National and International Attention*, in B. COOLSAET, F. BATUR, J. PITSEYS, T. DEDEURWAERDERE, *op.cit.*, 137-161.

⁴⁷ See article 71, law no. 42/2007. Recently, L. C. SILVESTRI, *Access and Benefit-Sharing Regime of Spain: Striking the Right Balance Between Its Interests as a Provider and a User of Genetic Resources*, in E. CHEGE KAMAU (ed.), *Global Transformations in the Use of Biodiversity for Research and Development*, *cit.*, 445-462.

⁴⁸ L. O. RODRÍGUEZ, M. DROSS, K. HOLM-MÜLLER, *Access and Benefit-Sharing in Germany*, in B. COOLSAET, F. BATUR, J. PITSEYS, T. DEDEURWAERDERE, *op.cit.*, 115-136.

⁴⁹ T. GREIBER, E. FREDERICH, *First Experiences in the Implementation of the EU ABS Regulation in Germany*, in E. CHEGE KAMAU (ed.), *Global Transformations in the Use of Biodiversity for Research and Development*, *cit.*, 525-546.

⁵⁰ C. CHIAROLLA, *Commentary on the ABS Provisions of the Draft Biodiversity Law of France*, in B. COOLSAET, F. BATUR, J. PITSEYS, T. DEDEURWAERDERE, *op.cit.*, 77-114. Thus, in 2017, three new national collections (i.e. dozens of plant varieties), managed by *l'Institut national de la recherche agronomique* (INRA), are deposited in the multilateral system provided by the International Treaty on Plant Genetic Resources for Food and Agriculture: 80 varieties of eggplant, 603 varieties of oats and 36 varieties of triticale. These varieties will be available to all interested research and breeding users on an international basis. This new deposit brings to seven the number

By 2015, the Nagoya Protocol is nationally adopted in Jordan where the Ministry of Environment took on its responsibility to advance national capacities to fulfil the obligation of the Nagoya Protocol.

By 2013, the Nagoya Protocol is nationally adopted in Morocco. This country is currently setting up the national legislative and institutional framework for the implementation of Nagoya Protocol, in order to generate potential additional resources for the conservation, sustainable use of biodiversity and the fight against poverty.

Turkey is not a party of the Nagoya Protocol. In Turkey, the National Biodiversity Strategies and Action Plans (NBSAP) has been updated twice. The NBSAP 2018-2028,⁵¹ containing a new working schedule, entered into force with approval by the Ministry of Agriculture and Forestry, and includes recent action plans based on the country's biodiversity politics. Nowadays the National Biodiversity Coordination Council has been established for effective implementation of the Biodiversity Convention.

6. The Nagoya Protocol towards an intra-generational solidarity

At present, in Europe, there are no cases of violation of Nagoya and not even any sanctions have been imposed. The application discipline is rather recent and, nowadays, the research bodies are moving in the direction of compliance to the Nagoya Protocol.

From the study conducted,⁵² it has been discussed that the Nagoya Protocol, and the EU Regulations that implement it, are the central component for the sustainable use of genetic resources to preserve ecosystem goods (e.g. food) and ecosystem services (e.g. water supply) which are fundamental for humanity. In this framework, genetic resources are identified and exchanged for research for conservation purposes as well as wanting to benefit the agri-food sector.

In the context of agronomic selection (to cope with climate change and with agricultural raw materials contraction), the protection of biological diversity is fundamental and requires solidarity between present and future generations. To this end, it is strategic that citizens, businesses and public authorities take responsible decisions towards the common good of the environment: an important example is the recent Nature Restoration Law, a proposal introduced on 22 June 2022 by the European Commission. The law proposal would require EU Member States revive ecosystems and conserve biodiversity marred by human development.⁵³

For that reason, the sustainable management of resources for agri-food systems needs to achieve the procedures to make the system of genetic resource exchanges more efficient and effective in the interest of present and future generations.

of collections deposited by France in the multilateral system since 2005 (eggplant, oats, soft wheat, fodder, corn, potato and triticale) when France became part of FAO Treaty on Plant Genetic Resources for Food and Agriculture.

⁵¹ See <https://cdniys.tarimorman.gov.tr/api/File/GetGaleriFile/417/DosyaGaleri/426/ubep-ingilizce.pdf> (last visited 23/07/2022).

⁵² Since VEG-ADAPT project, Adapting Mediterranean Vegetable Crops to Climate Change-induced Multiple Stress: see note 4.

⁵³ European Commission, COM(2022) 304 final 2022/0195 (COD), Brussels, 22.6.2022.

The rules of food and agriculture must have a view to security, safety and adequacy,⁵⁴ passing through the local and traditional production system.⁵⁵

Ecosystem protection involves intra-generational responsibility.⁵⁶ Thus, on the one hand, it requires equity in the distribution of the outcomes of development within one generation at both inter and intra state level.⁵⁷ On the other hand, people living today have an inter-generational right of equitable access to use and benefit from the natural resources: this right derives from the equality among all generations.

It is thus necessary to enhance an ethics of responsibility that significantly takes in future generations,⁵⁸ called to sharing life in an environment in which the possibility of using natural resources is preserved, with a quality that is acceptable to the whole community.

With this in mind, the objective of the Nagoya Protocol is unambiguous in requiring fairness and equity in benefit-sharing arising from the use of genetic resources held by indigenous peoples and local communities and from the use of their traditional knowledge.

It therefore remains to be seen in future practice when implemented how Parties of the MTA can balance contractual freedom of private parties with the need to achieve fair and equitable benefit-sharing in the light of the objectives of the Protocol.

As a final point, it can be observed that EU ABS Regulations are still new legal instruments which require a little bit more time and implementation experiences to reach their full operationalization.

⁵⁴ There are growing efforts underway to transform agrifood systems to ensure that the rising global population has access to food that is nutritious, safe and affordable. FAO, 2022. *Thinking about the future of food safety – A foresight report*, www.fao.org/3/cb8667en/cb8667en.pdf (last visited 23/07/2022).

⁵⁵ Within the production system, local productions are very important. By involving local institutions and citizens, especially the youngest, a community of food and biodiversity is promoted: see Italian law no. 30 of 2022.

⁵⁶ “In many instances, however, the actions needed to achieve intragenerational equity are consistent with those advancing intergenerational equity”, E. BROWN WEISS, *In Fairness To Future Generations and Sustainable Development*, in *American University International Law Review*, 8, 1, 1992, 19-26, at 22-23. Available at <https://digitalcommons.wcl.american.edu/auilr/vol8/iss1/2/> (last visited 19/08/2022).

⁵⁷ V. BARRAL, *Sustainable development and equity in biodiversity conservation*, in E. MORGERA, J. RAZZAQUE (eds.), *Biodiversity and Nature Protection Law*, Cheltenham, 2017, 59-69.

⁵⁸ E. BROWN WEISS, *op.cit.*, at 25 remarks that the “most important strategy is to give representation to the interests of future generations in decision-making processes, including the market. The decisions we make today will determine the initial welfare of future generations, but they are not effectively represented in our decision-making processes. Future generations might be willing to compensate present generations to prevent certain actions or to have us undertake others if they had a way of voicing their preferences. This representation has to take place in several forms: in administrative decision-making, judicial decision-making, and most importantly, in the marketplace”.