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Accessing biological control genetic resources and sharing benefits resulting from their utilization

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Abstract With the adoption of the Convention on Biological Diversity (CBD) in 1992, the sovereign rights of states over their natural resources were explicitly recognized and the authority of national governments to determine access to genetic resources confirmed. The CBD had a major impact on the global exchange of genetic resources, including genetic resources for food and agriculture. At national level, the CBD triggered the development of access and benefit-sharing (ABS) measures through which governments aim to enforce national sovereignty over genetic resources with the aim to partake in the benefits derived from the use of these resources. At global level, the CBD triggered multiple normative initiatives, including the adoption of an international instrument on plant genetic resources and the development of a Protocol to the CBD. The history of the Commission on Genetic Resources for Food and Agriculture, established in 1983 by the Food and Agriculture Organization of the United Nations (FAO), is paradigmatic for the historical transition from "common heritage" to "national sovereignty" over biological diversity, including genetic resources. This article briefly recapitulates key milestones in the development of ABS policies and measures. The article identifies some of the difficulties ABS measures may create for relevant stakeholders, in particular the biological control sector and explores options for this sector to cope with the new reality of the Nagoya Protocol and the diversity of national ABS measures. It is of pivotal importance that national governments when developing and implementing ABS measures take into account the distinctive needs and features of the food and agriculture sector, including those of the biological control sector.

Keywords Access and benefit-sharing (ABS) · Nagoya Protocol · Food and Agriculture Organization of the United Nations · Commission on Genetic Resources for Food and Agriculture · International Treaty on Plant Genetic Resources for Food and Agriculture

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Introduction

Many agricultural stakeholders have not paid much attention to the development of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol 2010) and relevant national measures. New rules on access and benefit-sharing (ABS) that have been and still are being developed by

governments have therefore taken many agricultural stakeholders by surprise. In many countries, their views have neither been actively sought, nor have their interests and practices been taken into account in the development of national ABS measures, although these measures may have significant impact on these stakeholders, be they plant or animal breeders, geneticists or entomologists developing biological control strategies. Although governments, in designing their ABS measures, may choose from a wide range of options, ABS measures in practice often require significant changes in the way researchers access and exchange genetic materials, including cumbersome contractual negotiations over the modalities of benefit-sharing. ABS measures may also contain specific requirements to record the legal status and the exchange of genetic resources to facilitate documentation and allow competent authorities to monitor compliance with relevant ABS obligations.

The Nagoya Protocol itself, by explicitly recognizing "the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions" (Nagoya Protocol, Preamble recital 15), appears to suggest that a one-size-fits-all model does not do justice to all the different sectors of research and development involving genetic resources. The Protocol is open to the development of specialized international ABS arrangements. It does not prevent Parties "from developing and implementing other relevant international agreements, including other specialized ABS agreements, provided that they are supportive of and do not run counter to the objectives of" the Convention on Biological Diversity (CBD) and the Nagoya Protocol (Nagoya Protocol, article 4.2). For genetic resources for food and agriculture (GRFA), the Protocol explicitly requires Parties to consider "in the development and implementation of its access and benefit-sharing legislation or regulatory requirements […] the importance of genetic resources for food and agriculture and their special role for food security" (Nagoya Protocol, 8c).

The Protocol, however, does not indicate how the distinctive features of GRFA may or should be reflected, be it in national or international ABS instruments. Most national ABS measures therefore do not distinguish between GRFA and other genetic resources, except for plant genetic resources for food and agriculture (PGRFA) for which a special regime exists: the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty) (FAO 2001), negotiated between 1993 and 2001 by the FAO Commission on Genetic Resources for Food and Agriculture (Commission).

From "common heritage" to "national sovereignty"

International Undertaking on Plant Genetic Resources: plant genetic resources as common heritage

Since its establishment in 1983, the Commission has been dealing with the topic of access to GRFA and the fair and equitable sharing of benefits derived from their utilization. In 1983, the Conference of the Food and Agriculture Organization of the United Nations (FAO) adopted the International Undertaking on Plant Genetic Resources (International Undertaking) (FAO 1983a), which was based on the "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction" (International Undertaking, article 1). The International Undertaking, as stated in the accompanying Conference Resolution, recognized plant genetic resources as "heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations" (FAO 1983b). At the time of its adoption, the International Undertaking was the only international (even though non-binding) instrument specifically dealing with the collection, conservation and global exchange of GRFA. The Commission was tasked with overseeing the operation of the Undertaking and providing advice on relevant policy matters (FAO 1983c).

During subsequent years, the Commission played an active role in providing interpretations of the International Undertaking. The Commission recognized, on the one hand, that granting plant breeders' rights for newly bred varieties of plants was not inconsistent with the International Undertaking and, on the other hand, endorsed the concept of Farmers' Rights, meaning "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the International Community, as trustee for present and future generations of farmers, for

the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions, as well as the attainment of the overall purposes of the International Undertaking" (FAO 1989a, b). Anticipating the outcome of the 1992 United Nations Conference on Environment and Development and, more specifically, the adoption of the CBD and following wide-ranging and intensive discussions and negotiations among countries, the FAO Conference, in 1991, finally accepted that the wind had turned and agreed that "the concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the states over their plant genetic resources" (FAO 1991). The FAO Conference recognized that "nations have sovereign rights over their plant genetic resources" (FAO 1991).

The CBD recognizes the sovereign rights of states over their natural resources and explicitly states that the authority to determine access to genetic resources rests with national governments and its subject to national legislation (CBD, article 15.1). It also stipulates that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources (CBD, article 15.5) and that access, where granted, shall be on mutually agreed terms (CBD, article 15.4). Following the adoption of the CBD, the FAO Conference gave the Commission the go-ahead for the adaptation of the International Undertaking and, after more than seven years of negotiations, was able to adopt the first legally binding and fully operational international instrument for ABS for a genetic resource: the Plant Treaty.

Plant Treaty: facilitating access and benefit-sharing through a multilateral system

Recognizing the sovereign rights of states over their own PGRFA, including the authority of national governments to determine access to these resources, Contracting Parties to the Plant Treaty agreed "in the exercise of their sovereign rights" (Plant Treaty, article 10.2), to establish a Multilateral System of Access and Benefit-sharing (MLS). While the Plant Treaty applies to all PGRFA (Plant Treaty, article 2), its MLS covers PGRFA of 35 crops and 29 forages that are listed in Annex I to the Plant Treaty. Contracting Parties to the Plant Treaty are required to provide "facilitated access" to PGRFA within their jurisdiction, provided that these are under their management and control and in the public domain. Other holders of PGRFA are invited and shall be encouraged by Contracting Parties to also include PGRFA in the MLS (Plant Treaty, articles 11.2, 11.3). The MLS also covers materials held by international institutions that formally agree to bring these materials under the MLS (Plant Treaty, article 15). In particular, PGRFA held in the *ex situ* collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research, including PGRFA that are not listed in Annex I to the Plant Treaty are included in the MLS (Plant Treaty, articles 11.5, 15.1). Some Contracting Parties and other holders also provide "facilitated access" to Non-Annex I crops.

PGRFA qualifying for "facilitated access" of the MLS, may be accessed freely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses (Plant Treaty, article 12.3a). Recipients of PGRFA from the MLS are bound by a so-called Standard Material Transfer Agreement (SMTA), which sets out in detail the terms and conditions for the use of the materials and the sharing of resulting benefits, including benefits resulting from commercial use. Benefits shall be shared fairly and equitably through information exchange, technology transfer and the sharing of benefits arising from commercialization. The SMTA also requires those who receive PGRFA under an SMTA to transfer them to other persons or entities only under the same conditions under which they received them. Thus, the initial providers and recipients as well as subsequent recipients of PGRFA are bound by the standardized terms and conditions of the SMTA (Plant Treaty, article 12.4). In short, the MLS facilitates ABS by determining ABS modalities for all the genetic resources to which it applies. Efforts to enhance the functioning of the MLS, including by increasing the benefits that it generates and expanding the crops and plant genetic diversity available through the MLS, are currently underway (FAO 2022).

Nagoya Protocol: operationalizing the Convention on Biological Diversity

The objectives of the CBD are "the conservation of biological diversity, the sustainable use of its

components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of technologies, taking into account all rights of those resources and to technologies, and by appropriate funding" (CBD, article 1). By reasserting the right of states to regulate access to their genetic resources and requiring recipients of genetic resources to share the benefits arising from their use, the CBD aims to encourage Parties to conserve and make available genetic resources. To this end the CBD stipulates, as mentioned before, that access to genetic resources be subject to prior informed consent of the Contracting Party providing such resources (CBD, article 15.5) and requires that access, where granted, shall be on mutually agreed terms (CBD, article 15.4).

However, quite a number of countries, obviously unsatisfied with the benefits generated through the CBD (or, where existent, national ABS measures adopted in the follow-up), started to call in the early 1990s for legally binding international ABS rules. While multiple reasons may have motivated these calls, an actual or alleged lack of compliance with national ABS measures was time after time identified as one of them (Greiber et al. 2012).

In 2002, when the World Summit on Sustainable Development agreed to launch negotiations of an "international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources" (United Nations 2002) compliance with national ABS measures was high on the agenda. The 'ABC' of ABS was considered: access, benefit-sharing and compliance (Davis and Borisenko 2017).

After six years of negotiations, governments agreed in 2010 on a supplementary agreement to the CBD: the Nagoya Protocol. The Protocol identifies specific obligations countries have with regard to access to genetic resources and associated traditional knowledge, the sharing of benefits derived from them and with regard to compliance. A key component of the Protocol are its provisions on compliance measures. Every Party to the Protocol has to take "appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party" (Nagoya Protocol, article 15.1). It is important to note that these "user country measures" focus on the compliance of users of genetic resources with relevant access requirements of the providing Party. To the extent that disputes arise between providers and users over the terms and conditions (or, in the language of the Protocol, the "mutually agreed terms") of the use of genetic resources, the Protocol relies on principles and rules of private international law and requires Parties to ensure "that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements […]" (Nagoya Protocol, article 18.2).

According to the Protocol, benefits arising from the utilization of genetic resources, as well as subsequent applications and commercialization, have to be shared fairly and equitably. "Utilization of genetic resources" means, according to the Protocol, "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in article 2 of the CBD"(Nagoya Protocol, article 2c).

Access and benefit-sharing and biological control

As early as in 2009, in anticipation of the Nagoya Protocol, the Commission considered the use and exchange of GRFA, including of biocontrol agents and the possible impact of ABS measures on use and exchange practices (Cock et al. 2009). Since then, the possible implications national ABS measures may have on the exchange and use of biocontrol agents have been widely studied (Cock et al. 2010; Barratt et al. 2017; Smith et al. 2017; Mason et al. 2018; Smith et al. 2018; Silvestri et al. 2020; van Lenteren 2021; Buitenhuis et al. 2023), including through a recent survey targeted at the biological control community, including providers and recipients of biological control agents, those assessing risk, and those releasing and conducting follow-up monitoring (Mason et al. 2023a).

Perhaps the most frequent complaint of many user communities, including the biological control community, is the lack of legal certainty (Silvestri et al. 2020). Even though legal certainty was one of the key

goals of the creators of the Nagoya Protocol, it seems that national ABS measures have not delivered on this goal hitherto. One reason for this is that the Protocol neither contains any obligations to make genetic resources available, if certain conditions are met, nor does it in any way define the concept of fair and equitable benefit-sharing. In other words, the Nagoya Protocol does not provide a harmonized framework for ABS. Instead, while not ruling out the standardization of ABS conditions, it continues to rely, like the CBD, on the freedom of contract, the liberty of providers and recipients of genetic resources to agree case by case on the conditions for access and the modalities of benefit-sharing. While the Nagoya Protocol requires national ABS measures to comply with the so-called 'international access standards', such as legal certainty, predictability and transparency (Nagoya Protocol, article 6.3), the Protocol does not confer any right to access genetic resources once specific conditions are met, and it refrains from providing guidance on how benefits should be shared, leaving it up to providers and recipients of genetic resources to reach consensus on 'mutually agreed terms'.

Another reason for the lack of legal certainty is the inevitable "large variety across the globe in the scope of ABS laws as well as in the procedures to secure ABS compliance" (Michiels et al. 2022). While the impact of ABS measures may still be limited in some areas, such as the livestock sector (Martyniuk 2021), various user communities regularly complain about the variability of ABS measures, their complexity and the fact that, given the relative novelty of most of these measures, competent authorities are frequently reluctant to take decisions on matters for which there is no precedent. Users find it often difficult to receive accurate information on the applicable law and procedures and often wait extended periods of time for administrative decisions (see, e.g., Neumann et al. 2018; Silvestri et al. 2020).

The complexity and variability of ABS measures is not surprising given their usually very broad scope of application. Most ABS measures apply to all or at least most sectors using genetic resources for research and development, including non-commercial research, the pharmaceutical industry, plant and animal breeding, food production, biotechnology, agriculture, fragrance and cosmetics, and pest control, and most ABS measures treat them, notwithstanding their differences, in more or less the same way, with the exception of the plant breeding sector to the extent it benefits from the Plant Treaty rules. ABS measures may vary considerably, in their scope and focus, depending on whether countries are primarily providers of genetic resources or extensively import genetic resources for research and development purposes.

The biological control community faces a number of specific problems with the reality of ABS. For various activities that typically form part of research and development in biocontrol agents, it is often not clear if or under which circumstances they trigger ABS obligations. It may be unclear, for example, whether the collection, export or taxonomic identification of the pest or of the natural enemies, by morphological or molecular analysis, qualify as "utilization" and therefore trigger ABS obligations, i.e., the requirement to obtain prior informed consent of the country the organism originates from and to share eventual benefits with that country. Similarly, rearing, culturing/multiplication of biocontrol agents or optimizing rearing or culturing conditions may trigger ABS obligations in one country (because of their potential to impact the genetic composition of the biocontrol agent) and not trigger such obligations in another (as long as the genetic changes are unintentional) (European Commission 2021; Department for Environment, Food & Rural Affairs 2022).

A key characteristic of biological control research is the typical involvement of multiple countries at all the different stages. Taxonomic identification often takes place in countries different from the country where the pest or natural enemy originated. Following the usual environmental risk assessments, biocontrol agents may be circulated to many different countries affected by the pest (Cock et al. 2010). One and the same biocontrol research project may under these circumstances require multiple ABS permits by multiple countries.

In most countries, genetic resources that have been accessed and used prior to the entry into force of the Nagoya Protocol (or the CBD) fall outside the scope of the ABS measure (Humphries et al. 2021). But there are countries where benefit-sharing obligations may apply to such genetic resources, for example if they are marketed for newly discovered uses (Winter and Kamau 2022).

A review of national ABS measures indicates that many countries have selected a single competent national authority for the administration of their ABS

measures, rather than taking a sectoral or subsectoral approach. Most countries have selected environmental, natural resources or science/technology authorities as their competent national authority for ABS matters even when dealing with GRFA (Humphries et al. 2021). While some of the difficulties with the implementation of ABS measures may be typical teething problems that any new legislation may eventually face, especially legislation addressing a field previously unregulated, policymakers and stakeholders, including the biological control community, have every reason to consider possible remedies.

Accommodating the distinctive features of the biological control sector

Various options, including those the Nagoya Protocol explicitly refers to, are available to ensure that the distinctive features of the different sectors using genetic resources for research and development are taken into account in the process of developing ABS measures (or guidelines for their implementation). For all these approaches, it is important to: (1) assess the distinctive features of the subsectors concerned; (2) identify and consult relevant stakeholders; (3) integrate ABS measures with broader policy strategies, such as food security or sustainable development strategies; (4) consider and evaluate the options that exist for the design of ABS measures; (5) integrate the implementation of ABS measures in the existing regulatory landscape in a way that transaction costs are minimized; (6) communicate ABS measures to users and providers of genetic resources; and (7) test *ex ante* and monitor the effectiveness and impact of ABS measures (FAO 2019).

The first option is to identify possibilities to adapt ABS measures and/or administrative practices and procedures for their implementation to the special nature and the distinctive features of biological control research and development. This is the approach taken by the Commission when it prepared the ABS Elements (FAO 2019). The ABS Elements guide governments in developing and implementing ABS measures in a way that reflects the importance of GRFA and accommodates their distinct features. They stress the importance of establishing clear and transparent rules and encourage policy and decision makers to consider the different options they have to adjust ABS measures to the special needs and distinctive features of the different subsectors of GRFA. They may, for example, consider excluding specific GRFA or activities involving GRFA from the scope of their ABS measures and/or providing for simplified or standardized ABS arrangements for specific GRFA or related activities and supporting the conclusion of broad framework agreements that cover a whole range of research activities, including capacity building, knowledge and technology transfer, rather than just the exchange of specific genetic resources.

A second option, as envisaged by the Nagoya Protocol, is the development of model clauses or guidance documents for ABS (Nagoya Protocol, articles 19 & 20). Various organizations, including the International Organization for Biological Control (IOBC) have made remarkable efforts in this regard (Mason et al. 2018). The Access and Benefit-sharing Clearing-House of the CBD identifies 33 different documents in the category of "Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards" (ABS Clearing-House 2023). In 2021, the European Commission issued a (revised) guidance document on the scope of application and core obligations of its Regulation (EU) No. 511/2014 on compliance measures for users of genetic resources. The document provides quite detailed guidance on research activities in the area of biological control (European Commission 2021). However, whether such clauses and guidelines will ultimately be used largely depends on countries with ABS measures in place and on the willingness of their competent authorities to accept the suggested clauses and to follow the codes of conduct, guidelines and best practices and/or standards.

A third option, likewise envisaged by the Nagoya Protocol, is the development of a specialized ABS agreement for biological control genetic resources (Mason et al. 2023b). The Nagoya Protocol states explicitly that it does not prevent Parties from developing and implementing other international agreements, including other specialized ABS agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and the Protocol (Nagoya Protocol, article 4.2). Contracting Parties to the Nagoya Protocol have not yet agreed on criteria for specialized ABS instruments (Convention on Biological Diversity 2022a). While there seems to be currently no political appetite to

negotiate a specialized international ABS agreement for biocontrol agents, this option should not be completely discarded. Special international ABS rules may be the outcome of the ongoing negotiations of an international legally binding instrument 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. Specialized ABS rules for pathogens and genomic sequences may also be contained in the World Health Organization (WHO) convention, agreement or other international instrument on pandemic prevention, preparedness and response, which the second special session of the World Health Assembly initiated in December 2021 (Halabi 2023). If ABS measures develop into a major obstacle for the exchange and use of biocontrol agents, and if due to ABS measures accidentally exported pests, diseases and weeds invade new regions in the world because their naturally occurring biocontrol agents in their country of origin can no longer be exchanged, studied and released in affected areas (van Lenteren 2021), the development of a specialized international agreement is an option to be considered (Waage 2007). Various specialized organizations, including FAO with its Commission on Genetic Resources for Food and Agriculture, come to mind as potential discussion fora. Obviously, the future prospects of sectoral or specialized ABS rules may also depend on the outcome of the negotiations of the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, initiated in December 2022 by the Conference of the Parties to the CBD (Convention on Biological Diversity 2022b).

In the meantime, the awareness of policy and decision makers of the importance of biological control and the exchange of biocontrol agents needs to be raised and the biological control community should be encouraged to organize biological control research and development in an "ABS-friendly", collaborative way. ABS may become part and parcel of research and business collaborations that are much broader in scope, more comprehensive and more strategic than the discussions on ABS rules sometimes insinuate. Collaboration, capacity-development and continuous exchange of knowledge are the 'ABC' of ABS.

Declarations

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