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منظمة  
الأمم المتحدة  
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# COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

## Item 7 of the Provisional Agenda

### AD HOC INTERGOVERNMENTAL TECHNICAL WORKING GROUP ON AQUATIC GENETIC RESOURCES FOR FOOD AND AGRICULTURE

#### Second Session

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### PROCEEDINGS OF THE INTERNATIONAL WORKSHOP ON ACCESS AND BENEFIT-SHARING FOR GENETIC RESOURCES FOR FOOD AND AGRICULTURE

- Preliminary version -



Proceedings of the  
**International Workshop on  
Access and Benefit-sharing  
for Genetic Resources for  
Food and Agriculture**

Preliminary version

# Contents

Meeting report.....	1
<b>Opening remarks</b>	
<i>René Castro Salazar</i> .....	4
<i>Irene Hoffmann</i> .....	6
<i>Kathryn Garforth</i> .....	8
<i>Kent Nnadozie</i> .....	9
<b>INTRODUCTION</b>	
<b>An Introduction to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization</b> .....	11
<i>Kathryn Garforth</i>	
<b>The Multilateral System of Access and Benefit-sharing</b> .....	17
<i>Daniele Manzella</i>	
<b>Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture</b> .....	28
<i>Dan Leskien</i>	
<b>COUNTRY IMPLEMENTATION AND EXPERIENCES</b>	
<b>National Focal Point Survey on Access and Benefit-sharing for Genetic Resources for Food and Agriculture</b> .....	36
<i>Sélim Louafi and Eric Welch</i>	
<b>Namibia’s Access and Benefit-Sharing and Associated Traditional Knowledge Law</b> .....	50
<i>Pierre du Plessis</i>	
<b>Access and Benefit-sharing Legislation in Malaysia</b> .....	55
<i>Gurdial Singh Nijar</i>	

<b>Regulation (EU) No 511/2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union</b> .....	59
<i>Elzbieta Martyniuk and Alicja Kozłowska</i>	
<b>National Implementation of Access and Benefit-sharing in Brazil</b> .....	73
<i>Henry Philippe Ibanez de Novion and Letícia Piancastelli Siqueira Brina</i>	
<b>Proposed Regulations on Access and Benefit-sharing for Biological and Plant Genetic Resources of Lebanon</b> .....	81
<i>Lamis Chalak</i>	
<b>Regulating Access and Benefit-sharing in Australia</b> .....	94
<i>Brad Sherman and Jocelyn Bosse</i>	

# Meeting report

## OPENING OF THE MEETING

The International Workshop on Access and Benefit-sharing for Genetic Resources for Food and Agriculture (Workshop) was held in Rome, Italy from 10 to 12 January 2018. The meeting was organized by the Secretariat of the Commission on Genetic Resources for Food and Agriculture (Commission) in collaboration with the Secretariats of the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty) and the Convention on Biological Diversity (CBD).

Mr William Wigmore (Cook Islands), Chair of the Commission, welcomed participants. He reminded the participants that the Commission, at its last session, requested the Secretariat to convene, in collaboration with the Secretariats of the Treaty and the CBD, an “international workshop to assist countries to identify and raise awareness of distinctive features and specific practices of subsectors of genetic resources for food and agriculture in the context of the Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture (ABS Elements)”<sup>1</sup>. He also noted that the Commission had agreed to produce non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture (GRFA), to complement the ABS Elements and that it had mandated the Workshop to provide outputs for subsequent elaboration into non-prescriptive explanatory notes.

Mr René Castro Salazar, Assistant Director-General, Climate, Biodiversity, Land and Water Department, FAO, opened the meeting. Mr Castro Salazar welcomed participants; he noted that access to GRFA and the fair and equitable sharing of benefits derived from these genetic resources are at the heart of FAO’s and the Commission’s mandates. He stressed that benefit-sharing is equally important as it provides an important incentive as well as a reward for the conservation and sustainable use of genetic resources. He pointed out that the workshop provided not only a forum for participants to exchange information, experiences and views but would also contribute to providing outputs for the subsequent elaboration of non-prescriptive explanatory notes describing the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture.

Ms Irene Hoffmann, Secretary of the Commission, thanked participants for attending the meeting and provided a brief history of the Commission’s work on access and benefit-sharing (ABS). She stressed that the workshop was a meeting to exchange views, to brainstorm, to listen to each other and to develop a better understanding of ABS. She echoed the comments made by Mr Castro Salazar and reiterated that the Commission is committed to ABS as well as to the sustainable use and conservation of genetic resources for food and agriculture.

Ms Kathryn Garforth, Programme Officer, Nagoya Protocol Unit, Convention on

<sup>1</sup> <http://www.fao.org/3/a-i5033e.pdf>

Biological Diversity, welcomed participants and conveyed her keenness with regard to the outcomes from the workshop and how they would allow for the further elaboration of explanatory notes to the ABS Elements. She encouraged participants to share their experiences in order to be able to draw on those experiences and better understand how ABS and genetic resources for food and agriculture are related to one another.

Mr Kent Nnadozie, Secretary, International Treaty on Plant Genetic Resources for Food and Agriculture, expressed his gratitude for the continued collaboration with the Commission and the Convention on Biological Diversity. He noted that ABS remains a fundamental area of work and that the programme of the workshop features an ideal combination of multi-disciplinary and multi-sectoral expertise that combines the presentation of progress of the international frameworks with the review of selected national experiences with ABS implementation.

### **SESSION I: INTRODUCTION**

The first session provided an introduction to the Nagoya Protocol, the Treaty and the ABS Elements. Ms Kathryn Garforth, Programme Officer, CBD gave an introduction to 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). This was followed by Mr Daniele Manzella, Technical Officer, Treaty who provided an introduction to the Treaty. Mr Dan Leskien, Senior Liaison Officer, Commission presented the ABS Elements. .

### **SESSION II: COUNTRY IMPLEMENTATION AND EXPERIENCES**

The second session was devoted to country implementation of ABS measures and related experiences. Mr Sélim Louafi, Senior Research Fellow, CIRAD, France, and Mr Eric Welch, Professor and Director of the Center for Science, Technology & Environmental Policy Studies, Arizona State University, United States of America presented first results of a country survey on ABS for GRFA. Mr Pierre du Plessis, Senior Consultant, Centre for Research Information Action, Namibia presented Namibia's Access and Benefit-Sharing and Associated Traditional Knowledge Law. Mr Gurdial Singh Nijar, former Professor of Law, University of Malaya, Malaysia, then presented the access and benefit-sharing legislation of Malaysia, followed by Ms Elzbieta Martyniuk, Professor of Warsaw University of Life Sciences/ Professor of the National Research Institute of Animal Production, Poland, who presented the Regulation (EU) No 511/2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

The session continued the following day with a presentation by Mr Henry Philippe Ibanez de Novion, Director of the Genetic Heritage Department, Vice-President of the ABS National Competent Authority-CGEN, Ministry of Environment, Brazil, on the national implementation of access and benefit-sharing in Brazil. He was followed by Ms Lamis Chalak, Professor, Faculty of Agronomy, The Lebanese University, Head of the National Committee for Plant Genetic Resources, Ministry of Agriculture, Lebanon who presented

the proposed regulations on access and benefit-sharing for biological and plant genetic resources of Lebanon. Mr Brad Sherman, Professor of Law, Australian Research Council Laureate Fellow, University of Queensland, Australia, presented the access regime of Australia for biological and genetic resources.

### **SESSION III: ACCESS AND BENEFIT-SHARING AND THE DISTINCTIVE FEATURES OF GENETIC RESOURCES FOR FOOD AND AGRICULTURE**

During the third session, participants considered the document *Developing non-prescriptive explanatory notes, describing within the context of the ABS Elements the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture.*<sup>2</sup> Participants identified distinctive features of the different subsectors of GRFA and areas in which the ABS Elements required subsector-specific explanation or clarification. The work was done in five working groups (Animal Genetic Resources; Aquatic Genetic Resources; Forest Genetic Resources; Micro-organisms and Invertebrate Genetic Resources; and Plant Genetic Resources).

### **SESSION IV: CLOSURE OF THE MEETING**

During the final session, the working groups reported back the distinctive features of the different subsectors of GRFA and on ABS Elements which required subsector-specific explanation or clarification. The outputs of the working groups will be made available to the Commission's intergovernmental technical working groups. The outputs will also be used for elaboration into draft non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of GRFA. The Commission's intergovernmental technical working groups will review and revise, as appropriate, the draft explanatory notes, for consideration by the Commission's Team of Technical and Legal Experts on Access and Benefit-Sharing and the Commission.

In a short closing address, Ms Hoffmann thanked participants for their valuable contributions. She noted that there are still many knowledge gaps and the need to learn more. She concluded that ABS is complicated, and even more so when considered in conjunction with GRFA. It was, however, important for the Commission and its Members to continue working on ABS for GRFA. She also expressed gratitude to all participants and speakers for their great work in making this workshop a success.

Mr William Wigmore thanked all speakers for their presentations, the Secretariat for the preparation of the workshop and all the participants for having taken the time to attend and contribute to the meeting.

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<sup>2</sup> <http://www.fao.org/3/I9052EN/i9052en.pdf>



# Opening remarks

*René Castro Salazar*

*Assistant Director-General, Climate, Biodiversity, Land and Water Department, Food and Agriculture Organization of the United Nations*

Excellencies,  
Distinguished Guests,

It is a great pleasure to **welcome** you to this International Workshop on Access and Benefit-Sharing for Genetic Resources for Food and Agriculture .

This workshop is being **convened at the request of FAO's Commission** on Genetic Resources for Food and Agriculture in collaboration with the Secretariats of the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture.

The workshop forms part of the Commission's work programme on access and benefit-sharing (ABS) and it serves multiple purposes:

- It provides a **forum for participants to exchange information, experiences and views** on the important topic of access and benefit-sharing for genetic resources for food and agriculture. For this purpose the Commission invited countries and stakeholders to report on their experiences in implementing national ABS measures related to genetic resources for food and agriculture and some countries have kindly agreed to report today and tomorrow on their experiences.
- The Commission also requested this workshop to provide outputs for subsequent elaboration into "**non-prescriptive explanatory notes** describing, within the context of the Commission's so-called ABS Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture, the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture". The "non-prescriptive explanatory notes" may complement the ABS Elements.

During this workshop, experts and stakeholders representing the five different "subsectors", as the Commission calls them, will have the opportunity to consider the distinctive features of animal, aquatic, forest, plant, micro-organism and invertebrate genetic resources and to go through the ABS Elements with a view to identify issues that would benefit from clarification or more detailed explanation.

Access to genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from these genetic resources are at the heart of FAO's and the Commission's mandates. Access is key for agricultural development and adaptation. The term "agriculture" includes, according to FAO's Constitution, not only plants and animals, but also fisheries, marine products, forestry and primary forestry products.

Benefit-sharing is equally important as it provides an important incentive as well as a reward for the conservation and sustainable use of genetic resources.

However, sometimes the devil is in the details and I hope this workshop may contribute to address some of the complexities and specificities of ABS for genetic resources for food and agriculture.

When I was serving as Minister of the Environment in my home country, Costa Rica, I was informed that a new species was discovered in Costa Rica basically every single day. I suggested at that time that one could offer individuals to name a new species against payment. Many scientists, at that time, considered this as a breach of taboo, a terrible faux pas. It is indeed interesting to see how this debate has evolved over the years.

Before I end, I would like to thank very much the Secretariats of the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture who agreed to collaborate with the Commission Secretariat in the convening of this workshop. The Commission, the Treaty Governing Body and the Conference of the Parties of the CBD have stressed on numerous occasions that collaboration among them on this and many other issues is crucial if we want to make progress in mainstreaming biodiversity for food and agriculture. The workshop is another milestone in our collaboration.

Last but not least, I want to thank all of you for attending and contributing to this workshop.

I wish you successful deliberations over the next three days and I thank you for your attention.

*Irene Hoffmann*

*Secretary, Commission on Genetic Resources for Food and Agriculture, Food and Agriculture  
Organization of the United Nations*

Excellencies,  
Distinguished Guests,

Welcome to the International Workshop on Access and Benefit-sharing for Genetic Resources for Food and Agriculture!

The Commission's history is closely intertwined with the history of access and benefit-sharing (ABS) for genetic resources. In fact, the International Undertaking on Plant Genetic Resources of 1983 made reference to many of the issues addressed by later ABS instruments and to a number of issues that we are still discussing today, possibly even at this meeting.

Today, the Commission, according to its mission, very officially “strives to halt the loss of genetic resources for food and agriculture, and to ensure world food security and sustainable development by promoting their conservation and sustainable use, including exchange, access and the fair and equitable sharing of the benefits arising from their use”.

ABS is neither new for the Commission, nor has it become obsolete with the successful conclusion of the revision of the International Undertaking and the adoption of the International Treaty on Plant Genetic Resources that, as you all know, operates under the guidance of its Governing Body and is administered by the Treaty Secretariat.

Very soon after the adoption and entry into force of the Treaty, the Commission realized that there may still be work to be done in the area of access and benefit-sharing. At its Tenth Session in 2007, the Commission recommended that “FAO and the Commission contribute to further work on ABS, in order to ensure that it move in a direction supportive of the special needs of the agricultural sector, in regard to all components of biological diversity of interest to food and agriculture”. This started a process that ultimately generated the ABS Elements, which the Commission and the FAO Conference welcomed in 2015.

While the Commission and the Conference welcomed the ABS Elements, there was a general sentiment that more could be done to make the ABS Elements more useful, more relevant to the subsectors of animal, aquatic, forest, micro-organism and invertebrate and plant genetic resources.

This workshop will allow us to look at the distinctive features and practices of the

different subsectors of genetic resources for food and agriculture within the context of the ABS Elements. You will hear from the experiences of countries with the establishment and implementation of ABS measures and you will have the opportunity to discuss how explanatory notes could improve the ABS Elements, and make them more useful for policy- and decision-makers.

This workshop is not a formal and it is not a negotiating meeting. It is a meeting to exchange views, to brainstorm, to listen to each other and to develop a better understanding of ABS on the one hand, and of the distinctive features and practices of our subsectors on the other.

Based on the outputs of this workshop, explanatory notes to the ABS Elements will be elaborated for review by the Commission's Working Groups, the group of seven experts on micro-organism and invertebrate genetic resources, the ABS Expert Team and, ultimately, the Commission.

The Commission is committed to ABS and it is equally committed to the sustainable use and conservation of genetic resources for food and agriculture. Policies to achieve these three objectives have to be in harmony with each other and this is the ultimate goal of the Commission's work on ABS.

*Kathryn Garforth*

*Programme Officer, Secretariat of the Convention on Biological Diversity*

Good morning, everyone,

It is a great pleasure to see so many of you here this week ready to discuss access and benefit-sharing (ABS) and genetic resources for food and agriculture.

The Secretariat of the Convention on Biological Diversity was very pleased when the 16th Session of the Commission on Genetic Resources for Food and Agriculture agreed to the convening of this international workshop on access and benefit-sharing and we were happy to collaborate with the Secretariat of the Commission and the Secretariat of the Treaty in organizing this event.

We have been participating in the Team of Technical and Legal Experts on Access and Benefit-sharing and are very much looking forward to seeing the outcomes of the discussions this week and how these will help to elaborate upon the ABS Elements.

One of the strengths of the Nagoya Protocol is its flexibility. It allows and indeed encourages different sectors to develop tools that take into account the specific practices of the sector and how these relate to the three pillars of the Protocol on access, benefit-sharing and compliance.

I believe that the work that will be undertaken here this week will be very valuable in identifying the practices of these different subsectors of genetic resources for food and agriculture. I encourage everyone to participate openly and share your experiences from these different perspectives as this will help to inform the functioning of ABS in the context of genetic resources for food and agriculture.

I would also like to mention that we are receiving encouraging information through the interim national reports on implementation of the Nagoya Protocol. The majority of countries have indicated that they are aware of the special considerations associated with genetic resources for food and agriculture and are taking these into account in the development of their access and benefit-sharing measures. I will elaborate on this a little bit later on during my presentation in the session that follows.

Finally, I would just like to conclude by thanking Irene and her colleagues in the Secretariat of the Commission. While this workshop has been organized in collaboration with us and with the Secretariat of the Treaty, it has been the colleagues at the Secretariat of the Commission that have been doing the heavy lifting in preparing the documents and raising the necessary funds for this workshop.

I look forward to fruitful and interesting deliberations in the days to come.

Thank you very much.

*Kent Nnadozie*

*Secretary, International Treaty on Plant Genetic Resources for Food and Agriculture*

Many thanks to colleagues in the Commission, the Secretariat of the Convention on Biological Diversity and participants

The presence of the Treaty at this workshop continues a long tradition of close cooperation and coordination with the Commission, at both the Secretariat and intergovernmental levels, and on both technical and policy matters.

As we all know, the Treaty was negotiated under the aegis of the Commission and, even though the formal governance is now largely separate, programmatic and operational synergies are numerous and flourishing, based on the reciprocal guidance of the respective governing bodies.

Thanks to FAO management, which has brought the Commission and the Treaty under the same department, these synergies will continue growing and will be set in the broader context of sustainable agriculture contributing to achieving the Sustainable Development Goals (SDGs).

As this workshop signifies, ABS remains a fundamental area of work for both the Commission and the Treaty. Although the specificities of genetic resources for food and agriculture (GRFA) and plant genetic resources for food and agriculture (PGRFA) in particular are the drivers of our work, we operate in the framework of an international access and benefit-sharing (ABS) regime, and representing the needs and practices of agriculture within the international governance framework is a mission that brings together the Commission and the Treaty, and indeed FAO as a whole.

### **The relationship with the Nagoya Protocol**

For the Treaty, the relationship with the Nagoya Protocol is vital to ensure mutually supportive implementation. The relationship with the Convention on Biological Diversity (CBD) (and by extension, its Nagoya Protocol) is entrenched in the Treaty text and is, essentially, constitutional.

On the other hand, the Protocol obliges Contracting Parties to consider, in the development and implementation of their ABS legislation or regulatory measures, “the importance of genetic resources for food and agriculture and their special role for food security”. The Parties that adopted it recognized the International Treaty as one constituent of the international ABS regime, in harmony with the CBD.

Furthermore, in the context of profound restructuring of the global policy framework, in the aftermath of the 2030 Development Agenda and the SDGs, the environmental and

agricultural constituencies now share the common goal of advancing ABS on practicable, realistic and equitable grounds.

I am delighted to note that the programme of this workshop features an ideal combination of multi-disciplinary and multi-sectoral expertise, and combines the presentation of progress with international frameworks with the review of selected national experiences with ABS implementation.

ABS is transaction-based and its governance needs management at multiple levels. Although the International Treaty is one example of collective and multilateral management of a subset of GRFA, the role of governments and the ensuing domestic instruments remains fundamental for ABS implementation. Equally fundamental remains the analysis and review of subsector practices and normative tools, including in areas such as the management of information/data, which have not been part of the ABS discourse so far but whose relevance to realizing the objective of ABS is getting recognition.

ABS has precise legal foundations and tools. However, to stay relevant, it needs to cater for new political and technological realities. In other words, it needs to continually evolve and adapt. The Treaty perfectly symbolizes this. The Multilateral System, which in its ten years of existence has resulted in an enormous flow of plant germplasm, to advance research and breeding, and in four rounds of the Benefit-Sharing Fund for a total capitalization of over USD 20 million, is undergoing an enhancement process that is developing a comprehensive package of measures, aimed at increasing user-based payments and consolidating non-monetary benefits.

As this process is still ongoing, this meeting and any relevant follow-up will need to take this into account in order to avoid duplication and pre-emption. However, in the course of the negotiations for the enhancement and related processes, many submissions and views have been received from multiple stakeholders and I hope that this considerable body of experience will be useful to the present meeting.

I am eager to listen to and learn more from the experts who will present in the course of the workshop. Representatives of the Secretariat will also contribute to the breakout groups and I am sure that in such a positive environment we will continue fostering mutual learning, understanding and coordination.

# An Introduction to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

*Kathryn Garforth*

*Programme Officer, Secretariat of the Convention on Biological Diversity*

## **ABSTRACT**

Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization is the third objective of the Convention on Biological Diversity. The Convention's provisions on access and benefit-sharing have now been elaborated in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which entered into force in October 2014. The Protocol's provisions rest on three pillars: access, benefit-sharing and compliance. The Protocol also contains a number of linkages to genetic resources for food and agriculture.

## **INTRODUCTION**

The conservation and sustainable use of biological diversity are among the most pressing issues that the world currently faces. The Convention on Biological Diversity (CBD) was negotiated to address biodiversity in a comprehensive manner rather than focusing on specific ecosystems or species and was one of the first international treaties to reflect principles of sustainable development by integrating environmental, economic and social considerations

The Convention has three objectives:

- the conservation of biological diversity;
- the sustainable use of its components; and
- access to genetic resources and the fair and equitable sharing of benefits arising from their utilization.

The CBD was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development – the Rio “Earth Summit”. It entered into force 18 months later – December 1993 – and now has near universal membership with 196 Parties.

As will be explored below, the issue of access to genetic resources and benefit-sharing (ABS) has continued to evolve under the Convention and the linkages between ABS and genetic resources for food and agriculture remain very relevant.



## **THE CBD AND ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING**

As described, the third objective of the Convention concerns access to genetic resources and benefit-sharing. Article 15 of the Convention addresses this aspect in more detail. Paragraph 1 of the Article recognizes the sovereign rights of States over their natural resources and provides that the authority to determine access to genetic resources rests with national governments and is subject to national legislation. This marked a shift in international law. Previous instruments addressing ABS, particularly the International Undertaking on Plant Genetic Resources adopted by the Conference of the Food and Agriculture Organization of the United Nations in 1983, considered genetic resources to be the common heritage of humankind.<sup>1</sup>

By considering genetic resources subject to the sovereign rights of States, the CBD introduced an equity dimension whereby States grant access to genetic resources in exchange for fair and equitable benefit-sharing arising from their use.

While the CBD establishes the basis for ABS, many countries had difficulties implementing its provisions. There were also difficulties with allegations of misappropriation of genetic resources and associated traditional knowledge and ensuring that mutually agreed terms were being complied with. A number of Parties to the Convention thus advocated for the development of an international regime on ABS.

As a result, the Conference of the Parties to the Convention, at its seventh meeting in 2004, mandated its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) of the Convention and its three objectives (CBD, 2011).<sup>2</sup> The result of these negotiations was the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which was adopted by the Conference of the Parties of the Convention at its tenth meeting in Nagoya, Japan, in October 2010.<sup>3</sup> The Protocol entered into force in October 2014 and has received 105 ratifications to date.<sup>4</sup>

The Protocol elaborates the equity relationship of the Convention by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources and thus builds trust between users and providers of genetic resources and associated traditional knowledge. It does this through establishing more predictable conditions for access to genetic resources and helping to ensure benefit-sharing when genetic resources leave the country of origin.<sup>5</sup> By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

<sup>1</sup> FAO, *International Undertaking on Plant Genetic Resources*, UN FAOOR, 22nd Session, UN Doc. C/83/REP (1983).

<sup>2</sup> See decision VII/19 D, especially paragraph 1, <https://www.cbd.int/decision/cop/?id=7756>.

<sup>3</sup> Decision X/1.

<sup>4</sup> As of February 2018.

<sup>5</sup> <https://www.cbd.int/abs/about/default.shtml/>

## **NAGOYA PROTOCOL**

The Nagoya Protocol sets out core obligations for its Contracting Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance.

### **Access**

The first pillar of the Protocol is access obligations. Under both the Convention and the Protocol, access to genetic resources is subject to the prior informed consent (PIC) of the provider country, unless otherwise determined by that country. The Nagoya Protocol's provisions on access go beyond those in the CBD by providing for the establishment of clear and transparent procedures for access and thereby responding to the concerns of users of genetic resources with respect to the need for greater legal certainty.

### **Benefit-sharing**

The second pillar is benefit-sharing obligations. The Protocol requires that benefits are to be shared in a fair and equitable way with the Party providing the genetic resources. The Protocol also specifies that it is benefits "arising from the utilization of genetic resources as well as subsequent applications and commercialization" that are to be shared. The term "utilization of genetic resources" is defined in the Protocol to mean "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 Convention".<sup>6</sup>

To share benefits, the provider and user of the genetic resource must negotiate an agreement, known as mutually agreed terms (MAT). Benefits may be monetary or non-monetary, such as royalties and the sharing of research results. The Protocol includes an annex with an indicative list of different types of monetary and non-monetary benefits.

### **Compliance**

The third pillar of the Protocol is compliance obligations. The Protocol's provisions on compliance are one of its key innovations that are intended to support benefit-sharing once genetic resources have left the provider country and are being utilized in another country. The Protocol creates specific obligations to support compliance with the domestic legislation or regulatory requirements of the Party providing genetic resources, and the contractual obligations reflected in MAT. In addition, it creates a system for monitoring the utilization of genetic resources, which is undertaken through the establishment of checkpoints and through the internationally recognized certificate of compliance. Parties are to establish at least one checkpoint in order to monitor the utilization of genetic resources.

The Protocol also establishes an Access and Benefit-sharing Clearing-House for the sharing of information on ABS. The ABS Clearing House (<https://absch.cbd.int>) is a key tool for facilitating the implementation of the Nagoya Protocol, by enhancing legal certainty and transparency on procedures for access and benefit-sharing and for

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<sup>6</sup> Nagoya Protocol, Art. 2(c). "Biotechnology" is defined in the Convention to mean "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

monitoring the utilization of genetic resources along the value chain, including through the internationally recognized certificate of compliance.

Parties to the Protocol must publish certain information in the ABS Clearing-House including information on their national focal points and competent national authorities, ABS measures and permits issued at the time of access. Information on a permit that is published in the ABS Clearing-House constitutes an internationally recognized certificate of compliance which serves as evidence that the genetic resource covered by the certificate has been accessed in accordance with PIC and that MAT have been established. Internationally recognized certificates of compliance can be used to provide necessary information to checkpoints thus contributing to the monitoring of the utilization of genetic resources.

A fully functional ABS Clearing House was launched in 2014 with the entry into force of the Protocol. The first internationally recognized certificate of compliance was issued in October 2015 by India and now more than 100 certificates have been issued. By making relevant information available regarding ABS, the ABS Clearing House facilitates and increases opportunities for users and providers of genetic resources and associated traditional knowledge to connect and create fair and equitable ABS agreements.<sup>7</sup>

### **Indigenous peoples and local communities**

In addition to addressing genetic resources, the Protocol also addresses traditional knowledge associated with genetic resources. It includes provisions on access to such knowledge, benefit-sharing from the use of such knowledge and compliance with measures on such knowledge. It also encourages the development of community protocols on access to traditional knowledge associated with genetic resources and benefit-sharing.

The Protocol also addresses genetic resources where indigenous peoples and local communities have the established right to grant access to the resources. Parties are to take measures with the aim of ensuring that the PIC of indigenous peoples and local communities is obtained for access to genetic resources where they have the established right to grant access and that the benefits arising from the utilization of genetic resources held by indigenous peoples and local communities are shared in a fair and equitable way.<sup>8</sup>

## **LINKAGES BETWEEN THE NAGOYA PROTOCOL AND GENETIC RESOURCES FOR FOOD AND AGRICULTURE**

The Nagoya Protocol includes a number of linkages to broader issues such as genetic resources for food and agriculture, poverty alleviation, climate change, and domestic research and innovation capacity. Several of the Protocol's preambular paragraphs refer to genetic resources for food and agriculture and acknowledge the importance of genetic resources to food security and the special nature of agricultural biodiversity. For example, the preamble highlights the links to food security, sustainable development of

<sup>7</sup> <https://www.cbd.int/abs/theabsch.shtml>

<sup>8</sup> <https://www.cbd.int/abs/about/default.shtml/>. See in particular Art. 5(2), 6(2) and 7 of the Protocol.

agriculture, poverty alleviation and climate change.<sup>9</sup> It also includes a specific reference to the International Treaty on Plant Genetic Resources for Food and Agriculture and the Commission on Genetic Resources for Food and Agriculture in the context of their roles in achieving food security.

Article 8 of the Protocol addresses special considerations and in subparagraph (c), Parties to the Protocol are required, in the development of their ABS measures, to consider the importance of genetic resources for food and agriculture and their special role for food security.

Information on Article 8(c) is currently being received through the interim national reports on the implementation of the Nagoya Protocol. In examining the responses, the majority of countries, about 68 percent, responded positively, i.e. that they have considered the importance of genetic resources for food and agriculture and their special role for food security in the development and implementation of their national ABS frameworks.<sup>10</sup>

A number of countries provided additional information on the steps they are taking to implement Article 8(c). For example, Mongolia indicated that it is developing a law on animal genetic resources for animal husbandry and awareness raising actions on the importance of genetic resources are planned. Norway stated that its pending access regulations will not cover use and further breeding or cultivation in agriculture or forestry. Switzerland explained that plant and animal breeders have the possibility to simplify the notification procedure that is part of the country's ABS measures.

In addition, Article 4 addresses the relationship between the Protocol and other international agreements and instruments. Paragraph 3 states that the Protocol is to be implemented in a mutually supportive manner with other relevant international instruments. It provides that due regard should be paid to useful and relevant ongoing work or practices under such instruments and relevant international organizations, provided they are supportive of and do not run counter to the objectives of the Convention and the Protocol. Paragraph 4 of Article 4 states that the Protocol is the instrument for the implementation of the ABS provisions of the Convention. Where a specialized international ABS instrument applies that is consistent with, and does not run counter to, the objectives of the Convention and the Protocol, then the Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resources covered by and for the purpose of that specialized instrument.

At the second meeting of the Parties to the Protocol, held in Cancun, Mexico, in December 2016, the Parties requested the Secretariat of the CBD to commission a study to explore criteria that could be used to identify what constitutes a specialized international ABS instrument and a possible process for recognizing such an instrument. This study is

<sup>9</sup> The Preamble of the Nagoya Protocol recognizes “the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change”. It also acknowledges “the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard”.

<sup>10</sup> See question 35.4 of the format for the interim national reports on the implementation of the Nagoya Protocol, which may be analysed using the national report analyser: <https://absch.cbd.int/reports>

currently underway and will be considered at the second meeting of the Subsidiary Body on Implementation, which will be held in July 2018.

Finally, Articles 19 and 20 of the Protocol, which address model contractual clauses, codes of conduct, guidelines, best practices and standards require Parties to the Protocol to encourage the development, update and use of these different types of tools which can be very valuable in enabling different sectors to identify their practices and shape ABS arrangements for their sectors accordingly. A number of these tools have already been published in the ABS Clearing-House<sup>11</sup> and a stocktaking will be done at the third meeting of the Parties to the Protocol, to be held in November 2018.

## CONCLUSION

By creating legal certainty, clarity and transparency, the Nagoya Protocol will promote the use of genetic resources and associated traditional knowledge. Furthermore, by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biological diversity, sustainably use its components, and further enhance the contribution of biological diversity to sustainable development and human well-being.

## REFERENCES

**CBD (Convention on Biological Diversity).** 2011. *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, Text and Annex*, Montreal, Canada (available at <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>).

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<sup>11</sup> <https://absch.cbd.int/search/referenceRecords?schema=modelContractualClause>

# The Multilateral System of Access and Benefit-sharing

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## **EXECUTIVE SUMMARY**

The Multilateral System of Access and Benefit-Sharing (Multilateral System) was established by State Contracting Parties to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in the exercise of their sovereign rights over genetic resources within their respective territories. In recognition of the need for the continuous flow of plant genetic resources for food and agriculture (PGRFA) on a global scale, based on the interdependence of countries with respect to those resources, the system aggregates a pool of PGRFA and standardizes contractual access and benefit-sharing (ABS) conditions. It decouples monetary benefit sharing from individual providers through the Benefit-Sharing Fund (BSF). Such distinctive features and specific ABS practices regarding PGRFA are recognized through the Multilateral System, in a binding instrument of international law.

The Multilateral System was devised as an ABS mechanism subject to reviews in the course of implementation. At present, the Multilateral System is undergoing a process of enhancement, under the guidance of an open-ended, multi-stakeholder working group established by the Governing Body of the ITPGRFA, primarily in order to improve the generation of income into the BSF, advance the scope and terms of access, and address the implications of digital sequence information on the functioning of the system.

## **INTRODUCTION**

In January 2018, the Secretariat of the Commission on Genetic Resources for Food and Agriculture (Commission) convened, in collaboration with the Secretariats of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Convention on Biological Diversity (CBD), an international workshop to assist countries to raise awareness of distinctive features and specific practices of subsectors of genetic resources for food and agriculture (GRFA) in the context of the *Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture* (ABS Elements). The Commission also agreed to produce non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of GRFA, to complement the ABS Elements.

The ABS Elements recognize the ITPGRFA, and the Multilateral System of Access and Benefit-Sharing (Multilateral System) that the State Contracting Parties to the ITPGRFA have established in the exercise of their sovereign rights over genetic resources, as one component of the international legal framework (Element no. 19). To date, the ITPGRFA has a membership of 144 State Contracting Parties, from all regions of the world.

This information note is intended to contribute to awareness raising and specific recognition of the distinctive features and specific practices regarding PGRFA within the purview of the Multilateral System.

## **RATIONALE OF THE MULTILATERAL SYSTEM**

The Multilateral System is a global gene pool of crops and forages. The gene pool is comprised of samples of genetic material from a set of crops, which are listed in Annex I to the ITPGRFA. Samples are included in the gene pool by the state governments and the institutions that they control. Samples also come into the gene pool from international institutions through agreement as well as from natural and legal persons – i.e. anyone – within the jurisdiction of the Contracting Parties, on a voluntary basis. These samples are pooled in that they are administered under a common set of rules. These rules are contained in the ITPGRFA and further specified in a contractual instrument, namely the Standard Material Transfer Agreement (SMTA). The Multilateral System was created to address the specific features and needs of PGRFA in relation to access and benefit sharing. The Multilateral System is enshrined in the ITPGRFA, the objectives of which are the conservation and sustainable management of PGRFA as well as the fair and equitable sharing of the benefits arising from their use. These objectives are in harmony with the CBD.

Agriculture has always been based on seed exchange. Farmers and farming communities have been swapping their crops, and the genes within their crops, since the beginnings of agriculture. Through 12 000 years of cultivation and exchange, many plant varieties for food and agriculture were, and continue to be, developed. As a result, countries have become interdependent as they all depend very largely for food and agriculture on crops that have originated elsewhere. Agriculture needs an enabling access and benefit sharing system that recognizes interdependence, ensures that genetic resources continue to flow worldwide, and rewards those communities and individuals who conserve and develop those resources.

With the adoption and entry into force 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 respectively in 2010 and 2012, the underpinning reasons for a multilateral system of facilitated access and benefit sharing for PGRFA have been reaffirmed. The special nature of agricultural biodiversity, its distinctive features and the problems needing distinctive solutions are recognized. The interdependence of all countries with regard to genetic resources for food and agriculture, as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change, are also restated. In this regard, the fundamental role of the ITPGRFA is acknowledged, with a specific recognition of the Multilateral System.

## **THE LEGAL BASIS OF THE MULTILATERAL SYSTEM AND ITS SCOPE**

The ITPGRFA sets forth certain obligations for State Contracting Parties with regard to the Multilateral System. Through the exercise of their sovereign rights over plant genetic resources for food and agriculture, the State Contracting Parties have agreed that facilitated access to PGRFA under the Multilateral System will be regulated by the conditions established in the ITPGRFA itself. The State Contracting Parties have also agreed to take the necessary legal or other appropriate measures to provide such facilitated access to other contracting parties as well as to legal and natural persons under their jurisdiction. These obligations are the legal cornerstone of the Multilateral System and set the foundations of a multilateral approach that aggregates a pool of resources under common rules for access and benefit sharing.

These common rules extend to individual transactions. The Multilateral System practically functions through a standard contract between two individuals or legal entities, namely the SMTA. The contract contains rules that apply to individual transfers of these samples (for example, from a gene bank to a breeder) for certain purposes, namely the utilization and conservation for research, breeding and training for food and agriculture. The rules specify not only how to obtain access to the plant genetic material but also how to share the results of research and breeding on that material.

Aggregation and standardization are limited in scope. The Multilateral System covers the PGRFA of the crops and forages that are listed in Annex I to the ITPGRFA and it “contains” – albeit not physically in one place – these resources. The Multilateral System does not include all of the Annex I PGRFA that are in the territory of the contracting parties. It applies only to some of them – namely those that are “under the management and control” of the Contracting Party and those that are “in the public domain”. The fact that governments have not committed to include PGRFA that they do not manage and control does not mean that the Multilateral System’s gene pool is precluded for those resources. The ITPGRFA foresees the possibility for natural and legal entities holding Annex I PGRFA to voluntarily place them in the system. Furthermore, governments have agreed to take measures to encourage those holders to include those resources.

The Multilateral System is not only constituted by PGRFA from national collections and territories, but also “contains” PGRFA that are in the international gene banks of the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). The IARCs have been collecting PGRFA from farmers’ fields for many decades, and have been holding and distributing those PGRFA in trust for the benefit of the international community since 1994. With the advent of the ITPGRFA, the State Contracting Parties have recognized the importance of these collections for the objectives of the ITPGRFA and have called upon the IARCs to make them available under the terms and conditions of the Multilateral System. Through a series of agreements with the Governing Body of the ITPGRFA, Annex I, PGRFA that the IARCs maintain in their gene banks are accessible through the SMTA. The Governing Body authorized the IARCs to also apply the SMTA for distributing non-Annex I PGRFA that were collected before the entry into force of the ITPGRFA. Some State Contracting Parties have also adopted policies to apply the SMTA to some samples of non-Annex I crops and forages.



Not all the uses of PGRFA that are in the Multilateral System are covered by the rules of the system. Facilitated access through the Multilateral System is granted for the purposes of “utilization and conservation for research, breeding and training for food and agriculture” (Article 12.3(a) of the ITPGRFA). Such purposes do not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

## **ACCESS TO PLANT GERMPLASM UNDER THE MULTILATERAL SYSTEM**

Access to PGRFA under the Multilateral System is facilitated in the sense that those who want to access the genetic material in the system do not need to negotiate access agreements on a case-by-case basis with national competent authorities. Instead, the resources are available, currently, at no cost or at minimal administrative cost to anyone who wants them under the SMTA. The text of the SMTA was approved by the Governing Body of the ITPGRFA at its first session in 2006. The terms and conditions of the SMTA have four basic objectives: (i) simplifying access; (ii) creating a chain of SMTAs when the accessed material is transferred by the original recipient to a third party, so that the obligations are passed on to subsequent recipients; (iii) ensuring that access to another sample of the same type and kind remains possible to others under the same terms and conditions; and (iv) recognizing that, once the accessed material is improved by the recipient (for instance, by plant breeding), such a recipient can decide not to make it available to a third party. Thus, access is to be accorded expeditiously, without the need to track individual samples and free of charge. If the recipient conserves PGRFA accessed under the Multilateral System, he or she shall continue to make them available to others. He or she must do so by passing on the same obligations to the subsequent recipients who, in turn, will be bound to the same obligation. The recipient is not allowed to appropriate the received material by claiming intellectual property rights, or other rights that limit the facilitated access to the same material, in the form that it is received from the system. If the recipient changes the material or works on it, he or she will have the discretion of either making or not making the changed material (“PGRFA under development”) available to others. If the recipient decides to transfer the changed material to someone else, he or she will be able to request additional terms and conditions, separate from the SMTA.

## **BENEFIT SHARING UNDER THE MULTILATERAL SYSTEM**

Benefit sharing is attained through monetary and non-monetary benefits. The ITPGRFA recognizes that facilitated access to PGRFA is in itself a major benefit, making it possible for farmers, plant breeders and researchers, in both the public and private sectors, to have access to the widest possible range of PGRFA. The ITPGRFA identifies and makes a provision for a wide range of non-monetary benefit sharing, including the exchange of information, the access to, and transfer of, technology, and capacity building. These forms of benefit sharing are largely based on general obligations of state governments under the ITPGRFA.

With regard to monetary benefits, the recipient has two alternative options for monetary benefit sharing. Under the first option, the recipient pays 0.77 percent on the net sales of the commercialized (and restricted) product for a period corresponding to the duration of such restriction (for instance, 20 years in the case of intellectual property rights-based restrictions).

In the SMTA, this monetary benefit sharing scheme is articulated as follows:

*a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay ... an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment (SMTA, Article 6.7).*

Under the second option, the recipient pays 0.5 percent on the sales of all PGRFA products of the same crop to which the accessed material belongs. In the latter case, the recipient pays regardless of the restrictions for further research and breeding on the products, and for a period of ten years, which is renewable (SMTA, Article 6.11).

Benefits resulting from the use of a PGRFA sample accessed under the SMTA do not go back to the individual provider of the sample. Rather, they pooled and are shared multilaterally and, as such, decoupled from the individual provider.

SMTA-generated monetary benefits flow into a multilateral fund - namely the Benefit-Sharing Fund. This fund is also open to direct contributions from the Contracting Parties, the private sector, non-governmental organizations and other sources, such as institutional donors. Under the ITPGRFA, the state governments agreed that benefits arising from the use of PGRFA that are shared under the Multilateral System would flow primarily to farmers, especially in developing countries, who conserve and use PGRFA in a sustainable manner. Resources in the Benefit-Sharing Fund are under the direct control of the Governing Body, which means that the Contracting Parties decide how much to allocate, to whom and for what, and also how much the fund is expected to capitalize within a certain period of time. In practice, calls for proposals under the Benefit-Sharing Fund are open on a regular basis, so that any governmental or non-governmental organization, including gene banks and research institutions, farmers and farmers' organizations and regional and international organizations, based in countries that are eligible Contracting Parties, may apply for grants.

## **THE CURRENT STATUS OF THE MULTILATERAL SYSTEM**

Implementation of the Multilateral System started in 2007 with the adoption of the SMTA by the Governing Body at its first session in 2006. From 2011, the Multilateral System has been operating with the support of information technology infrastructure, in the form of a Data Store and an online tool to generate SMTAs (namely, Easy-SMTA) and facilitate reporting of transactions by providers. This infrastructure, together with a notification facility for PGRFA holders to communicate the availability of germplasm under the Multilateral System, has enabled the production of aggregated information and statistics on the flow of germplasm through the SMTA, on a biennial basis for the Governing Body and other interested stakeholders. Some real-time statistics and charts on the distribution of PGRFA within the Multilateral System are also available online for consultation.<sup>1</sup>

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<sup>1</sup> <https://mls.planttreaty.org/itt/index.php?r=stats/pubStats>

By way of an example, as of August 2017, the Data Store has recorded 58 971 SMTAs from providers located in 42 countries, distributing material to recipients based in 179 countries. This figure represents an increment of 31 637 SMTAs reported or 53.6 percent since May 2015. The statistical module indicates an average of 38 SMTAs reported per day since May 2015. The analysis of the data contained in the Data Store confirms and consolidates two important trends. The number of SMTAs has constantly increased from the set-up of the Multilateral System until 2011, with a plateau phase following between 2011 and 2013. Since then, the average numbers increased sharply and the reporting figures more than tripled between 2014 and 2016. The reporting figures signify an improved uptake of the SMTA infrastructure and processes and provide a clearer picture of the flow of material in the Multilateral System.

As of August 2017, more than 4.1 million samples of PGRFA had been transferred with the SMTA. The statistics at crop level show that 46 percent of the material reported belong to wheat, 20 percent to rice, 8 percent to maize, 6 percent to barley and 4 percent to chickpea. The availability of material is expected to increase with the recent membership of the United States of America, which holds some of the largest public crop gene bank collections, with approximately 576 600 crop accessions. Authorities have identified the material that is available in the Multilateral System and provided relevant information including on how the material may be accessed by prospective recipients with the SMTA.<sup>2</sup>

Similarly, the implementation of the Global Information System of Article 17 of the ITGRFA through the establishment of Digital Object Identifiers (DOIs) provides more detailed information on the material available under the Multilateral System.<sup>3</sup> DOIs were adopted in 2017 as a new mechanism for Contracting Parties, and natural and legal persons to inform about material available in the Multilateral System in an accurate and reliable way and following internationally agreed standards, in the form of descriptors of individual PGRFA samples that are associated with one or more DOIs. To further facilitate the identification of the material that are in the Multilateral System, the Secretariat has updated Easy-SMTA in order to enable the assignation of a DOI to the material transferred with SMTAs.

With regard to the benefit sharing component of the system, the Benefit-Sharing Fund disbursed funds for 61 technical projects in 55 developing countries for a total of over USD 20 million. The projects have supported the development, testing and use of climate ready crops, resulting in over 3 000 new samples of crop varieties now available to the international scientific and breeding community. At the time of this publication, the call for proposals under the fourth cycle of the Benefit-Sharing Fund had been opened. These projects will further support farmers to sustainably use and conserve adapted crop varieties, leading to increased productivity, more income and nutrient-rich food, as well as enhancing resilience to production shocks and reducing adverse impacts on the environment. The call also emphasizes new partnerships, including bringing technology and knowledge to the

<sup>2</sup> 'Implementation and Operations of the Multilateral System'. IT/GB-7/17/9 (available at <http://www.fao.org/3/a-mu380e.pdf>).

<sup>3</sup> <https://ssl.fao.org/glis/>

community and farm levels, and sustains the role of women in biodiversity management, farming and rural development. Partners of the projects are selected to establish and strengthen linkages between projects and across geographic regions.

In the context of the review of the overall funding strategy for the ITPGRFA, measures are under consideration to strengthen the programmatic approach of the Benefit-Sharing Fund, in order to make the Fund's operations more attractive and predictable to prospective donors and recipients. In particular, the thematic coherence between individual projects, and over project cycles, will be improved and a long-term investment strategy, with objectives, expected results and indicators and an appropriate monitoring and evaluation system, will be developed.

Most of the financial resources have accrued so far through voluntary contributions by donors that are State Contracting Parties and not yet, as was expected in the design of the system, from user-based payments under the SMTA. The fourth call for proposals of the Benefit-Sharing Fund represents a shift in private sector financing of the Fund, with some contributions made by seed industry representative bodies. The need to augment user-based contributions and to improve certain SMTA provisions for the benefits of both providers and recipients, alongside overall policy evolutions of access and benefit sharing with regard to digital sequence information, have led to a process for enhancing the functioning of the Multilateral System.

## **THE ONGOING ENHANCEMENT OF THE MULTILATERAL SYSTEM**

Three reviews of the Multilateral System are provided for within the ITPGRFA.

The Governing Body is mandated to conduct an assessment of progress in the inclusion of germplasm into the Multilateral System by natural and legal persons and take a decision as to whether facilitated access should continue to be granted to those who have not included their germplasm (Article 11.4 of the ITPGRFA).

The Governing Body is also mandated to review the levels of payment that it decided to include in the SMTA with a view to achieving fair and equitable sharing of benefits. In addition, the Governing Body may decide to establish different levels of payment for various categories of recipients who commercialize products; it may also decide on the need to exempt from such payments small farmers in developing countries.

The Governing Body may also assess whether the mandatory payment requirement in the SMTA shall apply also in cases where the commercialized products are available without restriction to others for further research and breeding (Article 13.2 d(ii) of the ITPGRFA).

Together with those three review mechanisms, the ITPGRFA sets forth the possibility of a formal process, equivalent to the one established for amendments to its provisions, to change its Annex I, in particular to expand the list of crops within the purview of the Multilateral System (Article 24.2 of the ITPGRFA).

That the Multilateral System is subject to adjustments based on its progress is witnessed by the in-built reviews of its functioning and scope. However, the Governing Body repeatedly postponed the reviews. In 2013, it decided to consider a comprehensive enhancement of the Multilateral System with the objectives of increasing user-based payments and contributions to the Benefit-Sharing Fund in a sustainable, predictable and

long-term manner, as well as of enhancing the Multilateral System by additional measures. The objectives of the enhancement are thus broader than the two reviews mandated by Article 13.2d(ii) of the ITPGRFA. Accordingly, an intergovernmental open-ended Working Group was established in order to negotiate and make recommendations on the enhancement for the consideration of the Governing Body. The process has advanced with the representation of various stakeholder groups (seed industry, CGIAR, farmer organizations, civil society) and with numerous submissions in writing by members of the Working Group, regional groups and stakeholders. The Working Group has also benefited from a number of technical studies that the Governing Body requested, and from the support of expert groups, such as a standing group of legal experts, and other groups (“Friends of the Co-Chairs”) on access mechanisms and payment rates, scope of the Multilateral System, user and crop categories, termination clause.<sup>4</sup> The deliberations of the Open-ended Working Group have progressed through four years and the group’s mandate has been extended until 2019 by the Governing Body at its Seventh Session, in November 2017. At the same Session, the Governing Body also decided to conduct the review under Article 11.4 of the ITPGRFA in 2019.

Some of the main axes of discussions and negotiations within the Open-ended Working Group have been articulated around a number of considerations, including the following:

- as access and benefit sharing are mutually dependent, measures to enhance access and benefit sharing are to be taken at the same time and will determine each other;
- enhanced access is likely to be achieved through an expansion of the list of crops and forages in Annex I to the ITPGRFA, but also through other means such as by creating conditions for the revised SMTA that are attractive to potential users;
- enhanced benefit sharing is likely to be achieved by revising the SMTA, for example through the introduction of a subscription system, but also through other means (e.g. by enhancing access).

The discussions, consultations, deliberations and negotiations of the Working Group have translated the above considerations into a draft package of measures that the Governing Body considered at its Seventh Session, including a draft revised SMTA proposed by the Working Group, modalities to give effect to a possible expansion of the coverage, and a proposal for modalities that would allow for a coordinated and balanced process for the measures to come into effect. The Seventh Session of the Governing Body requested the Working Group to finalize the package of measures, consisting of a proposal for a Growth Plan to attain the enhanced Multilateral System, a revised SMTA, a possible adaptation of the coverage of the Multilateral System, and recommendations on any other issues related to the enhancement process. It also recognized that nothing is agreed until everything is agreed.

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<sup>4</sup> The four technical studies that were prepared in the biennium 2014–2015 are available at <http://www.fao.org/plant-treaty/meetings/meetings-detail/en/c/397262/>. The reports of the “Friends of the Co-Chairs” groups and those of the standing group of legal experts are available at <http://www.fao.org/plant-treaty/meetings/meetings-detail/en/c/414961/> and <http://www.fao.org/plant-treaty/meetings/meetings-detail/en/c/414992/>.

Although a significant evolution of the negotiations can be expected in the biennium 2018-2019, the current draft package of measures to enhance the functioning of the Multilateral System includes the following elements.<sup>5</sup>

The main features of the subscription system would revolve around the strengthening of access and benefit sharing by eliminating, for the purpose of monetary benefit sharing, the need to track single germplasm samples down to the commercialization of products. Under the subscription system, access to the germplasm samples available under the Multilateral System (of all or some crops) would be granted to recipients willing to make a monetary benefit sharing payment based on the sales of all products that are PGRFA, regardless of whether those products are derived from germplasm accessed under the system. This approach is developing further the payment option contained in the current Article 6.11 of the SMTA.

As it currently stands, the subscription system would not replace all the current mechanisms of access. Rather, the enhancement would result in an effective and balanced dual access mechanism, consisting of the subscription system and a single access mechanism, provided that access to PGRFA under both mechanisms would only be granted under conditions of mandatory payments.

The Working Group is considering making the subscription not permanent for users of germplasm under the Multilateral System. Instead, there would be the option for subscribers to voluntarily withdraw from the subscription. Although the system is intended to be designed in such a way that subscribers would not have any incentive to withdraw, the current common understanding of the Working Group is that a minimum period of subscription of ten years would be set forth, while the Third Party Beneficiary would be given the capacity to activate termination provisions in the SMTA under both access mechanisms in cases of violation of the terms and conditions of the SMTA. Within the Open-ended Working Group, consensus is still to be reached, including on the length of any continuing subscription obligations after withdrawal and on the inclusion of a withdrawal option in relation to the single access mechanism.

In the current version of the draft revised SMTA proposed by the Working Group, monetary benefit sharing under the subscription system would consist of annual payments made by the subscriber based on different payment rates for the sales of products available with or without restriction, respectively. Subscribers whose total sales and licence fees do not exceed a certain threshold would be exempted from monetary benefit sharing obligations in the current draft. Although the payment schemes are still subject to further analysis and consideration, the Working Group appears to converge on their importance for realizing effective benefit sharing.

The Open-ended Working Group has expressly considered enforceability of the dual system. To date, there seems to be general agreement that the SMTA should be an enforceable contract but consensus is still pending as to whether the current SMTA provides for effective

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<sup>5</sup> The elements are captured from the “Co-Chairs’ Summary Arising from the Seventh Session of the Governing Body, including Co-Chairs’ Proposed Consolidated Text for the Revised Standard Material Transfer Agreement”, in Annex 2 to Resolution 2/2017, are available at <http://www.fao.org/3/a-mv104e.pdf>

enforcement measures. While some stakeholders are of the opinion that revisiting Article 8 defining the rights of the Third Party Beneficiary would be sufficient to guarantee enforceability, others would favour new provisions strengthening the enforceability of the SMTA, presumably under general contract law.

With regard to the expansion of the list of crops and forages within the scope of the Multilateral System, the Governing Body at its Seventh Session has taken note of a formal proposal for amending the Annex I made by the Government of Switzerland.<sup>6</sup>

The Governing Body of the ITPGRFA and the Open-ended Working Group has begun addressing the implications of the use of digital sequence information on the functioning of the reformed Multilateral System. Within the Nagoya Protocol forum, the issue of digital sequence information (or any other term that may be adopted in the future) is under discussion in relation to the possible by-passing of benefit sharing obligations, which are linked to the utilization of genetic resources. In the context of the enhancement process, consensus will have to be sought as to whether and how to reflect the issue in the text of the revised SMTA.

Given the complex interlinkages between the different thematic areas of the enhancement process, the Working Group is considering how to effectively launch the new mechanisms and the overall package of measures. While some components would have to be incorporated in the new and revised SMTA, others may require separate decision-making by the Governing Body. Moreover, the mechanism to launch the package of measures is expected to strike a balance between the option to make the effective generation of funds as a precondition for expanding crop coverage, and the option to simultaneously expand crop coverage and implement new benefit sharing provisions. The Working Group is accordingly considering a “growth plan” that would allow for a coordinated and balanced process for the measures to come into effect.

## CONCLUSION

Based on the experience gained in ten years of implementation, the Multilateral System of the ITPGRFA is undergoing a process of enhancement that would strengthen both sides of the access and benefit sharing equation, i.e. access, by expanding its scope and further simplifying its mechanisms, and benefit sharing, by finding business-sound and equitable solutions to generate predictable and consistent income into the Benefit-Sharing Fund and rationalizing the investments made out of the Fund. The enhancement of the Multilateral System would constitute a further specification of the distinctive features and specific practices of the PGRFA sector in regard of access and benefit sharing.

The enhancement process will continue in parallel with the relevant processes of the Commission, including those for which the international workshop has been convened by the Commission. At its Seventh Session, the Governing Body of the ITPGRFA welcomed the invitation by the Commission to closely coordinate in order to address in a complementary

<sup>6</sup> The text of the proposal can be found in ‘Proposal for Amendment of the International Treaty’. IT/GB-7/17/8 (available at <http://www.fao.org/3/a-mt574e.pdf>).

way the distinctive features and specific uses of PGRFA, bearing in mind the ongoing activities and processes under the ITPGRFA, which include the current process of enhancement of the Multilateral System as well as the harmonious implementation of the ITPGRFA, the CBD and the Nagoya Protocol. Based on such guidance by the Governing Body, cooperation between the Commission and the ITPGRFA for the biennium 2018-2019 will continue encompassing access and benefit sharing.

## BIBLIOGRAPHY

- FAO.** 2006. *Report of the First Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture*. IT/GB-1/06/Report. Rome.
- FAO.** 2016. *ABS Elements. Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture*. Rome.
- FAO.** 2017. *Report of the Seventh Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture*. IT/GB-7/17/Report. Rome.
- Khoury, C.K., Bjorkman, A.D., Dempewolf, H., Ramírez-Villegas, J., Guarino, L., Jarvis, A., et al.** 2014. Increasing homogeneity in global food supplies and the implications for food security. *Proc. Natl. Acad. Sci.*, 111: 4001-4006.
- Manzella, D.** 2012. The design and mechanics of the multilateral system of access and benefit sharing. In M. Halewood, I. López Noriega & S. Louafi, eds. *Crop genetic resources as a global commons: challenges in international law and governance*. London, Earthscan.
- Moore, G. & Tymowski, W.** 2005. *Explanatory guide to the International Treaty on Plant Genetic Resources for Food and Agriculture*. Gland, Switzerland, IUCN.



# Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture

*Dan Leskien*

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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) has been hailed as a giant step towards the implementation of the third objective of the Convention on Biological Diversity (CBD): the fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to them. Implementing this third objective is intended to contribute to the conservation of biological diversity and the sustainable use of its components, the other two objectives of the CBD.

The Nagoya Protocol confronts policy-makers and administrators responsible for its implementation at the national level with a number of challenges. One of these challenges is the Nagoya Protocol's obligation to consider, in the development and implementation of access and benefit-sharing (ABS) measures, the importance of genetic resources for food and agriculture (GRFA) and their special role for food security. The Nagoya Protocol explicitly recognizes the importance of genetic resources for food security, the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions, as well as the interdependence of all countries with regard to GRFA, and the importance of GRFA for sustainable development of agriculture in the context of poverty alleviation and climate change. However, the Nagoya Protocol provides little guidance as to how the special features of GRFA might adequately be reflected in domestic ABS measures.

In 2013, the Commission on Genetic Resources for Food and Agriculture (Commission) of the Food and Agriculture Organization of the United Nations (FAO) put in place a process, the outputs of which are the *Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture* (ABS Elements). Developed by a Team of Technical and Legal Experts on Access and Benefit-sharing (ABS Expert Team) from all regions of the world, the ABS Elements were considered and welcomed by the Commission and, subsequently, by the FAO Conference, the highest Governing Body of FAO. The ABS Elements aim to assist governments

considering developing, adapting or implementing ABS measures to take into account the importance of GRFA, their special role for food security and the distinctive features of the different subsectors of GRFA, while complying, as applicable, with international ABS instruments.

This article provides some background on the Commission's work on access and benefit-sharing, gives an overview of key features of the ABS Elements and summarizes next steps, including, in particular, the development of non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture.

## **ACCESS AND BENEFIT-SHARING AND THE COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE**

FAO and its Commission have a longstanding history of dealing with issues related to GRFA, including access to them and the fair and equitable sharing of benefits derived from their utilization. In 1983, the FAO Conference adopted the International Undertaking on Plant Genetic Resources for Food and Agriculture, which provided a policy and planning framework for the Commission with respect to plant genetic resources. During the following years, the Commission negotiated further resolutions that interpreted the International Undertaking and, in 1994, started revising the International Undertaking. As a result of this process, the FAO Conference in 2001 adopted the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty), the first legally binding and operational international instrument for access and benefit-sharing for genetic resources.

The Commission, at its Tenth Regular Session, recommended that FAO and the Commission contribute to further work on access and benefit-sharing, in order to ensure that it moves in a direction supportive of the special needs of the agriculture sector, in regard to all components of biological diversity of interest to food and agriculture.<sup>1</sup> At its Eleventh Regular Session, the Commission agreed on the importance of considering access and benefit-sharing in relation to all components of biodiversity for food and agriculture, and decided that work in this field should be an early task within its Multi-Year Programme of Work (MYPOW).<sup>2</sup>

Accordingly, the Commission, at its Twelfth Regular Session, considered arrangements and policies for access and benefit-sharing for GRFA. It requested that the background studies<sup>3</sup> commissioned by the Secretariat on aspects of access and benefit-sharing for GRFA be transmitted to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing that negotiated at that time under the Convention on Biological Diversity (CBD) an "international regime of access and benefit-sharing", the later Nagoya Protocol. The Commission stressed the essential role of GRFA in achieving food security, and requested its Secretariat to report back to it on the outcome of the negotiations of the international regime. The Commission also prepared Resolution 1/2009, which formed the basis for FAO Conference Resolution 18/2009 on *Policies and Arrangements for Access and Benefit-sharing for Genetic Resources for Food and*

<sup>1</sup> CGRFA-10/04/REP, paragraph 76.

<sup>2</sup> CGRFA-11/07/Report, paragraph 71.

<sup>3</sup> Background Study Papers No. 42, 43, 44, 45, 46 and 47.

*Agriculture*.<sup>4</sup> Through the Resolution, the Conference invited the Convention on Biological Diversity “to take into account the special nature of agricultural biodiversity, in particular genetic resources for food and agriculture, their distinctive features, and problems needing distinctive solutions”. It also suggests that “in developing policies [the CBD] might consider sectoral approaches which allow for differential treatment of different sectors or subsectors of genetic resources, different genetic resources for food and agriculture, different activities or purposes for which they are carried out”.

In October 2010, the Conference of the Parties to the Convention on Biological Diversity adopted the Nagoya Protocol. The negotiations of the Protocol had revealed different views regarding the role food security and, more broadly, genetic resources for food and agriculture should play in the Protocol. The Protocol, as adopted, while reflecting to some extent this multiplicity of views reflects to a remarkable extent issues stressed and concerns raised by FAO and its Commission, as will be explained below.

At its Thirteenth Regular Session, the Commission decided to establish an Ad Hoc Technical Working Group on Access and Benefit-sharing for Genetic Resources for Food and Agriculture and mandated it to:

- identify relevant distinctive features of the different sectors and subsectors of genetic resources for food and agriculture requiring distinctive solutions;
- taking into account the relevant distinctive features identified, develop options to guide and assist countries, upon their request, in developing legislative, administrative and policy measures that accommodate these features; and
- analyse, as appropriate, possible modalities for addressing access and benefit-sharing for genetic resources for food and agriculture, taking into account the full range of options, including those presented in the Nagoya Protocol.<sup>5</sup>

The Ad Hoc Working Group met, at the invitation of the Government of Norway, from 11 to 13 September 2013 in Longyearbyen (Svalbard) and produced, as requested by the Commission, a “*List of distinctive features of genetic resources for food and agriculture requiring distinctive solutions for access and benefit-sharing*”.<sup>6</sup>

In response to the Ad Hoc Working Group’s report, the Commission decided, at its Fourteenth Regular Session, to develop *Draft Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture* (ABS Elements). These draft elements would be “voluntary tools to assist national governments, not new international access and benefit-sharing instruments”.<sup>7</sup> The Commission established its ABS Expert Team and mandated it to prepare, in close collaboration with the Commission’s intergovernmental technical working groups on plant, animal and forest genetic resources, the draft ABS Elements.<sup>8</sup>

The ABS Expert Team, in collaboration with the Commission’s working groups, prepared the draft ABS Elements which the Commission considered and welcomed at its Fifteenth

<sup>4</sup> CGRFA-12/09/Report, paragraphs 11–12.

<sup>5</sup> CGRFA-13/11/Report, paragraph 60; Appendix D.1.

<sup>6</sup> CGRFA-14/13/6, Appendix B.

<sup>7</sup> CGRFA-14/13/Report, paragraph 40.xv.

<sup>8</sup> CGRFA-14/13/Report, paragraph 40.xiii.

Regular Session in 2015. The FAO Conference welcomed the ABS Elements in the same year and invited countries to make use of them, as appropriate. The Commission, at its Fifteenth Regular Session, also requested its working groups to continue elaborating “subsector-specific ABS Elements including consideration of the role of traditional knowledge associated with genetic resources for food and agriculture and their customary use”. It also requested the ABS Expert Team to reconvene to consolidate the outputs of the intergovernmental technical working groups.

The ABS Expert Team convened in September 2015 and took note of the inputs from the Working Groups. However, it expressed the view that “more input is needed from the four Working Groups to further elaborate subsector-specific ABS elements”.<sup>9</sup> The ABS Expert Team recommended to convene an international workshop to raise the awareness of Commission Members and observers as well as other stakeholders and communities of practice of the issue of ABS and its relevance to GRFA and to provide a forum for participants to exchange information, experiences and views.

At its Sixteenth Regular Session, the Commission requested the Secretary to convene the proposed international workshop and requested the workshop “to provide outputs for subsequent elaboration into non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of GRFA”.

## **THE NAGOYA PROTOCOL AND GENETIC RESOURCES FOR FOOD AND AGRICULTURE**

An analysis of the Nagoya Protocol shows that in one way or the other the Protocol addresses each of the issues raised in 2009 by the FAO Conference Resolution 18/2009 and demonstrates that FAO’s appeal to the negotiators of the Protocol did not go unheard.

In adopting Resolution 18/2009, the FAO Conference had stressed the essential role of GRFA in food security and sustainable development and recognized the interdependence of countries with respect to these resources and the dependence of the resources for their survival on active cooperation among all stakeholders involved in their conservation, breeding and sustainable utilization as well as benefit-sharing. The FAO Conference therefore invited negotiators of the Protocol to:

- “take into account the special nature of agricultural biodiversity, in particular of genetic resources for food and agriculture, their distinctive features and problems needing distinctive solutions;
- “in developing policies [...] consider sectoral approaches which allow for differential treatment of different sectors or sub-sectors of genetic resources, different genetic resources for food and agriculture, different activities or purposes for which they are carried out; [...]
- “to explore and assess options for the International Regime on Access and Benefit-sharing that allow for adequate flexibility to acknowledge and accommodate existing

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<sup>9</sup> CGRFA-16/17/6, paragraph 9.

and future agreements relating to access and benefit-sharing developed in harmony with the CBD; [...]

- “to work closely with the Commission on Genetic Resources and the Governing Body of the International Treaty regarding access and benefit-sharing in the area of genetic resources for food and agriculture in a mutually supportive manner in future years”.<sup>10</sup>

The Protocol, in its preamble, explicitly recognizes the importance of genetic resources to food security,<sup>11</sup> the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,<sup>12</sup> as well as the interdependence of all countries with regard to GRFA and the special nature and importance of these resources for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change. In this regard, the Protocol also acknowledges the fundamental role of the International Treaty and the Commission.<sup>13</sup>

In its operational provisions, the Protocol requires Parties to consider, in the development and implementation of their access and benefit-sharing legislation or regulatory requirements, the importance of GRFA and their special role for food security.<sup>14</sup> Parties shall pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.<sup>15</sup> In addition, they shall create conditions to promote and encourage research that contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.<sup>16</sup>

The Protocol leaves ample room for other international agreements in the field of access and benefit-sharing. The Protocol does not prevent its Parties from developing and implementing other 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 and the Protocol.<sup>17</sup> Where a specialized international access and benefit-sharing instrument that is consistent with and does not run counter to the objectives of the Convention and the Protocol applies, the Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.<sup>18</sup> One of the instruments explicitly acknowledged by the Protocol is the International Treaty developed in harmony with the Convention.<sup>19</sup> Beyond this openness to other international instruments, the Protocol also states that due regard should be paid to “useful and relevant ongoing work or practices

<sup>10</sup> C 2009/REP, paragraph 174 ( Resolution 18/2009).

<sup>11</sup> Preamble paragraph 14 Nagoya Protocol.

<sup>12</sup> Preamble paragraph 15 Nagoya Protocol.

<sup>13</sup> Preamble paragraph 16 Nagoya Protocol.

<sup>14</sup> Nagoya Protocol, Article 8(c).

<sup>15</sup> Nagoya Protocol, Article 8(b).

<sup>16</sup> Nagoya Protocol, Article 8(a).

<sup>17</sup> Nagoya Protocol, Article 4.2.

<sup>18</sup> Nagoya Protocol, Article 4.4.

<sup>19</sup> Preamble paragraph 19 Nagoya Protocol; cf. also the document, Report of the Secretary (IT/GB-4/11/05), paragraph 18.

under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol”.<sup>20</sup> Thus, the Protocol seems to provide the flexibility the Commission may have had in mind when it invited the CBD COP and its Working Group to explore and assess options that allow for adequate flexibility to acknowledge and accommodate existing and future agreements relating to access and benefit-sharing.

The Protocol also requires Parties to encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms and of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing. The CBD COP, serving as meeting of the Parties to the Protocol shall periodically take stock of the use of the model contractual clauses, codes of conduct, guidelines and best practices and/or standards.<sup>21</sup> Sectoral approaches, including those in line with current commercial practices that allow for different treatment of sectors or subsectors of genetic resources may therefore form part of the International Regime, which, according to CBD COP Decision X/1, is constituted of the CBD, the Nagoya Protocol, as well as complementary instruments, including the International Treaty.

It remains to be seen which direct and indirect effects the Nagoya Protocol will have on the implementation and design of existing and future access and benefit-sharing laws and, thus, on the use and exchange of genetic resources, and GRFA in particular. Parties to the Protocol requiring prior informed consent will need to take measures, as appropriate, to provide legal certainty, clarity and transparency of their access and benefit-sharing laws as well as other measures listed in Article 6 of the Protocol. These measures might increase the predictability of access, and facilitate the operation and contribute to the user-friendliness of domestic access and benefit-sharing regimes. However, future access and benefit-sharing laws could also complicate and reduce the exchange and use of GRFA. Parties to the Protocol will also have to take measures to provide that genetic resources utilized within their jurisdiction have been acquired legally. It is hoped that these measures will improve compliance with ABS measures of countries of origin in countries where genetic resources are being used for research and development.

It will be more difficult to assess if or to what extent ABS measures actually contribute to the two other objectives of the CBD, the conservation of biological diversity and the sustainable use of its components.

### **ELEMENTS TO FACILITATE DOMESTIC IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING FOR DIFFERENT SUBSECTORS OF GENETIC RESOURCES FOR FOOD AND AGRICULTURE**

The ABS Elements address both the process governments developing, adapting of implementing ABS may wish to go through and the elements of ABS measures to which policy-makers should pay special attention to when regulating or implementing ABS for GRFA.

<sup>20</sup> Article 4.3 Nagoya Protocol.

<sup>21</sup> Articles 19–20 Nagoya Protocol.

While some of the considerations for the development and implementation of ABS measures may seem self-evident, ABS measures adopted in the past revealed at times quite some ignorance of the distinctive features of GRFA and even of the stakeholder affected by ABS for GRFA.

The ABS Elements therefore suggest taking the following steps in the establishment, adaptation and implementation of ABS measures:

1. Assessment of the concerned subsectors of GRFA, including their activities, socio-economic environments and use and exchange practices.
2. Identification and consultation of relevant governmental entities and non-governmental stakeholders holding, providing or using GRFA.
3. Integration of ABS measures with broader food security and sustainable development policies and strategies.
4. Consideration and evaluation of options for ABS measures.
5. Integration of implementation of ABS measures in the institutional landscape.
6. Communication of and awareness-raising regarding ABS measures for potential providers and users of GRFA.
7. *Ex-ante* assessment as well as monitoring of the effectiveness and impact of ABS measures.

In addition, the ABS Elements specify issues that are of particular relevance to ABS for GRFA.

- They point out, for example, that in the case of many GRFA, it may be difficult to determine with certainty their “country of origin”. GRFA have been widely exchanged across regions, countries and communities, often over long periods of time and many different stakeholders have contributed to their development, in different places and at different points in time.<sup>22</sup> ABS measures usually require that the country of origin has given its prior informed consent (PIC) to the use of a genetic resource for research and development.
- The ABS Elements also point out that significant amounts of GRFA are privately held, in particular in sectors such as the livestock sector. They, therefore, recommend that ABS measures need to be clear as to whether they apply to privately held or only to publicly held GRFA and point out that ABS measures may have a significant impact on the exchange of GRFA.<sup>23</sup>
- The ABS Elements further consider which kind of uses of GRFA could trigger the application of ABS measures. ABS measures usually require PIC for access to genetic resources “for their utilization.” “Utilization”, according to the Nagoya Protocol, means “to conduct research and development on the genetic and/or biochemical composition of genetic resources”.<sup>24</sup> While practices, such as the capture or collection of live material from the wild and its subsequent use in

<sup>22</sup> ABS Elements, paragraph 35; see also M. Schloen et al. (2011). Access and benefit-sharing for genetic resources for food and agriculture – current use and exchange practices, commonalities, differences and user community needs. Background Study Paper No. 59 (available at <http://www.fao.org/docrep/meeting/023/mb720e.pdf>).

<sup>23</sup> ABS Elements, paragraph 38.

<sup>24</sup> Nagoya Protocol, Article 2.

aquaculture, usually termed as capture-based aquaculture (CBA), might clearly not qualify as “research and development” and therefore not trigger the application of ABS measures, aquaculture may simultaneously contribute to genetic improvement and therefore be considered “research and development.”

- The ABS Elements also address various options policymakers may wish to consider in designing ABS authorization procedures, on the one hand, and benefit-sharing arrangements, on the other. They refer, for example, to the possibility of standardizing procedures and conditions for the granting of access to genetic resources and to the possibility of facilitating benefit-sharing through partnership agreements. Such agreements may cover a whole range of genetic resources and address the sharing of various benefits as part of a longstanding partnership.

While the ABS Elements do provide useful guidance with regard to ABS for GRFA, there is a general sense that they still lack some substance, examples and additional explanation with regard to the implications of ABS for the different subsectors of GRFA. The Commission has therefore agreed to produce non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture (GRFA), to complement the ABS Elements.

This International Workshop, which is attended by one representative per region of each of the Commission’s intergovernmental technical working groups on plant, animal, forest and aquatic genetic resources and regionally representative experts from the subsectors of micro-organism and invertebrate GRFA serves the purpose of providing outputs for elaboration of the explanatory notes.<sup>25</sup>

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<sup>25</sup> CGRFA-16/17/Report, paragraph 25 (v).



# National Focal Point Survey on Access and Benefit-sharing for Genetic Resources for Food and Agriculture

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## BACKGROUND

FAO and the Commission have long been committed to addressing issues of access to genetic resources for food and agriculture (GRFA) and the fair and equitable sharing of benefits derived from their utilization. In 1983, the FAO Conference adopted the International Undertaking on Plant Genetic Resources for Food and Agriculture, which provided a policy and planning framework for the Commission with respect to plant genetic resources for food and agriculture (PGRFA). During the following years, the Commission negotiated further resolutions that interpreted the International Undertaking and, in 1994, started revising the International Undertaking. As a result of this process, the FAO Conference, in 2001, adopted the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty), the first legally binding and fully operational international instrument for access and benefit-sharing (ABS) for genetic resources.

In 2007, at its Eleventh Regular Session, the Commission agreed on the importance of considering access and benefit-sharing in relation to all components of biodiversity for food and agriculture, and decided that work in this field should be an early task within its Multi-Year Programme of Work (MYPOW). It considered arrangements and policies for ABS for GRFA at its Twelfth Regular Session in October 2009. Between 2009 and 2013, a series of studies, reports and other inputs have been prepared<sup>1</sup> and an Ad Hoc Technical Working Group on Access and Benefit-sharing for Genetic Resources for Food and Agriculture was established at the Thirteenth Session in 2011 with the specific mandate to identify relevant distinctive features of the different sectors and subsectors of GRFA requiring distinctive

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<sup>1</sup> Studies on the use and exchange of aquatic, animal, forest, microbial genetic resources and of biological control agents for food and agriculture; a study on food security and access and benefit-sharing for GRFA; results of a multi-stakeholder dialogue; government submissions describing the conditions under which specific GRFA are exchanged and utilized; stakeholder submissions on voluntary codes of conduct, guidelines and best practices, and/or standards in relation to ABS for all subsectors of GRFA; and explanatory notes to the distinctive features of GRFA.

solutions and to develop options that would guide and assist countries in developing legislative, administrative and policy measures that accommodate these features.

In response to the report of its Ad Hoc Technical Working Group, the Commission established a Team of Technical and Legal Experts on Access and Benefit-sharing (ABS Expert Team) in 2013 consisting of two representatives from each region to prepare Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture (ABS Elements). The ABS Expert Team participated in relevant portions of the meetings of the intergovernmental technical working groups on plant, animal and forest genetic resources, informed their discussions and, after each meeting, considered the lessons learned from each of the subsectors. The ABS Elements were prepared for the Fourteenth Session of the Commission in January 2015 and brought to the attention of the FAO Conference that welcomed them at its Thirty-ninth Session in June 2015 and invited Members to consider and, as appropriate, make use of them. The Conference also noted the complementarity between the work of the Commission and 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) in regard to access and benefit-sharing for genetic resources.

## INTRODUCTION

At its Sixteenth Regular Session, the Commission agreed to produce non-prescriptive explanatory notes to complement the ABS Elements. The notes aim to describe the distinctive features and specific practices of different subsectors of GRFA within the context of the ABS Elements. As input for developing the explanatory notes, the Commission requested the Secretariat to collect survey-based information on:

1. use and exchange practices, relevant voluntary codes of conduct, guidelines and best practices, and/or standards and community protocols as well as model contractual clauses on ABS specifically addressing GRFA;
2. how prior informed consent (PIC) or approval and involvement of indigenous and local communities is obtained under their jurisdictions and on experiences with the implementation of any relevant ABS measures in the case of GRFA;
3. experiences and views of relevant indigenous and local communities and other stakeholders regarding how countries can consider approaching PIC or approval and involvement of indigenous and local communities in the case of GRFA and associated traditional knowledge;
4. experiences with the use of the ABS Elements; and
5. existing practices in the different subsectors with regard to different uses of GRFA to which ABS measures apply.

This document reports on the preliminary results of a survey conducted between 2 and 28 December sent electronically to all National Focal Points/Coordinators (NFPs/NCs) of the Commission for the different subsectors to collect information related to numbers 1, 2 and 4.

Given the information requested, it was determined that the NFPs and NCs for the different subsectors of GRFA, biodiversity and the Commission constituted a set of individuals with significant expertise and access to current in-country information.

Therefore, the sample frame consists of all known NFPs for plant, forest and aquatic genetic resources, the NCs for animal genetic resources, and the NFPs for biodiversity for food and agriculture and the Commission. Contact information for all NFPs/NCs was obtained from the CGRFA and was updated by official enquiry by the CGRFA to the member countries. The final list of NFPs/NCs consisted of 624 individuals from 189 countries. (Note: not all countries have designated individuals for all NFP/NC positions and some individuals serve in multiple capacities.)

The survey was developed over the course of several months with input from multiple experts, including the Commission Secretariat. The survey was administered online during December 2017. Administration included an advance email notification, an official invitation and three reminder notices. As part of the administration, the survey team responded to enquiries from invited participants and assisted with troubleshooting of any problems. No significant problems were reported during administration.

In total, 280 individuals from 136 countries responded to the survey, resulting in an individual response rate of approximately 45 percent.

This preliminary report is broken down in four sections: the first describes the characteristic of the sample, in particular the individual experience of respondents with ABS; the second section reports on the status of ABS activities for GRFA in countries; the third section covers countries' experiences with PIC implementation; and the final section deals with subsectoral perspectives.

## CHARACTERISTICS OF THE RESPONDENTS

### General overview

Most respondents identify as either plant genetic resource NFPs or animal genetic resource NCs because they are more represented in the sample frame. Almost one-fourth of the respondents (22.1 percent) identified more than one sub-sector for which they serve as NFP/NC. The average years served as a NFP or NC is just over six years.

### Information, awareness and involvement of NFPs on ABS

To understand the involvement of NFPs/NCs in ABS issues in their countries, the survey asked respondents to indicate if they were had undertaken a range of different types of associated activities. Figure 1 shows that a majority of NFP/NC respondents are involved in ABS consultation and policy advice, while just under half have advised others on sending or receiving GRFA internationally. Approximately 40 percent are or have been involved in international R&D in which GRFA are exchanged. This confirms that NFPs/NCs in the food and agriculture sector are not limited to administrative functions but are often directly involved in GR use and

**Table 1: Percent responses by type of NFP/NC**

Current NFP/NC	Percent Respondents
NFP Commission	20.7
NC AnGR	26.8
NFP PGR	27.1
NFP AqGR	8.6
NFP FoGR	12.1
NFP Biodiversity	16.8
None of the above	10.0

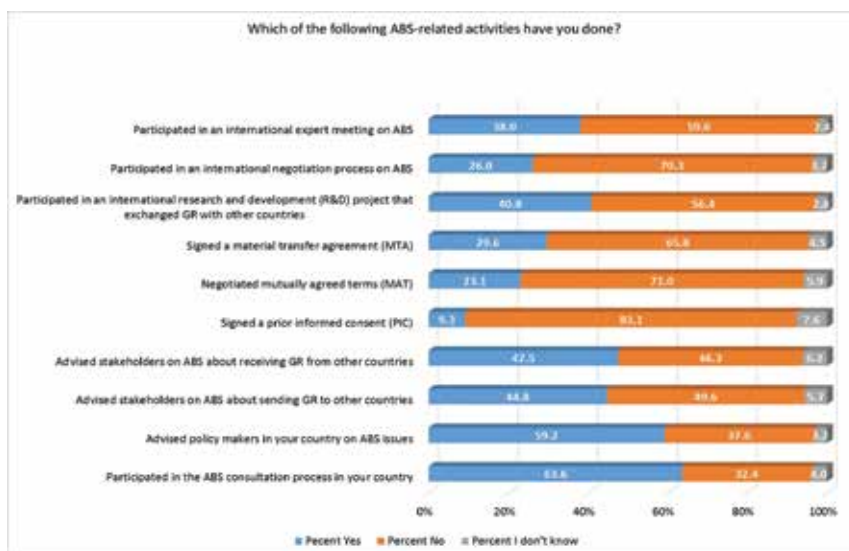


Figure 1. Involvement in ABS-related activities.

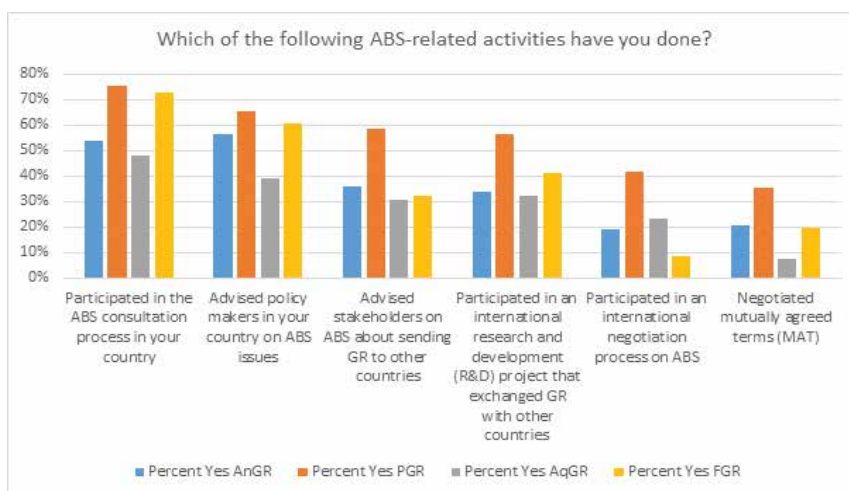


Figure 2. Involvement in ABS-related activities (by sectors).

exchange. This dual function is definitely an asset upon which the agriculture sector could build to design efficient and operational ABS rules.

There are substantial differences among sectors with regard to their level of involvement in ABS-related activities (Figure 2). The plant sector is much more involved than the other sectors. The forest sector is also quite involved in policy-related activities at national level. Except for plants, involvement in policy-related activities at international level is quite low.

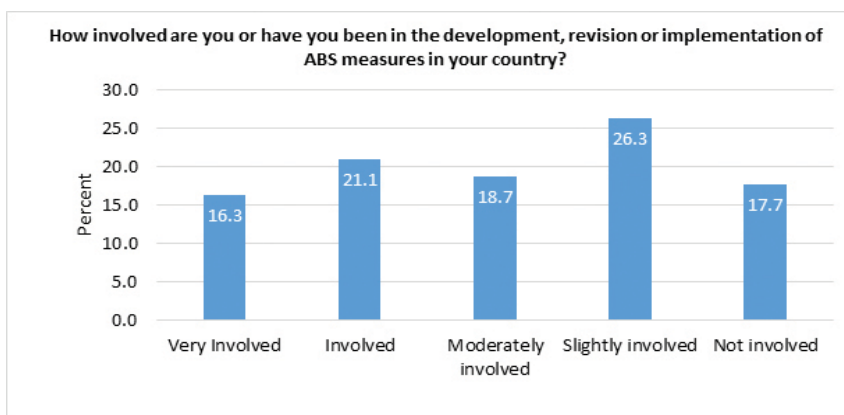


Figure 3. Involvement in development, revision or implementation of ABS measures.

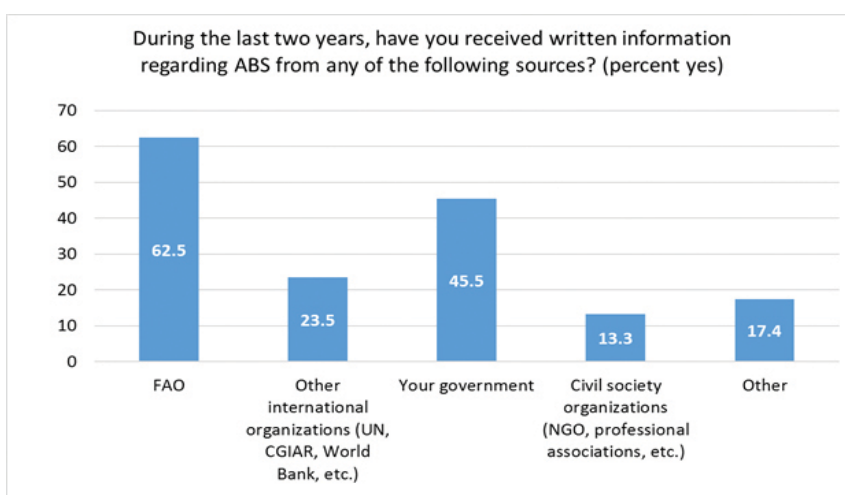


Figure 4. Source of information on ABS.

Almost one-third of respondents in all sectors have practical experience in exchanging GRFA in the context of R&D projects.

For those individuals who indicated that their country had begun to undertake ABS discussions and policy, Figure 3 shows that more than one-third of the respondents report being involved or very involved in ABS development, revision or implementation. Less than 18 percent are not involved at all.

The survey sought to understand whether NFP/NC recalled receiving information about ABS, what the source of the information was, and whether it was considered useful. Further, given the objectives of FAO's ABS Elements to facilitate the development of ABS measures, NFPs/NCs were asked whether they were familiar with the Elements. Findings show areas for improvement for both (Figure 4). Approximately 85 percent of all respondents reported

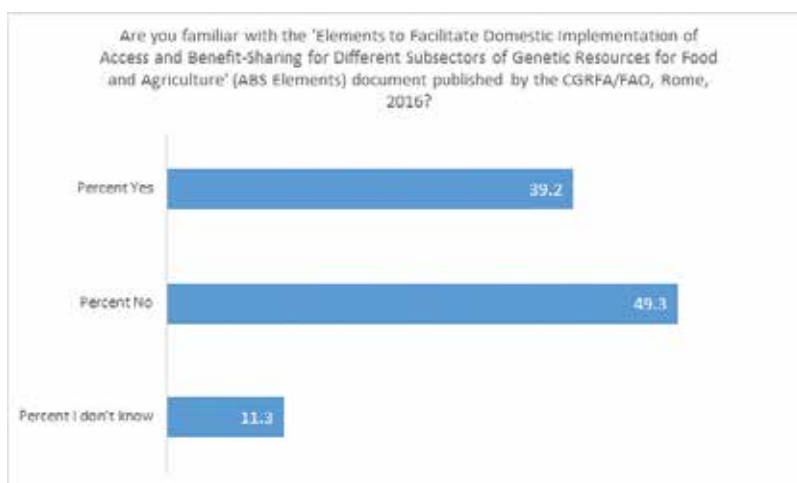


Figure 5. Awareness of the FAOs ABS Elements.

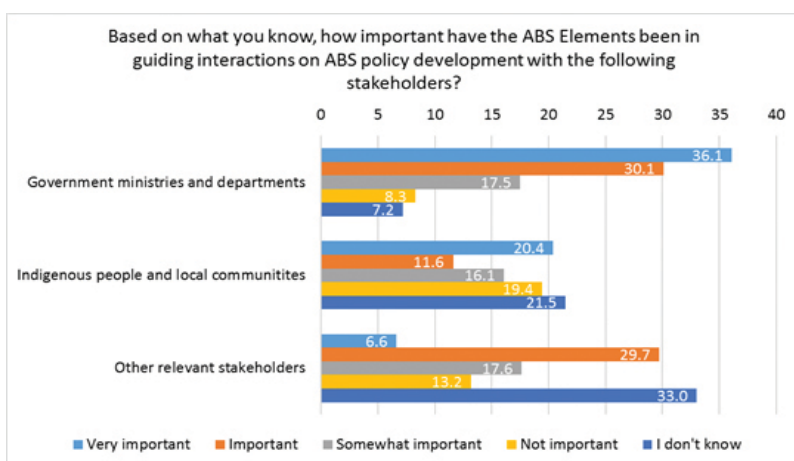


Figure 6. Relevance of ABS Elements in guiding policy interactions.

receiving some form of written information on ABS during the last two years, 62.5 percent of the respondents reported receiving information on ABS from FAO and almost half (45.5 percent) received information from their government and lower percentages reporting other sources. (Note: respondents were able to check multiple categories). Additionally, almost 50 percent of the respondents are not aware of the existence of the ABS Elements (Figure 5). It is possible that there is some misunderstanding about what the Elements are and how they are referred to. Nevertheless, there is significant opportunity for increased awareness and dissemination of FAO-produced information.

Finally, the survey asked NFPs/NCs who were familiar with the Elements, whether they had been useful for guiding interactions on ABS policy development with various stakeholders including government ministries and departments, indigenous

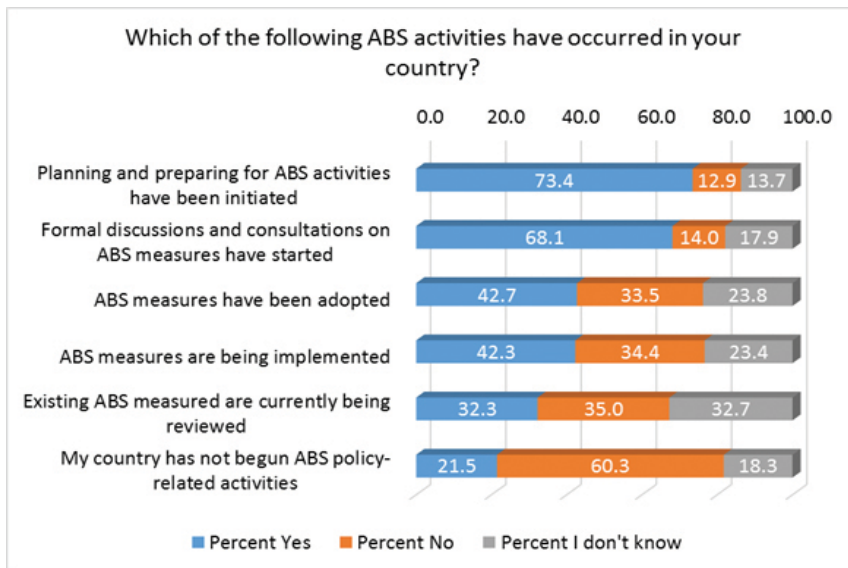


Figure 7. Status of ABS policy process.

people and local communities (IPLCs), and others. Two-thirds indicated that the Elements were important or very important for guiding discussions with government, while about one-third considered the Elements important or very important for discussions with IPLCs and others (Figure 6). The survey did not ask respondents additional information about why the Elements were or were not important, but this could be important to explore for the development of the Notes.

## STATUS OF ABS ACTIVITIES FOR GRFA IN COUNTRIES

### Status of ABS implementation

Figure 7 shows that the majority (73.4 percent) of respondents indicated that their country had initiated ABS activities. More than 40 percent of respondents reported that ABS measures have been adopted and are being implemented. Only one-fifth reported no ABS related activities have begun in their country.

## LEVEL OF CONSIDERATION FOR GRFA IN ABS

### GRFA in ABS discussions and/or measures

Of the 191 individuals indicating that ABS had begun in their country, nearly 81 percent confirm that ABS discussions and consultations consider GRFA. About 10 percent responded that their country had not considered GRFA while the remainder were unsure.

Fewer respondents confirmed ABS measures had been adopted, implemented or were being reviewed in their country (148 of the 191, or about half the total sample). Of the 148, about two-thirds (100 respondents) indicated the measures include GRFA. Less than one-fifth (18.9 percent) indicated that GRFA was not included in ABS measures. The rest were unsure.

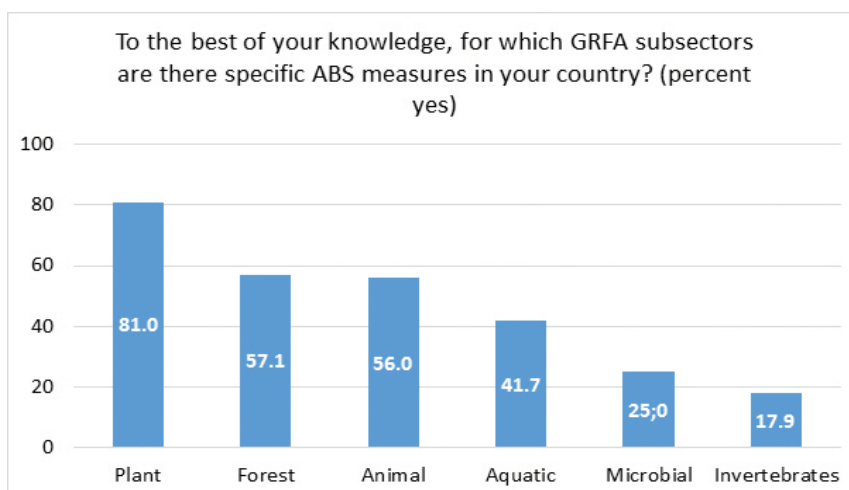


Figure 8. Existence of ABS subsector-specific measures.

In addition, the survey also asked whether ABS measures specifically mention some subsectors of GRFA (e.g. plant or animal GRFA). Of the 100 who confirmed the existence of ABS measures in their countries, 92 responded to this question. Of those, 82.6 percent responded that specific subsectors were included. This indicates that countries undertaking ABS measures that include GRFA are also considering subsector-level detail.

Down from 100 who said that measures in their country would include consideration of GRFA, and 92 who said there are sector considerations, only 84 respondents (about 30 percent of all the respondents) have specified subsector level GRFA measures in their countries (Figure 8). Plants are most frequently identified (81 percent), followed by FoGR (57 percent), AnGR (56 percent), AqGR (42 percent), MiGR (25 percent) and invertebrates (18 percent).

In sum, about half of all respondents confirm that ABS measures are at least adopted in their countries, while only about one-third of all respondents confirm ABS measures for GRFA, most of which are subsector-specific.

### Legal, policy and administrative measures

The survey asked respondents about the purposes and uses considered by existing ABS measures, including R&D for commercial and non-commercial purposes. Findings show that nearly all ABS measures accommodate research and breeding, while lower non-research purposes and food production are less likely to be covered (Figure 9).

In addition to specific administrative or legal measures covering subsectors such as PGRFA, it is increasingly common for GRFA stakeholders to develop specific practices for the use and exchange of genetic resources for research and development purposes. Survey findings show (Figure 10) that standard PIC or material transfer agreement (MTA) and best practices initiatives are reported as the most commonly used instruments to facilitate ABS implementation. However, the findings also confirm that 40 percent of respondents are making use of the ABS Elements and that other tools are also in evidence.



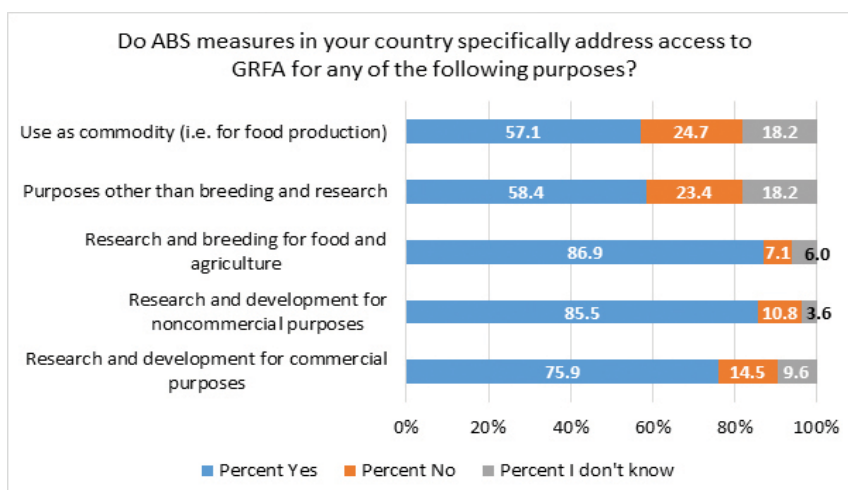


Figure 9. Consideration of the different purposes of GRFA use in ABS measures.

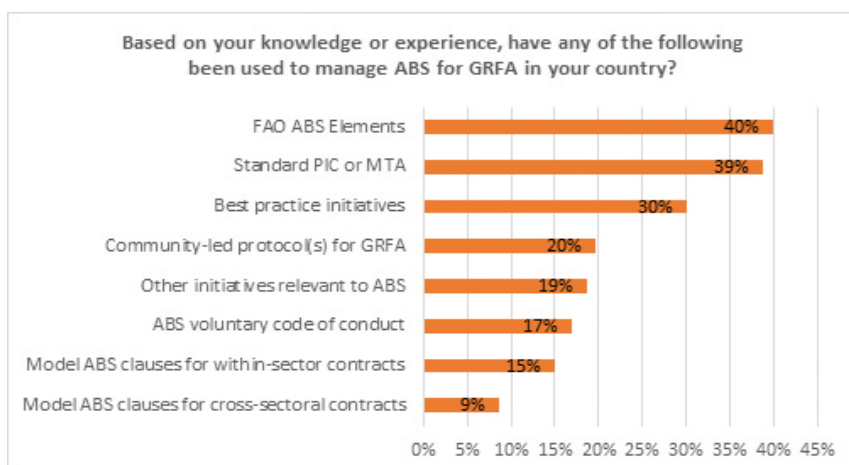


Figure 10. Use of specific instruments for managing ABS

### Level of involvement of GRFA stakeholders

Respondents reported extensive consultation with various stakeholders on the development, revision and implementation of ABS measures (Figure 11). These consultations frequently include coordination among national governmental entities, but also include non-governmental stakeholders providing or utilizing GRFA, including farmers and IPLCs, gene banks and collections, research institutions and private-sector entities.

### EXPERIENCES WITH PIC IMPLEMENTATION

The survey sought to obtain insights on how countries approach PIC or approval and involvement of IPLCs in the case of GRFA and associated traditional knowledge.

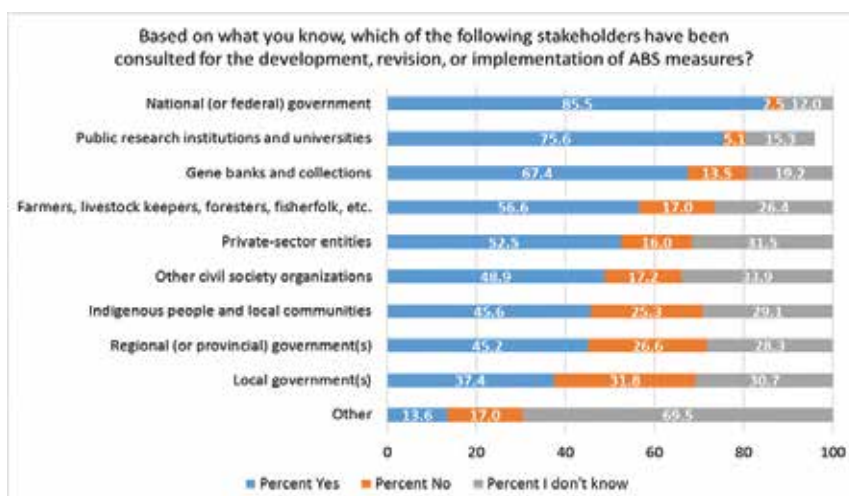


Figure 11. Stakeholder consultations in development, revision or implementation of ABS measures .

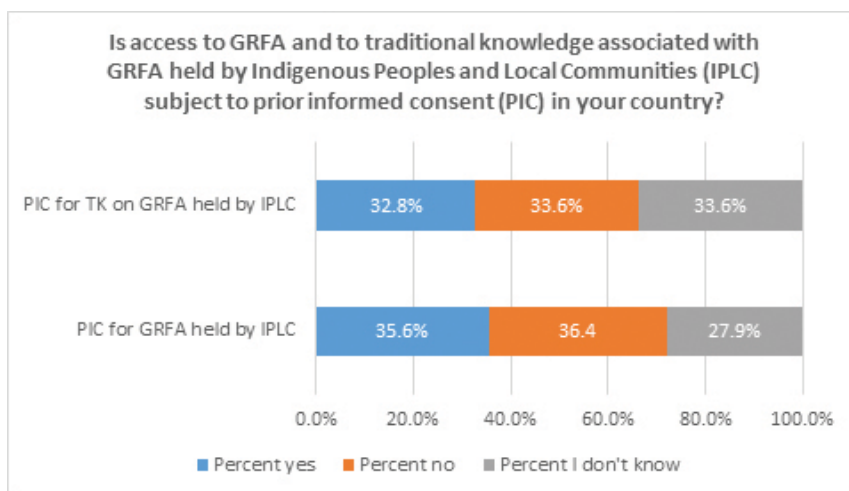


Figure 12. Experience with PIC implementation.

Figure 12 shows that almost one-third of respondents reported on the existence of PIC procedures in place for access to GRFA held by IPLCs and traditional knowledge on GRFA. There seems to be no significant differences between the physical material and the knowledge associated to it held by IPLCs.

In addition, the survey also asked about the approval process for PIC. Of the respondents who reported on the existence of PIC procedures, the majority of respondents indicated that PIC is sought from a community-designated committee or the community leader and to a lesser extent (approximately 30 percent) from the entire community (Figure 13). Consultations and meetings are by far the main vehicle used to obtain PIC from IPLCs (Figure 14).

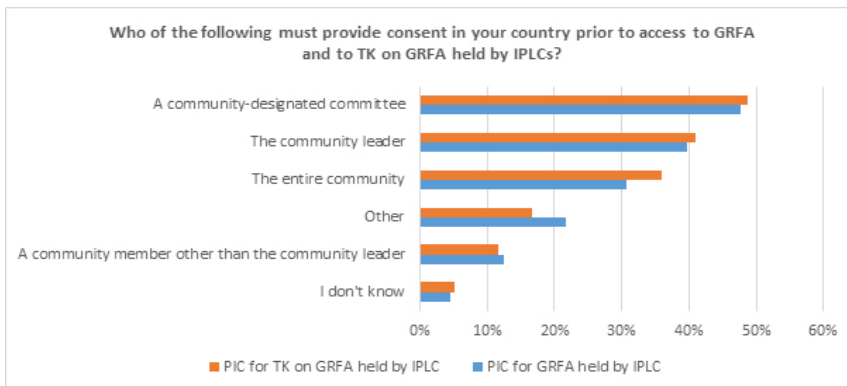


Figure 13. PIC approval for GRFA and TK on GRFA held by IPLC.

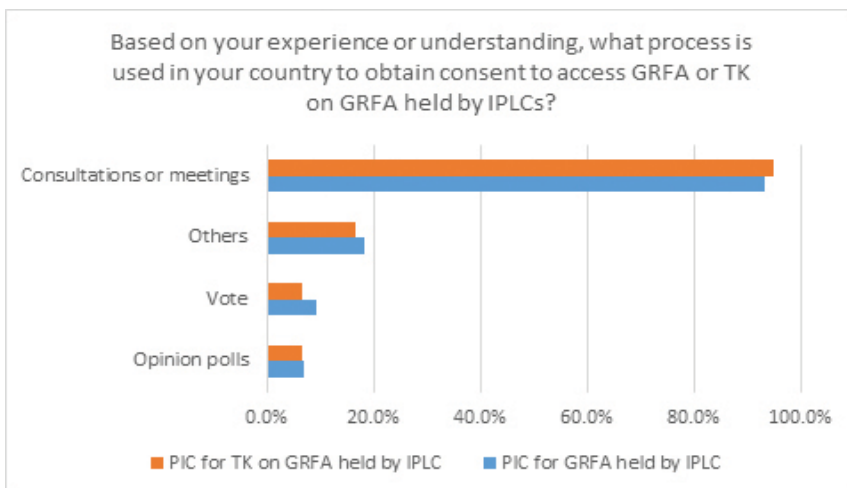


Figure 14. PIC process for GRFA and TK on GRFA held by IPLC.

Finally, 46.6 and 40 percent of respondents reported on the existence of measures or procedures to redistribute benefits to IPLCs arising from, respectively, the use of GRFA and the use of technical knowledge (TK) on GRFA held by IPLCs.

## SUBSECTOR SPECIFICITIES

### General considerations

To ascertain consistency across subsectors, the survey collected subsector-level responses to several agree/disagree questions about the characteristics of GRFA. Respondents were first asked to identify the subsector with which they were most familiar. All respondents were then asked three sets of agree/disagree questions with the specific subsector

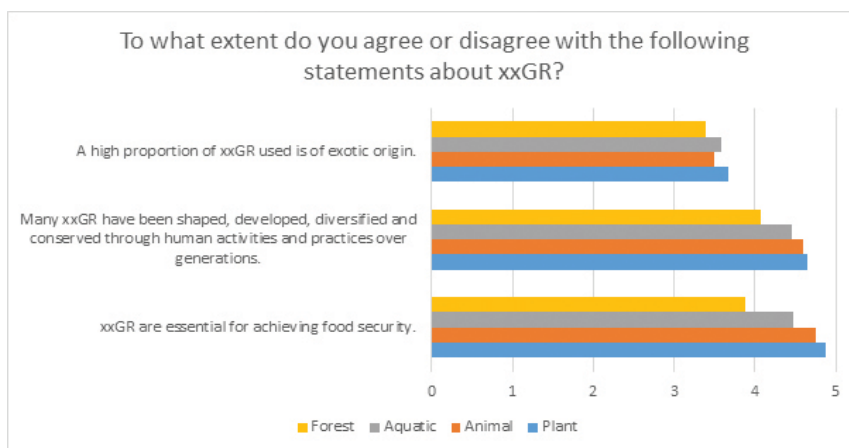


Figure 15. General agree/disagree statements about GRFA by subsector.

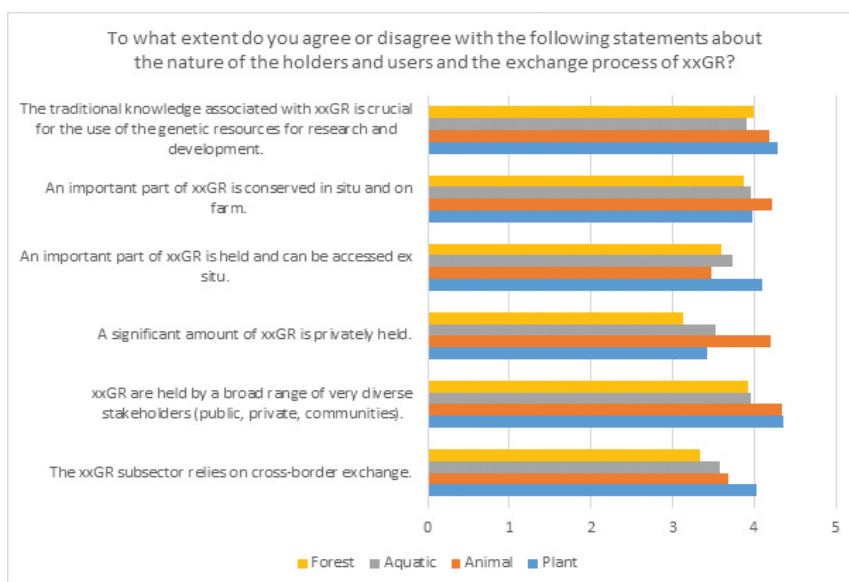


Figure 16. General agree/disagree statements about GRFA by subsector.

embedded within the question text (here noted as xxGR). Findings are presented in Figures 15, 16 and 17. The scale for all three sets of questions is: strongly disagree = 1; disagree = 2; neither agree nor disagree; agree = 4; strongly agree = 5.

The first set of general questions (Figure 15) shows relatively consistent question-level responses across subsectors, although respondents from the plant subsector are consistently more in agreement that GR are of exotic origin, have been shaped over generations and are essential for achieving food security. Differences across questions are consistently more striking with stronger agreement that GR are essential for achieving food security than for the other two statements.

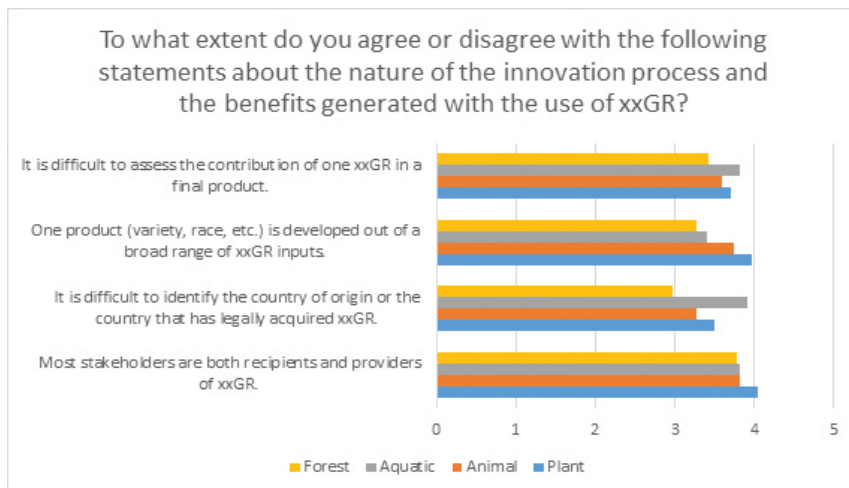


Figure 17. Agree/disagree statements about use and exchange of GRFA by subsector.

Figure 16 shows responses to a set of questions concerning the holders, users and exchange process of the particular subsector. These questions demonstrate consistency regarding the importance of traditional knowledge for R&D, as well as of *in situ* and on-farm conservation. As expected, animal subsector respondents are in stronger agreement on the importance of *in situ* and on-farm conservation, while plant subsector respondents agree more with the importance of *ex situ* conservation and access. Animal GRFA are more likely to be privately held, while plant respondents are more likely to agree that the subsector relies on cross-border exchange. Across questions, all respondents are generally more likely to agree on the importance of traditional knowledge for research, *in situ* conservation and the diversity of stakeholder holdings of GRFA, than with the other three questions.

Respondents were also asked about the innovation process and benefit-sharing at the subsector level. Findings, presented in Figure 17, show generally a lower level of agreement with all questions across all subsectors as average question responses rarely reach four (agree) on the five-point scale. Across subsectors, plant experts are more likely to find that products are developed from a range of GRFA inputs and that stakeholders are both providers and recipients. Aquatic experts are more likely to find it difficult to assess the contribution of on GRFA in a final product and country of origin.

## SUBSECTORS CONSIDERATIONS IN ABS MEASURES

As shown in Figure 18, all subsectors for food and agriculture report a fair level of specific consideration of their subsector in the initial phase of the ABS policy process (planning and discussion). The animal and aquatic sector representatives report the least subsector consideration at most stages of the ABS policy process. However, with the exception of the plant sector, the level of subsector consideration drops, sometimes by half, at the stage of review or implementation of ABS measures. In part this may be because many counties are in an earlier stage of ABS policy development. However, subsector consideration may also be eliminated as part of the policy process.

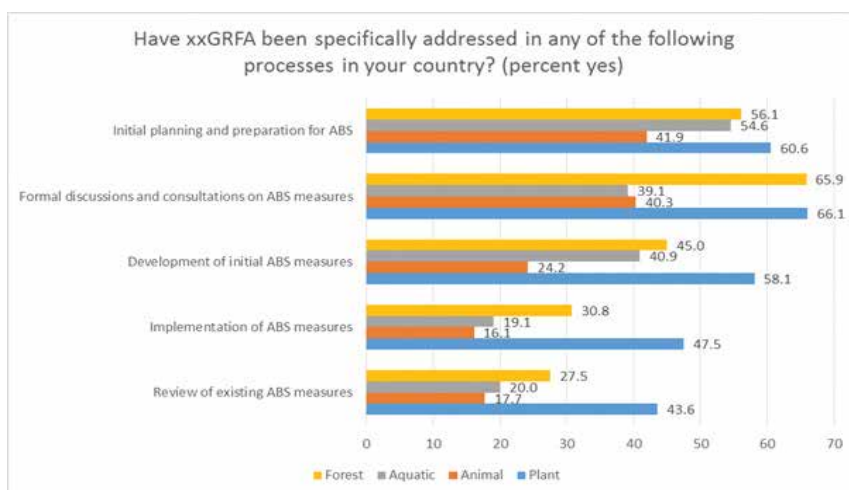


Figure 18. GRFA considerations in ABS policy process (by subsectors).

## CONCLUSION

Overall, the results tend to show a fair level of awareness of NFPs about ABS and involvement of NFPs both in ABS policy-related activities and in practical experience of exchanging and using GRFA. About half of all respondents confirm that ABS measures have been adopted in their countries, while only about one-third of all respondents confirm ABS measures consider GRFA. Results indicate that countries undertaking ABS measures that include GRFA are also consider differences by GRFA subsector, including the animal, forest or aquatic subsectors. Finally, there are few differences in the specific features of GRFA across subsectors.

These findings are preliminary in nature and require further analysis – especially for country or cross-sectoral comparisons. Additionally, there are also some limitations to this study. First, the sample frame is limited to individuals who have defined roles in the CGRFA and therefore on average have a higher likelihood of understanding ABS policy processes in their countries than other government or non-governmental actors. Nevertheless, not all NFPs/NCs are well integrated into policy processes and it is important to interpret the findings with care. Additionally, the findings may overstate the status of ABS policy globally as those countries that have not begun ABS policy processes may be less likely to respond. Nevertheless, the survey received responses from 139 countries, which is a high percentage of the FAO membership.

# Namibia's Access to Biological and Genetic Resources and Associated Traditional Knowledge Act, 2017

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## **INTRODUCTION**

Although it is predominantly a dry country, Namibia has a significant variety of habitats and ecosystems, from deserts with less than 25 mm of rainfall per year to subtropical wetlands and savannahs with over 600 mm of rainfall per year. It is one of the few dryland countries with two internationally recognized biodiversity “hotspots” – areas with extremely high species richness and endemism. The Namib Desert, one of the world’s oldest deserts, harbours organisms that have adapted to the harsh conditions in highly specialized ways for 50 million years. The entire Namibian marine environment falls within the Benguela Current system that features cool surface waters and exceptionally high biological productivity from relatively pristine habitats. Namibia’s biodiversity is not only the fundamental basis for the livelihood of rural people; the high level of species richness, ecosystem complexity, endemism and genetic variation makes it a significant global genetic asset. This is also true of Namibia’s genetic resources for food and agriculture (GRFA): most indigenous crops are hardy, drought- and heat-tolerant Sahelian domesticates at the very edge of their ecological niche, while indigenous livestock breeds are renowned for their ability to survive and maintain high productivity in extreme environmental conditions. The heat and drought tolerance characteristics of Namibian GRFA are particularly interesting considering climate change adaptation requirements.

Namibia’s biodiversity is not only a national and global asset, but also serves as the livelihood basis for most of the rural population, in a very multi-cultural society with a high level of traditional knowledge about wild foods, medicinal plants and other resources.

## **ABS IN NAMIBIA**

Namibia is of the view that benefits must be created before they can be shared, and that it is therefore in its national economic development interest to proactively promote biotrade and bioprospecting. Without a legal framework it would be difficult to provide controlled, legally secure access to potential users of locally available biological and/or genetic resources, which is key to negotiating appropriate benefit-sharing deals.

If greater benefits can accrue to Namibia's communities from their natural resources, then this should create a fairer and more equitable society and provide further incentives for the conservation and sustainable use of biodiversity.

Namibia has been working on draft access and benefit-sharing (ABS) legislation since 1999, which was finally promulgated in 2017 as the *Assess to Biological and Genetic Resources and Associated Traditional Knowledge Act*. It seeks to “regulate access to biological or genetic resources and associated traditional knowledge, and innovation, practices and technologies associated with biological and genetic resources and traditional knowledge; to protect the rights of the local communities over biological and genetic resources and associated traditional knowledge; to provide for a fair and equitable mechanism for benefit sharing; to establish the necessary administrative structures and processes for the implementation and enforcement of such principles; and to provide for incidental matters” (National Assembly, 2017).

Namibia's high level of traditional knowledge is at risk because much of it has not been recorded and is no longer automatically transferred to younger generations. The ABS Act puts in place a number of measures for the protection of traditional knowledge. These include (Schroder and Vranckx, 2012):

- mandatory applications for prior informed consent from resource owners and traditional knowledge holders;
- tripartite (State, provider, user) benefit-sharing agreements prior to the granting of access to biological resources by the appropriate authorities;
- emphasis on the inclusion of women in ABS decision-making (because women are often the custodians of traditional knowledge and responsible for transferring it from generation to generation).

From 1999 to 2006, five national workshops were held to develop draft ABS legislation. However, discussions were put on hold in 2006, until the “international regime” on ABS was finalized, so that the bill could be harmonized with the provisions of this legislation.

When the Nagoya Protocol was adopted in 2010, work recommenced on Namibia's domestic ABS bill. Throughout 2011, regional consultations were held with local communities, people on the ground, traditional authorities, etc. At the end of that process, another national consultation was held, to which parliamentarians, governors of regions and other high-level decision-makers were invited to inform them of what had been learned during the regional consultations. These consultations revealed that resource managers at local level were unaware of the concept of ABS, as were regional organs responsible for environmental governance such as traditional authorities, as well as parliamentarians at the highest decision-making level (Schroder and Vranckx, 2012).

Despite these wide consultations, there has not yet been a consistent or systematic consultation with sectors that are affected by ABS. Local communities and traditional authorities were consulted, but there has been only very limited formal consultation with the Ministry of Agriculture, the Ministry of Fisheries, the Ministry of Health and other sectors that will be impacted by the legislation.



After the legislative drafting process was put on hold in 2006 an Interim Bioprospecting Committee (IBPC) was established by Cabinet directive in September 2007 to:

- receive bioprospecting applications and scrutinize applications to assure that they are in the national interest;
- facilitate and ensure the granting of prior informed consent by indigenous and local communities when applicable;
- grant and issue a bioprospecting permit and set the conditions for such a permit – including benefit-sharing, local participation, capacity building, reporting and information-sharing arrangements;
- facilitate if appropriate the expedited granting of other permits (e.g. research collection permits);
- monitor compliance with agreements and permit conditions; and
- receive periodic reports and updates from permit holders and negotiate the terms of further collaboration.

An advantage of this interim measure was that it provided time to align the final Namibian legal and regulatory framework with the adopted ABS Protocol. The IBPC was designed to utilize the law of contract (private commercial law) to execute the role of Competent National Authority granting legitimate access to resources for bioprospecting purposes.

When it came to finalization of the ABS legislation, it was decided not to draft a prescriptive law, but instead to have enabling legislation, which basically gave the Minister of Environment and Tourism the power to regulate ABS through implementation regulations, as these can be adjusted through a simple notification in the Government Gazette, meaning there would be no need to go back to Parliament for amendment of the primary legislation. The Regulations are still being developed, but it has already become clear that the exemptions and delegations of power contained in the act will be very important when it comes to putting in place a functional ABS system. The Minister can, through notice in the gazette, determine that the ABS law does not apply to a particular set of resources or to a particular set of users of a particular set of resources, which allows policy space for special provisions for particular categories of genetic resources for food and agriculture (GRFA). It may also be possible to delegate power to other ministries further down the line.

The ABS Act has a strong focus on controlling access. Even though it is enabling legislation, it is quite clear that potential users need to apply for access for almost every use of an indigenous biological or genetic resource or associated traditional knowledge. This includes digital sequence information, or genetic information, in the set of objects for which access permits are required. The legislation is very prescriptive about the process that needs to be followed at community level, when accessing genetic resources controlled by indigenous and local communities. It is very protective of community rights, including community intellectual property rights. And although to a certain extent this is balanced by other clauses that oblige the Ministry to encourage utilization and to use genetic resources and traditional knowledge to develop the economy of the country, the main thrust of the legislation is clearly an attempt to extract benefit-sharing

by controlling access – an expression of the bilateral model of access and benefit-sharing that is contained in the Convention on Biological Diversity (CBD), ratified by Namibia in 1997, and in the Nagoya protocol.

### **NEXT STEPS**

Namibia has started drafting ABS Regulations; the immediate aim is to draft to a point where the basic thinking behind the implementation system can be shared with stakeholder groups and with sectoral representatives. Their feedback on specific sectoral concerns and practices can then be used to adapt the Regulations accordingly.

The establishment of a “one-stop shop” for access and benefit-sharing has been envisaged, based on the work that is being piloted now in the Bahamas and Kenya by the ABS Capacity Development Initiative. The main idea is to have an online permitting system with a single application portal, which will also allow the acquisition of all other necessary permits.

### **LESSONS LEARNED**

Namibia has found developing national ABS legislation to be a very arduous process, entailing a very high level of transaction costs, not only for driving around, or bringing people to the capital for consultation, but also in terms of the amount of staff time that has been taken up by this process over the decades. It is an enormous effort, and for that reason Namibia is very adamant that it will not agree to new ABS instruments or further duplication of efforts.

Some 30 years after the adoption of the CBD, there is still basically no benefit-sharing. This has caused an incredibly deep-seated and by now almost generational level of mistrust of all users by provider countries. Users are seen, almost by default, as potential biopirates, or at the very least reluctant to share benefits, who will do anything possible to get out of benefit-sharing.

Through the interim system of the IBPC it also became very clear that the transaction costs of a bilateral system of on ABS are completely overwhelming – at least for a country with the level of capacity of Namibia.

There seems to be some evidence that multilateral approaches to ABS do actually work better, at least from the access side. There is greater facilitation for access under multilateral systems and, since access in the context of GRFA is a very important benefit and a very important international policy objective, there is some reason to think that multilateral approaches have more to commend them than bilateral approaches. However, the lack of benefit-sharing also undermines provider confidence in multi-lateral systems, which is why there are ongoing negotiations to enhance the functioning of the multi-lateral system of the International Treaty. Namibia recognizes that multi-lateral systems work well for access, but not for benefit-sharing. If this imbalance can be rectified, multi-lateral solutions might be found for other subsectors of GRFA, although there are still major questions about whether and how such multi-lateral approaches can be extended to all GRFA.

## REFERENCES

- National Assembly.** 2017. *Access to Biological and Genetic Resources and Associated Traditional Knowledge Bill* (available at [http://www.parliament.na/index.php?option=com\\_phocadownload&view=category&download=8000:access-to-biological-and-genetic-resources-and-associated-traditional-knowledge-bill&id=162:bills-2017&Itemid=1269](http://www.parliament.na/index.php?option=com_phocadownload&view=category&download=8000:access-to-biological-and-genetic-resources-and-associated-traditional-knowledge-bill&id=162:bills-2017&Itemid=1269)).
- Schroder, K. & Vranckx, S.** 2012. *Country status review paper on access and benefit sharing and liability and redress in Namibia* (available at <http://www.met.gov.na/files/files/COUNTRY%20STATUS%20REVIEW%20PAPER%20ON%20ACCESS%20AND%20BENEFIT%20SHARING%20-%20Paper%20prepared%20for%20the%20Regional%20Agricultural%20and%20Environmental%20Initiatives%20Network%202012.pdf>).

# Access and Benefit-sharing Legislation in Malaysia

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## **EXECUTIVE SUMMARY**

As of late 2017, Malaysia has put in place a law regarding access and benefit-sharing in relation to biological resources and associated traditional knowledge. It is in the process of finalizing regulations to implement the law. The law not only operationalizes the provisions of the Nagoya ABS Protocol, it adds to these provisions to adapt to local circumstances as well as to fill the gaps left unaddressed by the Protocol. It is strong on protecting the rights of indigenous peoples and traditional knowledge; it provides for situations where the knowledge is shared across communities, where it is not possible to ascertain the holders of the traditional knowledge with due diligence and deals with how communities can make late claims in respect of traditional knowledge where access has been authorized. There is a differentiation for access for commercial and non-commercial purposes. The former is subject to a stringent regulatory process. Additionally, there is free exchange of biological resources and their derivatives among researchers in government agencies, public universities and institutions in respect of access for non-commercial purposes. Nonetheless, in each of these cases where associated traditional knowledge is accessed, the prior informed consent from indigenous and local communities is mandatory. Finally, the law, coupled with the regulations, includes measures to ensure that the use within Malaysia of resources accessed from other parties to the Protocol are in compliance with the law of the provider country.

## **INTRODUCTION**

Malaysia, as identified by Conservation International, is one of the world's 12 mega-diversity countries and has a rich biological heritage. It harbours some 185 000 species of fauna (FAO, 2007), more than 15 000 species of plants, 210 mammal species, 620 bird species, 250 reptile species and 150 frog species. The diverse species of animal and plant life continue to excite a great deal of scientific attention. It is extremely rich in biological resources. Tropical forests cover a considerable portion of the country and are among the world's most biologically diverse ecosystems. Biological diversity plays an important role, especially in the lives of the traditional native communities. The interaction of species within Malaysia's highly diverse ecosystems performs ecological functions that are extremely important to many human activities, such as maintaining hydrological cycles, regulating climate and recycling essential nutrients in the soil to maintain its fertility.

Malaysia's remarkable economic growth is largely due to its success in moving from a commodity-based and agricultural economy to a competitive manufacturing economy. It has diversified into resource processing, high technology and export industries. To meet the future environmental challenges, new technologies are being introduced and environmental education is being strengthened.

Access and benefit-sharing (ABS) in Malaysia is needed to:

- ensure all bio-prospecting initiatives are legally carried out with the prior informed consent (PIC) of the authority in Malaysia, as well as the holders of traditional knowledge associated with biological resources;
- ensure that an agreement is signed between the prospector and the authority in Malaysia (and communities, where applicable) so that benefits are fairly and equitably shared;
- ensure that not only monetary benefits but also gains from joint collaborations ensure transfer of technology so as to build the needed capacity for biotechnology development;
- promote the recognition of traditional knowledge associated with the biological resources;
- give value to Malaysia's biological resources and thus drive the need for conservation and sustainable use; and also help to ensure that local communities who are custodians of these resources and the associated knowledge reap benefits and that their livelihoods are reinforced;
- ensure harmonization of laws among states (Sabah and Sarawak have their own laws at the moment) and to create a standard framework for the whole of Malaysia. This will also ensure a fair benefit-sharing regime throughout Malaysia as all states share the same biodiversity.

## **ACCESS AND BENEFIT-SHARING IN MALAYSIA**

Malaysia ratified the Convention on Biological Diversity (CBD) in 1994. Like most CBD signatories, to date it has not enacted comprehensive legislation to implement the Convention. Malaysia also has not signed the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, a supplementary agreement to the CBD, which is intended to provide greater legal certainty regarding the Convention's access and benefit-sharing provisions. However, in July 2013, Malaysia's Ministry of Natural Resources and Environment (NRE) published the final draft of the Access to Biological Resources and Benefit Sharing Bill (CLJ Law, 2017) (the "Bill") after undergoing a robust consultation process involving various stakeholders such as federal and state agencies, non-governmental organizations (NGOs), indigenous and local communities and the private sector. It covers all biological and genetic resources (Nijar, 2012) and aims to regulate bio-prospecting activities in Malaysia, particularly research and development activities with commercial and potential commercial purposes, as well as non-commercial research. The Bill also complements Malaysia's obligation to fulfil the third objective of the CBD and the relevant articles to promote the fair and

equitable sharing of benefits arising from the utilization of biological resources. This draft Bill also has provisions to recognize the role of indigenous and local communities as holders of traditional knowledge associated with biological resources.

The objectives of Bill are to:

- promote local scientific research and development, within a transparent and not overly bureaucratic regulatory scheme;
- encourage bio-prospecting for research, development and commercialization within local universities and research institutions, the private sector and multinational corporations;
- provide ample opportunities for all stakeholders to participate;
- secure the maximum practical and enforceable sharing of benefits from the use of biological resources and associated traditional knowledge, including technology transfer and opportunities for securing livelihoods for local communities;
- ensure a practical and facilitative prior informed consent (PIC) procedure grounded in customary practices integral to their traditional governance structure;
- ensure adequate capacity to implement the law with a relevant degree of centralization and decentralization (Federal-State).

The Bill regulates the obtaining of “access” to biological resources, which means taking them for research and development purposes from their natural habitat or a place where they are found, kept or grown. “Research and development” is defined as “the study or systematic investigation or technological application by analysing, sampling, bioassaying, and inventorising or other methods for any purpose including taxonomic research and potential commercial product development”. One who wishes to obtain access to a biological resource must apply to a “Competent Authority”. The rules that govern applying for permission to access a biological resource differ, depending on whether the intended use of the resource is commercial or non-commercial. In this context, “non-commercial” means for a “pure academic and non-profit oriented” purpose. In respect of access for non-commercial research purposes, the research must be conducted “in collaboration with a public higher education institution, public research institution or government agency”, unless the Competent Authority decides otherwise.

The Bill finally passed into law in September 2017, after six years of consultations and discussions, as agreement had to be reached among the 13 states, each state constitutionally having exclusive jurisdiction over land. Consequently, access to natural resources and biodiversity on land is treated as also coming within a state’s exclusive jurisdiction. In addition, agreement had to be reached among the very large number of indigenous communities, who have always been zealous in protecting their rights to these resources as well as their associated traditional knowledge. The law also had to take into consideration prior international instruments and agreements relating to access to, and sharing of, biological and genetic resources.

The law has a strict regulatory framework; it is not just enabling but quite specific with regard to a variety of issues. It covers the use of biological resources and their derivatives, both *in situ* and *ex situ*, for research and development purposes only, clearly identifiable as

having been accessed from Malaysia. The scope also covers access to information. It also provides for access through intermediaries. Also, in any case, the applicant must obtain the PIC of any relevant indigenous and local community for access to:

- biological resources on land to which the community has a right as established by law; and
- traditional knowledge associated with the resource that is held by the community.

The law provides for the identification of the community representative, as well as the situation where such a person cannot be identified with due diligence. It also provides for communities making claims where their shared traditional knowledge has been accessed without providing for benefits to it. The applicant must also enter into a benefit-sharing agreement with the resource provider, based upon mutually agreed terms incorporating fair and equitable benefit-sharing terms. Upon the fulfilment of these preconditions, the applicant can obtain a permit, either for use for commercial or non-commercial purposes. However, the law allows for free exchange among researchers in government agencies as well as public universities, researchers and students in public universities. Decisions will be made and communicated to applicants within 60 days for non-commercial and within 90 days for commercial purposes. Access may be denied to users from countries that do not have effective ABS compliance measures in place.

## CONCLUSIONS

It is still work in progress and Malaysia is in the midst of finalizing regulations to implement the provisions of the law, after which Malaysia will accede to the Protocol. A user guide is also being produced, so that ordinary people who want to access do not have to go through lawyers. It is also proposed to conduct courses for implementers, so that they understand what the law is about and how they should implement it.

## REFERENCES

- FAO.** 2007. *Country report on the state of plant genetic resources for food and agriculture in Malaysia (1997-2007)* (available at <http://www.fao.org/docrep/013/i1500e/Malaysia.pdf>).
- Nijar, G.S.** 2012. *Malaysia's implementation of the multilateral system of access and benefit-sharing*. Biodiversity International, Rome, and the Malaysian Agricultural Research Development Institute, Kuala Lumpur (available at [https://www.biodiversityinternational.org/fileadmin/user\\_upload/online\\_library/publications/pdfs/1574.pdf](https://www.biodiversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/1574.pdf)).
- CLJ Law.** 2017. *Access to biological resources and benefit sharing bill 2017* (available at [http://www.cljlaw.com/files/bills/pdf/2017/MY\\_FS\\_BIL\\_2017\\_24.pdf](http://www.cljlaw.com/files/bills/pdf/2017/MY_FS_BIL_2017_24.pdf)).

# Regulation (EU) No 511/2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

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## **EXECUTIVE SUMMARY**

The Nagoya Protocol is implemented in the EU by Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (hereafter: the EU ABS Regulation) (EU ABS Regulation, 2014). The Regulation came into effect on 12 October 2014, with the exception of Articles 4, 7 and 9, which entered into effect a year later, thus on 12 October 2015.

The EU ABS Regulation is based on the concept of due diligence. The user (a natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resources) is under the obligation to ascertain that genetic resources and the associated traditional knowledge have been accessed in accordance with applicable access and benefit-sharing (ABS) legislation or regulatory requirements, and that benefits are fairly and equitably shared on mutually agreed terms. The user is also obliged to provide the information about the legal status of genetic resources and traditional knowledge associated with genetic resources through submitting a due diligence declaration.

The EU ABS Regulation establishes two checkpoints, i.e. one at the stage of receiving research funding (where such research involves utilization of genetic resources or associated traditional knowledge), and the other at the stage of final development of a product. In both situations the users are expected to declare either that they have exercised due diligence in accordance with Article 4, or that they have fulfilled the obligations of Article 4. In order to do so, the user of genetic resources and associated traditional knowledge may rely on an Internationally Recognized Certificate of Compliance (IRCC)



or on a number of relevant information and relevant documents that prove the legal source of the genetic resources. In both cases, the user needs to seek, keep and transfer to subsequent users either the IRCC (and information on the content of mutually agreed terms relevant for subsequent user) or a set of information and relevant documents concerning the genetic resource, such as the date and place of access, description of genetic resources (or associated traditional knowledge), the presence or absence of rights and obligations relating to ABS, etc.

Furthermore, the EU ABS Regulation provides for checks on user compliance to be carried out by the Member States. The Member States need to prepare risk-based plans for implementation of the checks and establish a dissuasive and proportionate penalty system for infringement of the EU ABS Regulation.

The EU ABS Regulation provides also for two voluntary mechanisms facilitating compliance with the obligations of the Regulation, namely best practices and registered collections.

The Commission Implementing Regulation - Regulation (EU) 2015/1866 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 - defines modalities and procedural aspects for implementation of Articles 5, 7 and 8 regarding the register of collections, monitoring user compliance and best practices.

A number of supportive measures have been implemented in the last few years. A Consultation Forum consisting of representatives of Member States and other interested parties (stakeholders) was established to ensure continuous input on the implementation of the EU ABS Regulation. The Commission also initiated development of a Web-based tool (DECLARE) to facilitate submission of due diligence declarations and their further transfer to the ABS Clearing House (a Web-based application developed under the Protocol for exchange of information). Much needed support has also been provided by development of guidance for users. In 2016, the Commission adopted guidance on the scope of application and core obligations of the EU ABS Regulation. Currently, work is ongoing on development of guidance addressing issues of various economic sectors and two groups of upstream users. The Commission, in collaboration with Member States, also facilitates communication and collaboration among competent authorities (CAs).

## **DEVELOPMENT OF EU ABS LEGISLATION**

The European Union continues to be committed to implementation of the third objective of the Convention on Biological Diversity. It was actively engaged in negotiation of the Nagoya Protocol. Upon the adoption of the Nagoya Protocol in 2010, the European Commission initiated a process to analyse the impacts of implementation of this new international treaty in the Union, and to develop a relevant regulatory framework.

The first step in this process was wide consultation with EU stakeholders in various sectors through their professional organizations and representatives. The European Commission also contracted preparation of an extensive background study to develop “the EU baseline” to better understand the scope and ways and means of utilization of genetic resources within the Union (IEEP/Ecologic/GHK, 2012).

Based on all these materials the Commission developed an initial legislative proposal (European Commission, 2012) and prepared the impact assessment study, identifying specific and operational objectives of the legislative proposal (European Commission, 2013). The specific objectives were:

- to support the conservation and sustainable use of biological diversity within the EU and worldwide;
- to provide EU collections, and researchers and companies in Europe, with improved and reliable access to quality samples of genetic resources at low cost and with high legal certainty for acquired material;
- to maximize opportunities for research, development and innovation in nature-based products and services, while establishing a level playing field for all EU users of genetic resources, with particular benefits for small and medium-sized enterprises (SMEs) and for publicly funded, non-commercial research;
- to protect the rights of indigenous and local communities that grant access to their traditional knowledge associated with genetic resources; and
- to fully respect other international specialized access and benefit-sharing instruments and to be mutually supportive with other relevant international instruments and processes.

The operational objectives of the proposed Regulation were the following:

- to establish a credible system for user-compliance measures;
- to improve information on access and utilization of genetic resources in the EU; and
- to minimize overall implementation costs and burdens, particularly for SMEs.

It was clear that out of a three building blocks of the Nagoya Protocol (access, benefit-sharing and compliance) the EU legislation should address only the last one. The access measures are not implemented at the EU level, as each Member State has sovereign rights over genetic resources within its jurisdiction and may decide on the scope of domestic access measures. Benefit-sharing is a subject of contractual agreement and has to be negotiated between the provider of genetic resources and users (bilaterally thus) and described in the mutually agreed terms (MAT). It was considered, however, that compliance measures should be harmonized across the EU to provide for the same conditions, rights and obligations for all users within the Union.

The background study has shown that compliance measures should take into account a number of conditions related to utilization of genetic resources in the Union such as a wide range of purposes and actors, the complex value chains, and continuous interest in research and development on genetic resources. However, the study noted also that the demand for *in situ* access was declining in most sectors (commercial users rarely collect in the wild) while *ex situ* collections became an important source of genetic resources. The study also indicated that the genetic resources are widely used by both non-commercial and commercial users, while use of traditional knowledge associated with genetic resources is of limited importance, and expected to decline even further. Moreover, the study specified there are already ABS best practices in place, particularly in the upstream user-chain.

The next analysis focused on various options to regulate user compliance. The options considered included prohibition to utilize illegally acquired genetic resources, due diligence as a self-standing obligation and due diligence supported by formally recognized trusted collections. The EU Member States had already substantial experience in the implementation of the legislation based on due diligence. The timber operators have an obligation to exercise due diligence, meaning that they are obliged to gather relevant information, assess and mitigate risks, if necessary, to ensure that they deal with timber coming only from legal sources (European Commission, 2010). Application of due diligence in the ABS context addresses a number of issues, such as complex value chains, multiple actors in the value chain, and also the potential change of intent in utilization of genetic resources.

### **KEY PROVISIONS OF EU ABS REGULATION (511/2014)**

The EU ABS Regulation (511/2014) was developed using ordinary legislative procedure, i.e. the European Commission proposed the legislative act (subject to extensive consultation with stakeholders). The proposal was further discussed and subsequently adopted by the European Parliament and Member States in the EU Council, acting as co-legislators. The European Economic and Social Committee and Committee of the Regions were also consulted on the legislative proposal. The Regulation entered into effect on 12 October 2014, the date on which the Nagoya Protocol itself entered into force for the Union. Some important obligations set up by the Regulation entered into effect only a year later, on 12 October 2015.

The Regulation is directly applicable in all Member States, regardless of their status of ratification of the Nagoya Protocol. Some provisions of the EU ABS Regulation (referred to sometimes as the “basic Regulation”) require further action by Member States.

### **User obligations**

The user is defined in Article 3 as a natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resources. In line with Article 4 of the EU ABS Regulation, users are under the obligation to ascertain that genetic resources and the associated traditional knowledge that they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared on mutually agreed terms.

The users of genetic resources and associated traditional knowledge have to exercise due diligence regarding legality of access. This approach is based on the recognition of users’ ability to “do the right thing”. The users have to seek, keep and transfer to subsequent users an Internationally Recognised Certificate of Compliance (IRCC). If such a certificate is not available, users have to seek, keep and transfer to subsequent users information on genetic resources and associated traditional knowledge including dates and places of access, the source of genetic resources and associated traditional knowledge and any rights’ obligations associated with them, as well as the prior informed consent (PIC) and mutually agreed terms (MAT). When the user determines that the information in their possession is insufficient they are obliged to discontinue utilization.

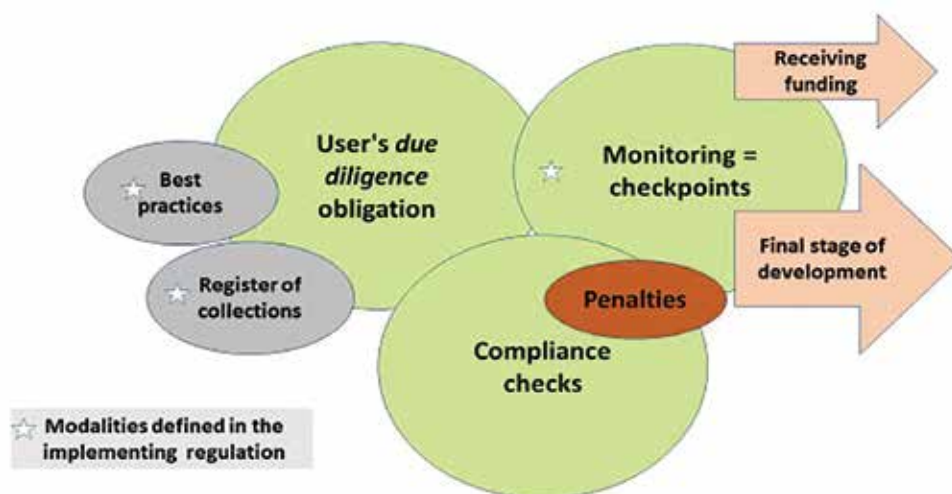


Figure 1. Building blocks of the EU ABS Regulation.

The only specific reference to genetic resources for food and agriculture in the EU ABS Regulation is contained in Article 4.4 (Obligations of users) that reads: “Users acquiring Plant Genetic Resources for Food and Agriculture (PGRFA) in a country that is a Party to the Nagoya Protocol which has determined that PGRFA under its management and control and in the public domain, not contained in Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), will also be subject to the terms and conditions of the standard material transfer agreement for the purposes set out under the ITPGRFA, shall be considered to have exercised due diligence in accordance with paragraph 3 of this Article”.

Some Member States that established access measures decided to use a standard material transfer agreement (sMTA) developed by the International Treaty for exchange of crops and forages included in the Annex 1 also for all plant genetic resources for food and agriculture (going thus beyond Annex 1 species). The user obtaining plant genetic resources using a sMTA from such a country is considered to have exercised due diligence. The use of sMTAs for exchange of non-Annex 1 species from countries that do not legislate on access remains outside of the scope of the Regulation.

### **Monitoring measures: checkpoints**

The users are obliged to submit a due diligence declaration to confirm that they are using genetic resources and associated traditional knowledge coming from a legal source. The EU ASB legislation established two checkpoints (further elaborated in the Implementing Regulation 2015/1866). The first is at the stage of research funding, where research involves utilization of genetic resources and associated traditional knowledge, and the second at the stage of pre-commercialization (final stage of development of a product).

The European Commission (2017) developed the Web-based application DECLARE to facilitate the process of submitting due diligence declarations by users, the exchange of information among the Member States, and between the Member States and the Commission, as well as the transmission of information to the ABS Clearing House (a Web-based application developed under the Protocol for exchange of information).

### **Enforcement measures: Member State level**

Even if Regulation 511/2014 is applicable directly in all EU States, the Member States have to develop national-level legislation or regulatory measures concerning some obligations under the Regulation. Namely, they have to designate competent national authorities that are responsible for implementation of the Regulation (Article 6), and set up a penalty system for breaches of the Regulation (Article 11). The penalties provided for shall be effective, proportionate and dissuasive. The penalties set by Member States are usually based on a gradation system: starting with awareness raising and caution, then administrative sanctions and, in some Member States, there are also criminal sanctions.

The competent authorities have to develop risk-based check plans that are periodically reviewed and carry out checks on user compliance (Article 9). Such checks may also result from substantiated complaints (including from the provider countries) received by competent authorities. Many Member States also engage in identification of users of genetic resources and associated traditional knowledge within their jurisdiction, and implement awareness-raising campaigns to inform users of their obligations arising from the EU ABS Regulation.

The competent authorities also play an important role by collaborating with the European Commission in implementation of supportive measures.

### **Supportive and complementary measures**

There are two voluntary mechanisms established to support implementation of the EU ABS Regulation.

The first is a register of collections within the Union (Article 5). Such a register (established and kept by the Commission) is to be Internet-based and easily accessible to users. The register is to include the collections of genetic resources, or of parts of these collections, that meet a number of criteria, i.e. they apply standardized procedures for exchanging and for supplying samples of genetic resources and related information to other collections, and to third persons for utilization; they keep records of all samples of genetic resources and related information supplied to third persons; establish or use unique identifiers for samples of genetic resources supplied to third persons and use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

The second supportive mechanism established under the EU ABS Regulation is recognition of best practices (Article 8), where associations of users or other interested parties may submit a combination of procedures, tools or mechanisms developed and overseen by them for recognition as a best practice. The application is to be addressed to

the Commission and needs to be supported by evidence and information. The procedure for processing applications for inclusion in the register and for recognition of best practices is set in the Implementing Regulation.

The EU ABS Regulation also provides for a number of complementary measures (Article 13) that should be applied both by the Commission and Member States. They include provision of information, awareness-raising and training activities to help stakeholders and interested parties to understand their obligations arising from the implementation of the Regulation. The complementary measures cover also development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly addressing the needs of academic, university and non-commercial researchers and SMEs as well as technical and other guidance to users in order to facilitate compliance.

They also include promotion of development and use of cost-effective communication tools and systems in support of monitoring and tracking the utilization of genetic resources and traditional knowledge associated with genetic resources by collection holders and by users.

In line with the objective of the Nagoya Protocol, it is also important to encourage users and providers to direct benefits from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components and promote measures supporting collections to enhance their contribution to the conservation of biological diversity and cultural diversity.

The EU ABS Regulation provides also for establishment of a Consultation Forum (Article 15) with balanced participation of representatives of the Member States and other interested parties in order to support the implementation of the Regulation.

## **IMPLEMENTING REGULATION 2015/1866**

The Implementing Regulation was developed and adopted through a “comitology” procedure.

The draft regulation was proposed by the European Commission and further developed in discussion with the Member States, then following the vote by Member States adopted by the Commission. The Implementing Regulation 2015/1866 was adopted on 13 October 2015 and entered into force on 9 November 2015 (European Commission, 2015). It is also directly applicable in all Member States, regardless of their status of the Protocol’s ratification.

The Implementing Regulation sets detailed rules on the implementation of three articles of the EU ABS Regulation: Article 5 (registered collections), Article 7 (monitoring user compliance) and Article 8 (best practices).

## **Checkpoints**

Regulation 2015/1866 describes specific requirements and procedures concerning due diligence declarations. In particular, it defines to whom and when the due diligence declarations should be submitted. It provides also for a template for such declarations.

The first checkpoint for monitoring user compliance is at the stage of research funding (where such research involves utilization of genetic resources or associated traditional knowledge). In accordance with Article 7(1) of the basic Regulation, the Member States and

the European Commission have to request all recipients of research funding (both public and private) to declare due diligence. Such requests can be associated, for instance, with an application for research funds. If there are mixed sources of funding or multiple recipients of funding, as it is in the case of international projects, it is possible to submit only one declaration, which should then be submitted by the project coordinator. Declarations are required to be submitted to competent authorities of the Member State where the user is established.

The Implementing Regulation also provides for the time of submission of due diligence declarations: they need to be submitted after receiving the first instalment of funding, when all the genetic resources and traditional knowledge associated with genetic resources have been obtained but no later than at the time of the final report, or in the absence of such a report, at the project end. The Implementing Regulation provides a template for a declaration (Annex II) that ensures uniformity of due diligence declarations.

The second checkpoint for monitoring user compliance is at the stage of final development of a product. The Implementing Regulation clarifies that the due diligence declaration needs to be made only once, prior to occurrence of the first of the defined events involving the utilization of genetic resources and traditional knowledge associated with genetic resources, namely:

- (a) market approval or authorization is sought for a product;
- (b) a notification is required prior to placing for the first time on the Union market is made for a product;
- (c) placing on the Union market for the first time a product for which no market approval, authorization or notification is required;
- (d) the result of the utilization is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c); and
- (e) the utilization in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

The Implementing Regulation defines also what a “result of the utilization” means, i.e. products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilization of the genetic resource and traditional knowledge associated with genetic resources.

A template for due diligence declaration for the second checkpoint is provided in Annex III to the Regulation. Both templates for due diligence declarations consist of two parts: Part A, containing information that is to be transmitted to the ABS Clearing House, and Part B, where information is not transmitted to the ABS Clearing House. Confidentiality rules may apply (to information contained in both parts of the declaration).

### **The register of collections**

The EU register of collections is a voluntary instrument to support users. Users obtaining genetic resources from registered collection are considered to have exercised due diligence regarding seeking of information.

The Implementing Regulation sets requirements for the collections or parts of the collections to be registered and a procedure for the application process. The register of collections (which is to be established by the Commission) needs to include a number of specified information sets for each collection or part thereof including: a registration code assigned by the Commission, a name given to the collection and its contact details, contact details of the collection holder, category and a short description of the collection or part thereof including links to its database (where available) and information on the institution of the Member State that verifies the capacity of the collection to comply with Article 5(3) of the EU ABS Regulation, the date of inclusion in the register and other existing identifiers where available.

In terms of procedure, the request for inclusion of a collection or a part thereof in the register should be submitted to the competent authority of the Member State where the collection is based and should be accompanied by the information specified in Annex I to the Regulation, especially evidence to prove the collection's capacity to comply with the requirements of Article 5(3) of the EU ABS Regulation. Such evidence may include codes of conduct, guidelines or standards that are applied by the collection, certification of the collection under relevant national or international schemes and information about participation of the collection in any international collection networks. The Member States are obliged to verify the submission and, in cases when the application is approved, grant recognition and pass all relevant documentation to the European Commission to include the collection in the register. The Member States are also obliged to perform risk-based checks on the collections.

Any changes in management of the collection should be communicated to the competent national authority.

### **Best practices**

The recognition of best practices is the second voluntary instrument established to support users. The authorities of the Member States should take into consideration recognized best practices implemented by users while carrying out checks on user compliance.

According to the procedure set in the Implementing Regulation, the European Commission receives applications from the associations of users. The application has to include the information and supporting documentation specified in Annex IV. Such supporting documentation should include a list of relevant personnel with the description of their duties in relation to the development and overseeing of best practices, a declaration of absence of conflict of interest on the part of the applicant and any subcontractors in developing and overseeing the combination of procedures, tools or mechanisms, and a description of tasks related to development of best practices or overseeing such practices by subcontractors, if relevant, and most importantly a description of combination of procedures, tools or mechanisms that when effectively implemented by a user enables that user to comply with its obligations under Articles 4 and 7 of the Regulation.

The Member States have to submit views on the application, and participate in the further process of assessing the application, and the European Commission grants (and if needed withdraws) the recognition of best practices.



## **SUPPORTING IMPLEMENTATION OF EU ABS LEGISLATION**

### **Consultation Forum**

The Consultation Forum, established on the basis of Article 15 of the EU ABS Regulation with a balanced representation of Member States and other interested parties (stakeholder representatives, non-governmental organizations [NGOs]), has a task to discuss implementation issues. So far, three meetings of the Consultation Forum have taken place. The first, held on 21 January 2016, focused on discussion of the so-called horizontal guidance document (see below); the second, held on 5 March 2017, discussed sectoral draft guidance documents. The last meeting on 18 December 2017 considered a number of unresolved issues contained in sectoral draft guidance documents.

### **Horizontal guidance**

As envisaged in Article 13 of the Regulation, the Commission initiated preparation of guidance documents to support users of genetic resources and traditional knowledge associated with genetic resources in implementation of the EU ABS legislation, and engaged in a number of other activities listed in the Article, contributing to this objective.

The guidance document **on the scope of application and core obligations** of Regulation (EU) No 511/2014 (referred to often as the “horizontal guidance document”) was developed by the Commission in close collaboration with Member States experts (gathered in the so-called ABS expert group). The draft was further discussed with the Consultation Forum. The guidance document was adopted on 22 August 2016 (European Commission, 2016).

The horizontal guidance document covers issues related to various criteria of defining the scope of the Regulation’s application, i.e. geographical scope (in relation to both the provenance of genetic resources and the place of their utilization), temporal scope, material scope and personal scope.

The guidance document explains *inter alia* that the user is within the scope of the EU ABS Regulation if he/she is utilizing the genetic resources and associated traditional knowledge accessed in a country that is a Party to the Protocol, and that has established access legislation. The information on national ABS legislation or regulatory measures can be found on the ABS Clearing House Web site (<https://absch.cbd.int/>). Users obtaining genetic resources from a non-Party to the Nagoya Protocol must respect relevant access legislation (where such legislation is established), but are not subject to obligations under the EU ABS Regulation.

The guidance document further clarifies that the EU ABS Regulation covers utilization of genetic resources that are found within national jurisdictions, so it does not cover genetic resources from areas beyond national jurisdiction or areas covered by the Antarctic Treaty System.

With regard to temporal scope, the user obligations take effect if genetic resources and traditional knowledge associated with genetic resources were accessed after the entry into force of the Nagoya Protocol. There is no retroactive effect in EU legislation. Therefore, the time of access (and not time of utilization) determines applicability of the EU law. However, provider-country legislation may diverge in this respect and should be respected.

With respect to the material scope of the EU ABS Regulation, the guidance document specifies that the Regulation does not cover genetic resources that are governed by specialized international ABS instruments (such as ITPGRFA, WHO PIP Framework). Utilization of traditional knowledge associated with genetic resources should be covered by MAT.

The horizontal guidance document explains also the core obligations of users, which include: due diligence obligation, establishing whether the Regulation is applicable and demonstrating due diligence when it has been established that the Regulation is applicable.

While utilization is defined as research and development (R&D), there is no legal definition of R&D or agreed lists of activities considered as R&D. It is assumed that users are best placed to assess the applicability of the definition of utilization to their activities performed on genetic resources.

### **Sectoral guidance**

Initially, the European Commission envisaged preparation of **sectoral guidance documents** for seven sectors: animal breeding, plant breeding, food and feed, biocontrol and biostimulants, pharmaceuticals, cosmetics and biotechnology.

The process of their preparation followed a different procedure to that of developing the horizontal guidance document: the Commission was assisted here by an external consultant. The consultant, under the supervision of the Commission, established Guidance Development Groups, i.e. drafting groups that included experts from various EU countries representing professional organizations concerned by the EU ABS Regulation. The draft guidance documents developed by the Guidance Development Groups were subsequently discussed during sectoral workshops, in which stakeholders and representatives of the Member States participated. The documents were then further discussed by the ABS Expert Group and the Consultation Forum. In addition, there were a number of opportunities to provide written comments during the process. Work on these draft documents is almost complete.

In the meantime, the need for additional guidance documents for upstream users (research sector and collection holders) has been identified, and work on them was initiated in early 2017, following the same process as in the case of the sectoral draft guidance documents.

A uniform approach was adopted in the development of all sectoral draft guidance documents. This includes a similar content structure, i.e. description of sector and analysis of specific cases. Each case contains a description of the specific situation/activity performed and is followed by an analysis leading to the conclusion if a given activity is in the scope of the EU ABS Regulation or not.

A number of crosscutting issues have been identified in all draft guidance documents, such as, for instance, large-scale screening. Some issues are truly sector specific, i.e. treatment and status of commercial plant varieties.

### **DECLARE**

As mentioned before, to facilitate the efficient and cost-effective flow of information, the European Commission developed an IT tool, DECLARE, for submission of due diligence

declarations from users to checkpoints (competent national authorities [CNAs]), then from CNAs to the ABS Clearing House. Only non-confidential information included in Part A of due diligence declarations, after verification by CNAs, is transferred to the ABS Clearing House. The DECLARE system for the first checkpoint has been operational since September 2017.

### **Additional activities to support implementation**

In the last two years, there have been many activities initiated by the European Commission and the Presidency of the Council, as well as individual Member States, to support implementation of the EU ABS Regulation.

The Commission contracted for the organization of a number of workshops for researchers that were carried out in several European cities in 2015 and 2016, to draw attention to the ABS legal landscape affecting research studies and research collaboration.

Many initiatives focused on facilitation of continuous collaboration of the CNAs of Member States. There were a number of meetings of competent authorities organized on the outskirts of ABS expert group meetings, as well as stand-alone meetings (i.e. a three-day meeting held in Germany in Vilm, in June 2017; another one is planned for April 2018).

Moreover, the European Commission established a forum for discussion between Member State's competent authorities. Experts can discuss experience in implementation challenges and share best practices on the devoted IT platform.

Significant efforts have been made to develop a better understanding of different ABS legal frameworks by competent authorities of the EU Member States and EU business companies. Similarly, significant efforts have been devoted to explaining the EU ABS legal framework to CNAs of the provider countries. The Commission organized a workshop (Brussels, November 2017), which provided an excellent opportunity to discuss issues related to implementation. A very successful meeting was also organized by the German competent authority in Vilm, in August 2017.

### **STATE AND CHALLENGES IN IMPLEMENTATION IN THE EU-28**

The EU Member States were committed to ratify the Nagoya Protocol. Already at the COP-MOP 1, three countries (Denmark, Hungary and Spain) as well as the EU were Parties to the Protocol.

In 2015, Belgium, Bulgaria, the Czech Republic, Croatia, Finland, Germany, Slovakia and the United Kingdom of Great Britain and Northern Ireland (UK) became Parties to the Protocol. In 2016, France, Sweden and the Netherlands, and in 2017, Luxembourg, Malta and Portugal joined the Nagoya Protocol as Parties. The ratification process is under way in other Member States.

As stated before, decisions on access measures belong to individual Member States. Some countries, such as Spain, France, Croatia, Malta and Bulgaria, have developed access legislation, while others (Italy, Portugal, the Czech Republic) are considering introducing access measures. The IRCCs were issued by these countries. By 14 February 2018, out of 146 IRCCs, seven were issued by Spain, three by Bulgaria and one by Malta (<https://absch.cbd.int/search/nationalRecords?schema=absPermit>).

Some countries that decided to regulate access to their genetic resources have applied specific access measures to genetic resources for food and agriculture: for instance, France and Spain decided to exempt livestock genetic resources from their access measures.

Other EU Member States have decided not to regulate access to their genetic resources. Denmark, Finland, Germany, Hungary, Poland, Sweden and the UK are the countries that decided not to introduce access measures. However, Finland and Denmark regulate access to traditional knowledge associated with genetic resources.

The implementation of the ABS measures is challenging, as implementation must take into account the high number and diversity of entities dealing with genetic resources and potentially traditional knowledge associated with genetic resources in the Union. Building awareness of ABS issues and ABS legislation in various economic sectors and among relevant stakeholders requires significant efforts and resources.

For competent authorities, it is difficult to identify all enterprises and all individuals that are users of genetic resources, which is important for developing risk-based plans and carrying out users' checks.

From a user perspective, there is insufficient clarity and legal certainty regarding the key concepts in ABS legislation (utilization – genetic resources). Also, users are struggling with analysis of their own activities – it is often extremely difficult to determine if a given activity falls under the definition of utilization or not.

Another problem faced by users comes from insufficient information about provider country legislation and insufficient clarity regarding procedures to apply for access. In this respect, one cannot overestimate the importance of placing all relevant legislation and information on the ABS Clearing House.

## REFERENCES

**EU ABS Regulation.** 2014. *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 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union OJ L 150, 20.5.2014, p. 59-71* (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0511>).

**European Commission.** 2010. *Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market Text with EEA relevance OJ L 295, 12.11.2010, p. 23-34* (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010R0995>).

**European Commission.** 2012. *Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union/\* COM/2012/0576 final - 2012/0278 (COD) \** (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52012PC0576>).

**European Commission.** 2013. *Initial appraisal of a European Commission Impact Assessment European Commission proposal on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the Union* (available at file:///C:/Users/EM/Downloads/(3-27)%20EU%20Initial%20appraisal%20of%20a%20European%20Commission%20Impact%20Assessment.pdf).

- European Commission.** 2015. *Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices OJ L 275*, 20.10.2015, p. 4-19 (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866>).
- European Commission.** 2016. *Commission notice - 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 Utilization in the Union OJ C 313*, 27.8.2016, p. 1-19 (available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29>).
- European Commission.** 2017. *User guide / Questions and answers - DECLARE NAGOYA IT system CONTACT: ENV-DECLARE-NAGOYA@ec.europa.eu*
- IEEP/Ecologic/GHK.** 2012. *Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*. Final report for the European Commission, DG Environment. Institute for European Environmental Policy, Brussels and London, April 2012 (available at <http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20FINAL%20REPORT.pdf>).

# Brazilian National Implementation of Access and Benefit-sharing

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## EXECUTIVE SUMMARY

Brazil is an important actor within the international discussions on access and benefit-sharing and, since 2000, has an established legislation on access to genetic resources, including the use of genetic information, traditional knowledge and benefit-sharing, in accordance with the Convention on Biological Diversity (CBD). This has been maintained through the new legal framework on access and benefit-sharing (ABS) (Law No 13,123/2015), regulated by Decree No 8,772/2016, which requires the identification of the genetic resource and its origin, even when the genetic resource was obtained *in silico*. It has implemented a new administrative procedure that only requires registry in an electronic system for the management of genetic heritage and associated traditional knowledge – an ABS single window – referred to as SisGen. It also has a governance system in place for access to genetic resources and to associated traditional knowledge – the Genetic Heritage Management Council (CGen).

## INTRODUCTION

Brazil occupies almost half of South America and is one of the 17 megadiverse countries (Shi *et al.*, 2005). It has six terrestrial biomes and three great marine ecosystems. The different climatic zones favour the formation of biogeographical zones such as: the Amazon rainforest, the largest rainforest in the world; the Pantanal great floodplain; the Cerrado, with its savannahs and forests; the Caatinga, composed of semi-arid forests; the fields of the Pampas; and the tropical rainforest of the Atlantic Forest. In addition, Brazil has a marine coastline of 3.5 million km<sup>2</sup>, which includes ecosystems such as coral reefs, dunes, mangroves, lagoons, estuaries and marshes (MMA, 2018a).

It is often considered the most biologically diverse country in the world (containing 22 percent of the world's biodiversity), due to the flora and fauna found in its continental territory. So far, 117 289 species of animals are known to Brazil, their majority being arthropods (about 85 percent, almost 94 000 species) and chordates representing 10 percent of fauna species (MCTIC/MMA, 2018). At this moment, 46 506 species are recognized for the Brazilian flora: 4 754 of algae, 33 109 of angiosperms, 1 564 of bryophytes, 5 718 of fungi, 30 of gymnosperms and 1 331 of ferns and lyophytes (JBRJ, 2018).

Brazil has more than 305 indigenous ethnic groups (IBGE, 2010) and around 40 other types of local communities (Comissão Nacional para o Desenvolvimento Sustentável dos Povos e Comunidades Tradicionais, 2018). Brazil's biodiversity is an essential resource for its people, not only directly because of the environmental services it provides, but also due to the development opportunities that these represent. Brazilian agriculture is a major user of exotic biodiversity, while the Brazilian cosmetic, pharmaceutical and biofuel industries are heavy users of national biodiversity. Brazil cherishes its biodiversity and, in the past decade, has made impressive progress in fighting threats to biodiversity on various fronts, particularly by establishing protected areas, fighting against deforestation and regulating sectors that either threaten the country's biodiversity endowment or propose to use it in a sustainable way across the country's various landscapes.

### **LAW 13,123/2015**

Brazil is an important actor within the international discussions on access and benefit-sharing. In 1992 it became a signatory to the Convention on Biological Diversity (CBD), whose provisions came into force in 1994. The CBD explicitly recognized the authority of states to determine rules on access to genetic resources as part of their sovereign rights over natural resources under their jurisdiction. Furthermore, it obliges all contracting parties to take legislative, administrative or policy measures, to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources.

Since the year 2000, Brazil has an established legislation on access to genetic resources, traditional knowledge and benefit-sharing, in accordance with the CBD, and regulates the use of genetic information, even when disengaged from the physical sample, since its first version. The Provisional Act No 2,186-16/2001 regulated Articles 1, 8 15 and 16 of the Convention and established a governance system for access to genetic resources and to associated traditional knowledge. It created the Genetic Heritage Management Council (CGen)<sup>1</sup> and devised an administrative procedure for obtaining access authorization, prior informed consent and mutually agreed terms. During the 15 years that the Provisional Act has been in force, CGen has granted over 2 600 access authorizations and established 295 benefit-sharing agreements (MMA, 2018b).

The regulation of the use of genetic information has been maintained by the new legal framework on access and benefit-sharing: Law No 13,123/2015 (Presidência da República, 2015), that revoked the Provisional Act No 2,186-16/2001, defines genetic heritage as the genetic information from plants, animals and microbial species, or any other species, including substances originating from the metabolism of these living organisms. This new law aims to overcome the many concerns raised though past experiences, while enabling access to genetic resources and associated traditional knowledge.

<sup>1</sup> CGen is a multi-stakeholder body, comprised of federal government (60 percent) and society (business sector, academic sector, indigenous peoples, traditional communities and traditional farmers) (40 percent), charged with the coordination, development and implementation of policy for ABS. It sets technical norms and guidelines, monitoring access, accrediting *ex situ* collections, managing the notification of final products and maintaining SisGen.

The law was regulated by Decree No 8,772/2016 (Presidência da República, 2016) in 2016, which required the identification of the genetic resource and its origin, including a georeferenced coordinate of the location where the physical sample was collected *in situ*, even if it was obtained from *ex situ* or *in-silico* sources. It implemented a new framework that only requires registry in an electronic system for the management of genetic heritage and associated traditional knowledge – an ABS single window – referred to as SisGen.

## **DIGITAL SEQUENCE INFORMATION ON INTERNATIONAL ABS REGIME**

A systemic reading of the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty) strongly influenced the elaboration of Law 13,123/2015 and its Decree No. 8,772/2016. The CBD defines “genetic material” as any material of plant, animal, microbial or other origin containing functional units of heredity.

According to the Oxford Dictionary, the word “material” can be defined as “information or ideas for use in creating a book or other work”. On the other hand, the definition of the word “matter” is “physical substance in general, as distinct from mind and spirit; (In physics) that occupies space and possesses rest mass, especially as distinct from energy” (Oxford University Press, 2018). The term “material” should not be confused with the term “matter”. The definition of the word “material” allows the interpretation of the term to include the set of information associated with the genetic resource, that is, the substrate information or working material (MRE, 2017).

Therefore, it is not only conceivable to understand the word “material” in the broader scope of its meaning, but it offers a more flexible and proper meaning. To restrict the understanding of the meaning of the word “material” to match the meaning of the word “matter” is to jeopardize the obligation to share benefits, the sovereignty of the countries parties over their genetic resources, the CBD and the Treaty.

Even if genetic information obtained digitally is to be considered as excluded from the concept of genetic material, a systemic interpretation of the CBD and the Nagoya Protocol leaves no doubt that the use of this information is subject to benefit-sharing. The means of transmission of genetic information, whether in the form of matter from a DNA sample or as information stored in silico, is irrelevant to the fulfilment of this obligation. Since there was a “utilization” of a physical sample to access this type of information, its application and subsequent commercialization should be shared in a fair and equitable way, in line with Article 5 of the Nagoya Protocol and Article 10 of the Treaty.

Accordingly, the discussion of digital sequence information (DSI) within the scope of international agreements ultimately does not impact the effective application of the CBD, the Nagoya Protocol or the Treaty.

Furthermore, under the Pandemic Influenza Preparedness (PIP) Framework, which has as one of its main objectives access to vaccines and sharing of other benefits, there is already a clear definition of “genetic sequences”, which “means the order of nucleotides found in a molecule of DNA or RNA. They contain the **genetic information** that determines the biological characteristics of an organism or a virus”. In another chapter, the PIP Framework establishes the procedure for best practices relating to genetic sequence data (WHO, 2011).



In this context, it is easy to perceive that the object of discussion within the context of “digital sequence information” is not the word “digital”, which corresponds only to the medium in which information is transferred, and neither in the word “sequence” since it only signifies the order in which nucleotides are presented, but in its main core: the genetic information transmitted through digital media or any other media in a sequenced form or any other form. Thus, international fora discussing DSI or any other terminologies, such as “genetic sequence data”, “dematerialized genetic resources”, “in-silico utilization” and “natural information”, should converge in adopting “genetic information” as the proper terminology.

### **IMPROVEMENTS ESTABLISHED BY LAW 13,123/2015**

Some solutions found by Law No. 13,123 of 2015 could be considered for the implementation of the use of genetic information in the CBD, the Nagoya Protocol, FAO and other relevant international fora:

- A facilitated mechanism for access to genetic resources, with a change in the regulation, previously focused on the control of access to genetic resources, now shifted towards control of the economic exploitation of products or reproductive materials arising from access.
- The development of an online registration system (SisGen) to trace, track and oversee access to genetic resources and associated traditional knowledge activities. The SisGen electronic system is declaratory, as opposed to the old *modus operandi* of the Provisional Act in which a procedure for validation of documents was in place.
- The registration must only be carried out prior to specific moments such as shipment, request for intellectual property rights, publication of results and commercialization. Research and development activities that do not result in any of the above-mentioned activities are not required to be registered.
- Registration is not needed prior to access (research and development) itself when only the genetic resources are accessed, without access to traditional knowledge: these activities are not restrained by any prior administrative procedure for granting access.
- Prior informed consent (PIC) for access to genetic resources was granted by the Law: there is no administrative procedure for access to genetic resources; PIC for access to traditional knowledge is mandatory and should be obtained directly with indigenous and local communities.
- Economic exploitation of a finished product or reproductive material was established as the single point of incidence of benefit-sharing obligations: this is the link of the value chain with the highest value added, discharging any research and development activity: economic benefits are to be shared when they do exist.
- Because of the single point of incidence, the economic exploitation of any intermediate product is exempt from benefit-sharing obligations.
- The percentage of monetary benefit-sharing from products or reproductive material derived from the use of genetic resources is established as 1 percent of net revenues

from the product or reproductive material sales: there is no speculation of values and no surprises for genetic resource users. It gives predictability and legal certainty to invest in bio-based products arising from access.

- The clearly established point of incidence combined with a defined percentage of benefit-sharing to be valued under a specific concept such as “net revenue” make the monitoring of compliance feasible, since they are based on fiscal and accounting principles and rules.
- When the user chooses to share the benefits through non-monetary means, such as a conservation or social project, benefit-sharing is equivalent to 75 percent of the predicted value for the monetary modality. This concession considers expenses the user might have in implementing the project and encourages the non-monetary modality.
- Licensing, transferring or permitting any use of intellectual property rights does not require benefit-sharing. Benefit-sharing obligations exist only when a finished product or reproductive material using the licensed intellectual property is commercialized to the final consumer.
- Micro-businesses, small businesses, micro individual entrepreneurs, traditional farmers and their cooperatives are exempt from benefit-sharing obligations.

Another solution was the establishment of a National Benefit-Sharing Fund for centralization and subsequent redistribution of benefits arising from the use of genetic resources and associated traditional knowledge through a management committee for actions focused on research, development and conservation of genetic resources and protection of associated traditional knowledge.

The Benefit-Sharing Fund is managed by a collegial committee, comprised of seven representatives from public administration institutions or entities, seven representatives from organizations representing indigenous peoples, traditional communities and traditional farmers and representation from the Brazilian Society for the Progress of Science (SBPC).

Once the due amount to be shared is given by law (1 percent of net revenues from the product or reproductive material sales), users can pay the benefits directly to the Fund, through an electronic voucher provided by SisGen, once the registration and notification requirements are fulfilled and when there are benefits to be shared. The need to sign the Benefit-Sharing Agreement (MAT) will occur only when users decide for the non-monetary modality or when traditional knowledge is accessed.

Furthermore, many have pointed out the difficulties in identification of either the genetic resource or its origin as an argument for preventing DSI from being considered within the scope of both the CBD and the Treaty. Brazilian Decree 8,772/2016 has already foreseen procedures to be adopted in cases of techniques that access micro-organisms that are not isolated from a specific substrate and have not been identified, such as metagenomics.

Brazil has also positioned itself in favour of using the Global Multilateral Benefit-Sharing Mechanism to resolve issues of benefit-sharing relating to situations in which prior informed

consent cannot be obtained, such as lack of origin information, transboundary situations or products and reproductive material resulting from multiple access from different origins (MRE, 2017).

With regard to the Treaty, this issue has already been solved since there is no need for PIC to access the genetic resources covered by the Multilateral System and there is already a Global Benefit-Sharing Fund in place.

Therefore, useful instruments are already in place to resolve issues for the use of DSI within the framework of the CBD and the Treaty. There are viable regulating strategies and the establishment of trigger points that will not impede the rapid sharing of information, crucial for our current scientific demands.

### **SPECIAL CONSIDERATIONS FOR FOOD AND AGRICULTURE**

Law No 13,123/2015 defines agricultural activities as those of producing, processing and commercializing food, drinks, fibres, energy and planted forests. It also describes reproductive material as any plant propagating material or animal reproductive material, originating from sexual or asexual reproduction.

The benefits resulting from the economic exploitation arising from access to genetic resources for food and agriculture are to be shared only on the commercialization of the reproductive material. In consequence, all the previous or following links on that same production chain (for example the sale of food to the final consumer) are exempt. This measure aims not to cause excessive encumbrances in food and agriculture chains.

On the grounds of Law No 13,123, of 2015, the only differentiation that is made is the purpose of use of a given genetic resources – whether for food and agriculture, or for other industrial activity. Thus, any genetic resource can be considered as a genetic resource for food and agriculture, whenever it is used with such intent.

Likewise, research and development on a genetic resource typically used for food and agriculture might result in a finished product used for purposes other than food and agriculture. In this scenario, the benefit-sharing for the economic exploitation of products arising from access to these genetic resources (that were originally aimed for agricultural activities and were used, in a change of intent, solely for generating a finished product into productive chains for other industrial activities) occurs only on the economic exploitation of the finished product, being the economic exploitation of the reproductive material exempt from it.

As such, there is no different procedure for obtaining access to genetic resources of any subsector, be it plants, animals, forests, aquatic genetic resources, micro-organisms or invertebrates. The same is valid for benefit-sharing rules: 1 percent of net revenue is applicable to any subsector.

### **ABS LEGISLATION AND FOREIGN INSTITUTIONS**

To obtain genetic resources from Brazil, a shipment registration is required by the Brazilian institution sending the resource, while the foreign institution requires a national partner (a scientific and technological research institution), which is responsible for the access/notification registration.

## CONCLUSION

The use of genetic information in the context of access and benefit-sharing has been regulated by the Brazilian legislation since 2000.

In line with the definitions of the Brazilian Law, the object of international discussions should not focus on digital sequence data but on their core object: the genetic information contained in them.

There are several alternatives to regulate access to genetic information for food and agriculture. Mainly, countries should change the focus from regulating processes towards regulating results. This shift relieves the bureaucratic burden of research and development and focuses on the end of the chain, the economic exploitation of products and reproductive material.

When national legislation focuses on monitoring end-products, instead of monitoring the process to obtain those, more user-friendly ABS systems will come to exist, strengthening confidence in the ABS international system.

For that, countries should invest in the creation of simple, declaratory and transparent regulations, but at the same time invest in effective tracking and tracing tools that allow monitoring of compliance. Additionally, they should provide for changing intention mechanisms (specially from non-agricultural research to agricultural research, and vice-versa), a clearly defined triggering event, quantifiable and non-speculative values for benefit-sharing, preferably based on fiscal and accounting principles and rules, and a strategy in which monetary benefit-sharing should be an obligation when there is a clear monetary benefit being obtained from the use of a genetic resource.

Predictable rules will allow users to foresee their costs and obligations, in the short and long term, and will provide legal clarity to users and thus encourage the use of genetic resources. Legal measures that facilitate and foster research and development will generate more benefits, which can be channelled to biodiversity conservation and sustainable use, fulfilling the objectives of the international agreements on ABS.

## REFERENCES

- Comissão Nacional para o Desenvolvimento Sustentável dos Povos e Comunidades Tradicionais.** 2018. *Portal Ypadê* (available at <http://portalypade.mma.gov.br/>).
- IBGE (Instituto Brasileiro de Geografia e Estatística).** 2010. Retrieved from Censo Demográfico: características gerais dos indígenas (available at [https://biblioteca.ibge.gov.br/visualizacao/periodicos/95/cd\\_2010\\_indigenas\\_universo.pdf](https://biblioteca.ibge.gov.br/visualizacao/periodicos/95/cd_2010_indigenas_universo.pdf)).
- JBRJ (Jardim Botânico do Rio de Janeiro).** 2018. Retrieved from Flora do Brasil 2020 em construção (available at <http://floradobrasil.jbrj.gov.br>).
- MCTIC/MMA (Ministério da Ciência, Tecnologia, Inovações e Comunicações/Ministério do Meio Ambiente).** 2018. *Sistema de Informação da Biodiversidade Brasileira*. Retrieved from *Catálogo Taxonômico da Fauna do Brasil* (available at <http://fauna.jbrj.gov.br>).
- MMA (Ministério do Meio Ambiente).** 2018a. Retrieved from Biodiversidade (available at <http://www.mma.gov.br/biodiversidade>).

- MMA.** 2018b. Retrieved from Atividades do CGen durante a vigência da MP nº 2.186-16/2001 (available at <http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/atividades-do-cgen-durante-a-vigencia-da-mp-n-2-186-16-2001/relatorio-de-atividades>).
- MRE (Ministry of Foreign Affairs of Brazil).** 2017. (available at <https://www.cbd.int/abs/DSI-views/Brazil-DSI.pdf>).
- Oxford University Press.** 2018. *Oxford Dictionary of English* (available at <http://www.oxforddictionaries.com>).
- Presidência da República.** 2015. *Brazilian Biodiversity Law*. Retrieved from <https://absch.cbd.int/database/record/ABSCH-MSR-BR-238963>
- Presidência da República.** 2016. *Decree 8,772*. (available at [http://www.planalto.gov.br/ccivil\\_03/\\_ato2015-2018/2016/decreto/D8772.htm](http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm)).
- Shi, H., Singh, A., Kant, S., Zhu, Z. & Waller, E.** 2005. Integrating habitat status, human population pressure, and protection status into biodiversity conservation priority setting. *Conservation Biology*, 19(4): 1273-1285. doi:doi:10.1111/j.1523-1739.2005.00225.x
- WHO (World Health Organization).** 2011. Pandemic influenza preparedness framework for the sharing of influenza - PIP Framework (available at [http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf)).

# Proposed Regulations on Access and Benefit-sharing for Biological and Genetic Resources of Lebanon

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## **EXECUTIVE SUMMARY**

Lebanon has a very rich and unique biodiversity of fauna and flora in a very limited area of land located in the heart of the Mediterranean Vavilovian Center, which contains the richest and most threatened reservoirs. The country enjoys substantial biological and genetic resources that benefit rural communities and farmers who often depend on them for their livelihoods and health care and to mitigate or adapt to climate change. As in many other countries, the biological diversity in Lebanon is subject to loss and damage due to various human activities and stresses. Therefore, it is very important for Lebanon to take appropriate measures to preserve and use its biological diversity sustainably and to regulate obtaining the biological and genetic resources present on its territory and the equitable sharing of the benefits arising from their utilization. The Lebanese Government ratified the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in 2017 and the International Treaty for Plant Genetic Resources for Food and Agriculture well before in 2004, and it was thus necessary to set up appropriate national regulations for the implementation of both international agreements. A draft law for the access to the Lebanese biological and genetic resources and sharing the benefits arising from their utilization was developed by the Ministry of Environment in the context of the application of the Nagoya Protocol. It applies to biological and genetic resources that are not food or agriculture related. A second draft law for the management of plant genetic resources for food and agriculture in Lebanon was prepared by the Lebanese Agricultural Research Institute in the context of implementation of the International Treaty for Plant Genetic Resources for Food and Agriculture. Presently, both draft laws have been submitted to the Council of Ministers for approval and are expected to be transmitted soon to Parliament for endorsement.

## **GENERAL CONTEXT**

Lebanon is a small country located in the Middle East at the east end of the Mediterranean, where domestication of species started 10 000 years ago. It covers an area of 10 452 km<sup>2</sup>

with an average width of 48 km and a length of 225 km. Lebanon's climate is typical of the Mediterranean region, with four distinct seasons that encompass a rainy period usually lasting from November to March followed by a dry period during which very little precipitation occurs. This makes Lebanon well endowed with water resources in a relatively very arid regional context, with an average annual precipitation reaching over 1 000 mm on the western slopes of Mount Lebanon and feeding a river system combining rich streams and groundwater. Almost 60 percent of the available water resources are used for agricultural activities.

Out of the total Lebanese area, about 36 percent are agricultural lands, 13.6 percent are covered by forests, 10 percent are wooded land, the remaining being non-cultivated lands and natural pastures. The agricultural outputs by subsector are around 47 percent for fruits and olives, 23 percent for vegetables and other field crops, 11 percent for livestock products, 10 percent for livestock, 4 percent for industrial crops, 3 percent for fishery products and 2 percent for cereals. The cultivated area was about 231 000 ha in 2010, of which almost 50 percent are irrigated. The agricultural lands are located mainly in the narrow coastal plains in Akkar, in the inland Bekaa Valley, in Marjayoun Plain in the South and on the terraces along the mountain sides. The main crops grown in Lebanon are fruit trees (31 percent), olives (23 percent), cereals (20 percent) and vegetables (17 percent), followed by pulses (4 percent), industrial crops (4 percent) and fodder (1 percent). Among the Arabic neighbouring countries, Lebanon is famous for its citrus, apples, grapes, cherries, tomatoes, potatoes and poultry, and is an exporter of fruits and vegetables. However, Lebanon is still a large net importer of food, importing more than 80 percent of its needs in wheat and animal products. Moreover, due to the high population density and the mountainous landscape of the country, the arable land per capita is very limited. Consequently, food security as a reasonable objective for some field crops, mainly cereals, has become a national priority.

Lebanon is situated in the heart of the Mediterranean Vavilovian Center, which contains the richest and most threatened reservoirs. Lebanon has a very rich and unique biodiversity of fauna and flora in a very limited area of land, with 4 633 plant species of which 2 863 terrestrials, 390 bird species, 52 mammal species, 51 reptile and amphibian species, 900 fish species and 1 300 insect and butterfly species. Lebanon covers 0.007 percent of the world's land surface area and hosts about 0.8 percent of the world's recorded and catalogued species. This high diversity over small surfaces is clear in terms of species-area ratio. Lebanon's fauna species-area ratio is considered high as well and reaches 0.028 species/km<sup>2</sup> compared with neighbouring countries, while Lebanon's vegetation has a very high species-area ratio of 0.25 species/km<sup>2</sup> compared with other countries that have larger green lands.

Lebanon enjoys substantial biological and genetic resources that benefit human well-being and sustainable development. Rural communities are often dependent for their livelihoods and health on the use of biological and genetic resources, and associated traditional knowledge, particularly for food, medicinal plants and timber. Moreover, these resources are crucial in carbon storage and in mitigating climate change or adapting to it.

As in many other countries, the biological diversity in Lebanon is subject to loss and damage due to various human activities and stresses. Therefore, it is very important for Lebanon to preserve and use the biological diversity sustainably and regulate obtaining the biological and genetic resources present on its territory and the fair and equitable sharing of the benefits arising from their utilization. For that end, it is necessary to set up appropriate regulations, which requires taking appropriate measures to control obtaining the Lebanese biological and genetic resources and their exploitation in a sustainable way.

The Lebanese Government acceded to the United Nations Convention on Biological Diversity by virtue of Law No. 360 issued on 1 August 1994, the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) by Law No. 559 issued on 11 February 2004 and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization by Law No. 3 issued on 3 February 2017.

On the other hand, the Environment Protection Law No. 444 in Lebanon issued in 2002 postulates that the natural resources management and the preservation of the biological diversity in Lebanon depend on developing a system for controlling the access to the biological, vital and genetic resources and their utilization in accordance with the international agreements and conventions ratified by Lebanon.

It is hence indispensable to draft the appropriate laws for regulating the access to the Lebanese biological and genetic resources and their utilization in a sustainable way, and the fair and equitable sharing of the benefits arising from their utilization. In this paper we review the national regulations proposed on access and benefit-sharing (ABS) for these resources, with an emphasis on the preparation process of the draft laws and their major elements. The first steps towards the implementation of these draft regulations in Lebanon are also presented.

## **DRAFT LAW FOR ACCESS TO LEBANESE BIOLOGICAL AND GENETIC RESOURCES AND SHARING THE BENEFITS ARISING FROM THEIR UTILIZATION**

### **Preparation process**

Being the national implementing authority of the Convention on Biological Diversity (CBD), the Ministry of Environment, with the collaboration of the Initiative for Biodiversity Studies in Arid Regions at the American University of Beirut (IBSAR), developed in 2005 a draft law regulating access to the biological and genetic resources of Lebanon and the benefit-sharing arising from their utilization (ABS). This was effected through the UNDP/GEF Top-Up Biodiversity Enabling Activity Project, with funds available from the USDA-Mercy Corps.

The preparation process leading to the elaboration of the draft law involved steps of capacity building for the parties addressing the issues along with regular participatory national meetings to raise awareness and derive feedback from various sectors of society. Foreign consultancies and advice were also sought to broaden the knowledge base. Following a year of consultations and workshops, a draft law was prepared in which avoiding future conflicts and responsibilities between ministries was considered.



This first draft law was then forwarded and reviewed by international experts from the Law Offices of Dodds and Associates, Washington, DC, and then discussed in national workshops with a delegation of experts from Costa Rica and consultants from the United States of America. This was followed by consultations with representatives from the Ministry of Environment, Ministry of Economy and Trade and Ministry of Agriculture. A follow up on comments and changes was conducted by an ad hoc committee that reviewed the draft law and recommended substantial change. This led to the preparation of a second draft that was reviewed by concerned people at the Ministry of Environment, namely the CBD focal point, the Head of Department of Conservation of Natural Wealth and also by the Legal Department. This version of the draft law was issued in May 2005 and submitted to the Council of Ministers who later sent it to the concerned ministries and academia for review. Suggestions and recommendations were again revised by the Ministry of Environment in accordance with the requirements of the Nagoya Protocol. The final draft was lately re-submitted to the Council of Ministers for approval and the latter will transmit it to Parliament for endorsement.

### **Major elements**

This draft law aims at regulating access to the Lebanese biological and genetic resources that are not food or agriculture related, the preservation of these biological and genetic resources and their elements, their utilization in a sustainable way and the fair and equitable sharing of the benefits arising from their utilization, in the context of the application of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization annexed to the CBD.

The draft law applies to biological and genetic resources occurring both *in situ* and *ex situ*. It stresses the sovereignty of the State over biological resources exercised in the name and for the benefit of local communities. The draft did not include indigenous knowledge and intellectual property. These are to be developed at a later stage by the Ministry of Economy and Trade, which has a dedicated department for intellectual property protection, and a registration mechanism for intellectual and industrial property rights, in close collaboration with the Ministries of Environment and Agriculture and in close consultation with the World Intellectual Property Organization (WIPO). However, in all cases, the right of the local communities regarding their biological and genetic resources remains governed by the provisions of ABS stipulated in this draft law and the signed ABS agreement.

Four types of agreements are provided for in the draft law: (i) academic research agreement; (ii) conservation of biological and genetic resources agreement; (iii) commercial research agreement; and (iv) commercial exploitation agreement.

The Ministry of Environment, through the relevant biodiversity department, is designated as the competent national authority to be responsible for the implementation and enforcement of the law provisions, in coordination with other relevant ministries.

The draft law proposes the creation of an advisory committee headed by the Ministry of Environment and including representatives from relevant ministries and organizations, to assist the Ministry in the implementation and enforcement of the ABS law.

Any person or entity that wishes to access the biological and genetic resources of Lebanon should file an application with the Ministry, which is then forwarded to the Advisory Committee for examination. The Committee will submit its recommendations to the Ministry, and the latter will take the final decision and communicate it to the applicant. Once the said application is approved, the Ministry invites the applicant to sign the ABS agreement. The signed agreement will constitute the applicant's official authorization to access the biological and genetic resources.

The applicant must deposit subsamples of all the vegetal samples that are accessed at the national gene bank affiliated with the Lebanese Agricultural Research Institute and deposit subsamples of all the animal samples that are accessed at the authority appointed by the competent national authority by virtue of a decision by the Minister of Environment.

The process for the access to the biological and genetic resources and the import and export of these resources involve the Ministry of Agriculture. In order to monitor the process of sampling from vegetal or animal resources from the concerned site, the applicant must be accompanied, during the plant sample-taking process, by a representative from the national gene bank affiliated with the Lebanese Agricultural Research Institute and a representative from the Ministry of Agriculture concerned with animal genetic resources. The competent national authority allows the export of biological and genetic resources, which should be monitored by the veterinary and plant quarantine offices affiliated with the Ministry of Agriculture and members of the Customs Bureau.

Concerning benefit-sharing, the draft law provides that any scientific, medical, pharmaceutical, commercial or legal results derived from the access to, use of, research, experiments and development of the biological and genetic resources should be shared with the State and the local landowner or owners and communities whose biological and genetic resources were involved in the activity of the applicant. The sharing of such results shall be provided for in the ABS agreement, which will describe the benefit-sharing method that the parties to the agreement agree upon, and the share of each one of them. According to this draft law, there are two different types of benefits that could be shared and included in the ABS agreement: monetary and non-monetary benefits. Moreover, the import and export of biological and genetic resources is authorized and regulated by the Ministry of Environment. Finally, the draft law provides for penalties that will apply in case the access to, use and development of, and trading in biological and genetic resources is carried out without the approval of the Ministry of Environment and without signing the required ABS agreement.

## **DRAFT LAW FOR THE MANAGEMENT OF PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE IN LEBANON**

### **Preparation process**

Being the national focal point for the ITPGRFA in Lebanon, in 2009 the Agricultural Research Institute (LARI), with the collaboration of the Arabic Organization for Agricultural Development (AOAD), has developed a partnership involving various stakeholders from several national institutions for the development of a draft law regulating the management

of plant genetic resources for food and agriculture (PGRFA) in Lebanon. This was done through funds available from LARI.

The preparation process leading to the elaboration of the draft law involved regular participatory national meetings to set up the law outlines and elements in accordance with the ITPGRFA. The draft law was produced by the lawyer appointed by LARI in 2014 and then reviewed by national stakeholders before being revised by the National Committee for Plant Genetic Resources in 2015. The draft law was then submitted to the Council of Ministers and revised by national authorities and academia in 2016, while the recommendations and suggestions were again considered by LARI. The new finalized draft law was re-submitted in 2017 to the Council of Ministers for approval and the latter will submit it to Parliament for endorsement.

### **Major elements**

The law aims to ensure the conservation and sustainable utilization of PGRFA, as well as the access to PGRFA and the equitable sharing of the benefits arising from their utilization. It also aims to direct the benefits to the conservation and the sustainable use of PGRFA and to continue/improve benefit from them through promoting scientific research, building human capacities, training national capacities, exchanging information, ensuring technology transfer to national bodies of PGRFA and agricultural development. The draft law promotes farmers' rights and the protection of farmers' varieties upon mechanisms that will be determined through decisions issued by the Minister of Agriculture and in accordance with the law 240-2000 on Patents issued by the Ministry of Economy and Trade, which ensures the protection of novel varieties.

LARI is designated as the competent national authority responsible for the implementation of the law provisions, in coordination with the Ministry of Agriculture.

The draft law proposes the creation of a national committee headed by the Minister of Agriculture and including representatives from relevant ministries and organizations, to assist in the enforcement of the law.

### **Comparison between the two draft laws**

As to their legal frameworks, the proposed regulations are initially designed in a way to complete each other and to avoid conflicts between the national competent authorities (Figure 1), depending on the use of genetic resources. Whereas the ABS draft law applies to the biological and genetic diversity beyond the plant and animal genetic resources used for food and agriculture, the draft law for the management of plant genetic resources for food and agriculture in Lebanon applies only to PGRFA.

## **PROGRESS TOWARDS THE IMPLEMENTATION OF THE PROPOSED REGULATIONS**

The first steps undertaken towards the implementation of the Lebanese draft laws on ABS are mostly directed to PGRFA, while little attention have been given to the other subsectors. The actions relevant to pre-breeding and breeding, seed systems, conservation, ABS agreements,

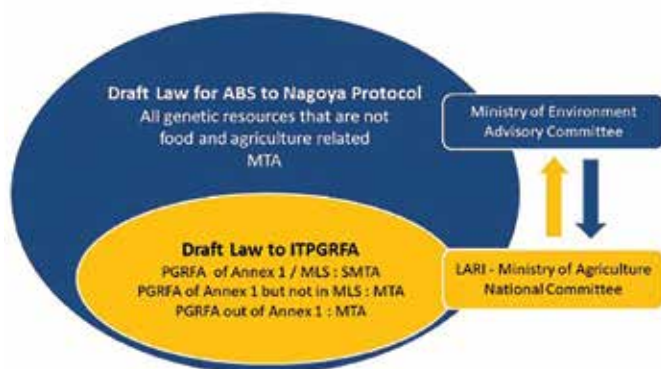


Figure 1. Proposed regulations on access and benefit-sharing for biological and plant genetic resources of Lebanon.

landraces and rarely address the wild relatives. This characterization is mostly done using morphological descriptors, while the challenging characteristics relevant to abiotic stresses, such as tolerance to drought and salinity and extreme temperatures, have rarely been addressed. Molecular characterization has only been applied to a limited number of crops using European funds while genomic investigations remain rare. Financial and technical support are needed to expand plant genetic resources characterization and evaluation by using advanced biotechnological tools, strengthening skills and acquiring adequate equipment.

Breeding programmes are conducted by the International Center for Agricultural Research in Dry Areas (ICARDA) on wheat, barley, fava bean, lentil and chickpea. The produced promising lines are shared with LARI for yield testing and selection before being released and given local names. Clonal selection is practised for olive and several fruit species such as grapevine, almond and fig.

### Seed systems

Lebanon imports most of its seed needs while local production does not exceed 3 percent of the seed market. The limited seed production exists for a few local varieties of cereals and pulses. The seed and seedlings supply system in Lebanon relies on the public sector (LARI production of cereal and pulse seeds); the private sector represents the main source of vegetable and some forage seeds based on importation (agricultural companies) and fruit seedlings based on local production (nurseries); and the informal sector corresponds to the on-farm seed and planting material production and distribution systems used in rural farming communities.

In 2010, the Ministry of Agriculture adopted a seed multiplication programme aimed at procuring certified seeds of improved and released varieties of wheat, barley, chickpea and lentils for farmers at subsidized prices, based on what LARI produced in 2013 and for the first time the national needs of certified seeds for wheat and barley (7 000 tonnes). ICARDA has provided the technical support for this government action including the establishment of seed health certification.

data management structure, education and public awareness, national committee for PGRFA and National Strategy for Conservation and Management of PGRFA are briefly presented.

### Pre-breeding and breeding

In recent years, the activities on characterization and evaluation of genetic resources have been substantially enhanced in Lebanon. These activities are conducted for

However, there is no seed Law in Lebanon, and thus the registration of varieties and a release system have not yet been implemented. Nevertheless, a seed law has recently been drafted by the Ministry of Agriculture and FAO to organize the seed system in the country within the framework of the TCP/LEB/3302 Seeds and Seedlings Policy project.

### **Conservation**

The collection of plant genetic resources in Lebanon started 50 years ago, covering mainly the traditional landraces of wheat, barley and forages through a collaborative project between LARI and ICARDA. Around 2 500 accessions are currently conserved at CGIAR/ICARDA gene banks. On the other hand, around 355 Lebanese accessions of wild and cultivated species are currently stored in European gene banks. Currently, the national gene bank of LARI is holding 1 380 seed collections stored under long-term conditions, with duplications held at Kew's Millennium Seed Bank of the Royal Botanic Gardens. These collections comprise wild edible, medicinal, aromatic, wild relatives of cultivated crops, wild forages and endemic species. Moreover, a great number of wheat and barley landraces, improved varieties of wheat, barley, lentil, chickpea and vetch are also conserved at LARI national gene bank and are regularly regenerated every five years. In-vitro facilities are already available but no conservation activity in this regard has been undertaken nor cryopreservation techniques. Although still far from completion, substantial collections and arboretum have been established at LARI as a means of *ex situ* conservation for landraces and advanced varieties for olive, grapes and stone fruits. Also, the national gene bank contains seeds of wild almonds, plums and pistachios. Over the last decade, ICARDA has organized several national capacity-building activities relevant to PGRFA utilization and management in Lebanon.

The *in situ* conservation of biodiversity including plant genetic resources has been approached during the last two decades through the implementation of several GEF funded projects, the development of national biodiversity strategies and action plans, improved capacity and increased awareness. These projects have contributed to the development of approaches for community-based, *in situ/on-farm* conservation of agro-biodiversity, recommendations for *in situ* sites and suggested elements for their management plans. Landraces were increasingly targeted by on-farm conservation, being better adapted to the prevailing harsh conditions in the region, including low-input agriculture. Fortunately, functional informal seed production systems facilitate the exchange of seeds and seedlings among farmers and, thus, have sustained cultivating landraces of crops. The GEF-ICARDA dryland agrobiodiversity project [1999-2005] has contributed to the development of a community-driven approach for on-farm conservation of landraces and wild relatives of several fruit trees.

Protected areas are valuable reservoirs for the crop wild relatives as well as all other components of the ecosystems. However, most of the existing protected areas and the newly established ones are targeting the ecosystems as a whole rather than the wild relatives of crops of global significance themselves. Furthermore, the Ministry of Environment has implemented some initiatives and projects related to rehabilitation and restoration of the forest sites outside protected areas mainly through the development and implementation of the National Reforestation Plan (NRP) (2002-present) and the "Safeguarding and restoring

Lebanon's woodland resources" project (MoE/GEF/UNDP; 2009–2014). This latter project aims at developing a strategy for safeguarding and restoring Lebanon's woodland resources and implementing it through capacity building and execution of appropriate sustainable land management policies and practices.

### ABS agreements

Until the initiation of the preparation of both draft laws, the only officially signed agreements were executed between LARI and the Royal Botanic Gardens, Kew (United Kingdom), whereby seeds were collected and stored in the latter institute within the context of the Millennium Seed Bank project.

LARI is authorized to facilitate any plant material transfer agreements including the Standard Material Transfer Agreements (SMTA). About 400 accessions representing more than 35 species of Annex 1 are stored in LARI national gene bank and are available for exchange through the Multi Lateral System (MLS) (<http://www.pgrfa.org/WIEWS>).

Several SMTA have been signed lately between LARI and foreign beneficiary institutions e.g. Norwegian University of Life Science, Royal Botanic Gardens, Kew (United Kingdom), Rijk Zwaan (Netherlands) and the Center of Biotechnology of Borj Cedria (Tunisia), to allow access to some Lebanese traditional varieties of wheat and barley in addition to crop wild relatives of more than ten crops (part of Annex 1), for research in pre-breeding and breeding (Table 1).

**Table 1: List of SMTA and MTA signed since 2013 between LARI and beneficiary institutions**

Lebanese PGRFA accessed through SMTA		
Year	PGRFA accessed through SMTA (number of accessions)	Recipient
2013	Wheat (3)	Norwegian University of Life Science (Norway)
2013	Barley (50)	Center of Biotechnology of Borj Cedria (Tunisia)
2015	<i>Daucus carota</i> (45)	Rijk Zwaan (Netherlands)
2016	<i>Aegilops</i> (41); <i>Hordeum</i> (5); <i>Medicago</i> (48); <i>Vicia</i> (1)	Royal Botanic Gardens, Kew (United Kingdom)
2017	<i>Aegilops</i> (10); <i>Avena</i> (2); <i>Hordeum</i> (22); <i>Lens</i> (7); <i>Lathyrus</i> (23); <i>Vicia</i> (55); <i>Medicago</i> (16); <i>Pisum</i> (7); <i>Triticum</i> (1)	Royal Botanic Gardens, Kew (United Kingdom)
2018	<i>Aegilops</i> (24); <i>Avena</i> (12); <i>Cicer</i> (6); <i>Hordeum</i> (4); <i>Lathyrus</i> (42); <i>Lens</i> (8); <i>Medicago</i> (21); <i>Pisum</i> (5); <i>Secale</i> (3); <i>Triticum</i> (12); <i>Vicia</i> (32)	Royal Botanic Gardens, Kew (United Kingdom)
Lebanese PGRFA accessed through MTA		
Year	PGRFA accessed through MTA (number of accessions)	Recipient
2015	<i>Rumex acetosa</i> (2) ; <i>Rumex acetosella</i> (2)	Biology Center ASCR (Czech Republic)
2015	<i>Ptilostemon chamaepeuce</i> (1); <i>Ptilostemon diacantha</i> (1); <i>Notobasis syriaca</i> (1); <i>Picnomon acarna</i> (1); <i>Carduus pycnocephalus</i> (1)	Institute of Biosciences and Bioresources, CNRS (Italy)
2016	<i>Sinapis</i> (3); <i>Raphanus</i> (2)	Unifert (private seed company, Lebanon)

At the same time, several Material Transfer Agreements (MTA) were signed between LARI and beneficiary institutions for the access to some Lebanese wild plants (out of Annex 1 of the ITPGRFA) that will be used in research for assessing the genetic diversity and the resistance of weeds to some herbicides (Table 1).

### **Data management structure**

Lebanon developed the first Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture (GPA1) in 2006. The National Information Sharing Mechanism (NISM) was established as an efficient tool for the implementation of ITPGRFA components through various national priority activities including *in situ* and *ex situ* conservation and sustainable utilization of PGRFA. In 2014, this GPA was updated (GPA2) and well promoted among national stakeholders for exchanging and analysing PGRFA information for future planning.

Lebanon is part of the Plant Genetic Resources Near East Network developed for the North Africa region (PGR-NENA) in 2008 by the Association of Agricultural Research Institutions in the Near East and North Africa (AARINENA). Since 2014, Lebanon is also part of the pilot knowledge and information exchange management system of national components of FAO Regional Plant Genetic Resources Platform of Near East and North Africa (<http://plantgenetic.com>). This regional network includes modules on documents, institutions, experts and projects, news, events, good practices, success stories, agricultural PGR bulletins, question and answer services and farmers' problems; it enables the exchange of information and knowledge relevant to PGRFA among stakeholder groups at national and regional levels.

### **Education and public awareness**

Advanced courses on plant genetic resources and their sustainable utilization with an introduction to the ABS concept are incorporated in the academic curricula of the Faculty of Agronomy of the Lebanese University (public university). Scientific collaboration, student training and facilities for master and PhD theses are provided mainly by ICARDA and LARI. The Lebanese National Council for Science Research (CNRS) is allocating funds and grants to research activities related to PGRFA.

Today, non-governmental organizations and the private sector are more involved in many activities related to biodiversity and environmental studies. National seeds companies have become more aware of the importance of genetic resources and the need for their utilization in a sustainable and equitable way.

### **National Committee for PGRFA in Lebanon**

The National Committee for Plant Genetic Resources for Food and Agriculture was established by the Minister of Agriculture (Decision 394, date 12/05/2014). It consists of germplasm curators, plant breeders, seed systems, import/export services and the private sector, in addition to academicians and researchers in genetics, plant biology, and agricultural and environmental sciences. It gathers representatives of authorities and

institutions involved in PGRFA from the Ministry of Agriculture, LARI (i.e. National Gene Bank and National Focal Point for the ITPGRFA), the Ministry of Environment (National Focal Point for the CBD and the Nagoya Protocol), the Lebanese University, the National Council for Scientific Research and the International Center for Agricultural Research in the Dry Areas. Policy-makers and regulators may be invited to join the committee when needed.

The mission of this National PGRFA Committee is to provide advisory functions to the Ministry of Agriculture (and other entities involved in the management of PGRFA), to map the different national stakeholders involved in PGRFA activities and to provide the practical mechanism for coordination and fostering synergies among stakeholders. The committee should: drive the process of preparing, finalizing and validating the National Strategy for PGRFA; select and advise ad hoc working groups of various stakeholders to participate in the implementation of activities relevant to the strategy; assist in mobilizing support and financial resources for the implementation of the strategy; serve as the interface for national responses regarding PGRFA to regional and international requests; advise on issuing permits for access (collecting, getting seeds) and benefit-sharing of PGRFA at national, regional and international levels; and advise on legislation and policies related to PGRFA including farmers' rights.

### **National Strategy for the Conservation and Management of PGRFA in Lebanon**

Within the framework of the FAO Technical Cooperation Project, TCP/SNO/3401, "Optimizing the Use of Plant Genetic Resources for Food and Agriculture for Adaptation to Climate Change" (2013-2015), the country developed its national strategy for an optimized management of plant genetic resources following a continuum approach, from conservation (*in situ* and *ex situ*), pre-breeding and breeding to seed delivery. The strategy aims to create/strengthen/rationalize coordination among involved PGRFA stakeholders and players within the Ministries of Agriculture and Environment for an efficient management of PGRFA in the country with respect to the priority areas of the GPA2 relevant to conservation, sustainable use, policy and building capacities. The ultimate goal of the strategy is to leverage these resources most effectively in improving the resilience cropping systems and hence the overall food security, nutrition and livelihoods of farming communities.

A National Plan of Action for PGRFA conservation and management is being formulated for the coming 20 years addressing the national development planning for agriculture, environment and socio-economic sectors. Four main thematic components are stipulated with a set of specific objectives convened for each component through a coordinated alliance and partnerships between national institutions. These specific objectives should be fully integrated into the national programmes within the relevant ministries and address the country's priority crops that are significant for food security in the country and are important for adaptation to climate change, including cereals, legumes, vegetables and fruit trees.

## **CONCLUSIONS**

Presently, both draft laws have been submitted to the Council of Ministers for approval. They are expected to be transmitted soon to Parliament for endorsement. However, the



issuance of these two laws may be delayed as they are not considered a priority mainly because of the prevalent unstable security and political situation of the country.

The major constraints that may hinder the implementation of these laws in Lebanon in the future are the absence of a specific law or specific provisions for the protection of farmers' rights and the traditional knowledge associated with genetic resources, in addition to the lack of comprehensive information regarding some subsectors of genetic resources.

## ACKNOWLEDGEMENTS

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## BIBLIOGRAPHY

- Arnold, N., Baydoun, S., Chalak, L. & Raus, Th.** 2015. A contribution to the flora and ethnobotanical knowledge of Mount Hermon, Lebanon. *Fl. Medit.*, 25: 13–55.
- Assi, R.** 2005. Project on “Conservation and Sustainable Use of Dry Land Agrobiodiversity in the Near East”. UNDP, GEF, LARI and ICARDA. Final Report of the Lebanese Component.
- Baydoun, S., Chalak, L., Dalleh, H. & Arnold, N.** 2015. Ethnopharmacological survey of medicinal plants used in traditional medicine by the communities of Mount Hermon, Lebanon. *Journal of Ethnopharmacology*, 173: 139–156.
- Bjørnstad, A., Tekle, S. & Goˆransson, M.** 2013. Facilitated access to plant genetic resources: does it work? *Genet. Resour. Crop Evol.*, 60: 1959–1965.
- Buck, M. & Hamilton, C.** 2011. 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. *RECIEL*, 20 (1): 47–61.
- Chalak, L. & Sabra, N.** 2007. *Second Country Report on the State of Plant Genetic Resources for Food and Agriculture*. 61 p. (available at [www.pgrfa.org](http://www.pgrfa.org)).
- Chalak, L., Noun, J., El Haj, S., Rizk, H., Assi, R., Attieh, J., Maalouf, F., Abi Antoun, M. & Sabra, N.** 2011. Current status of agro-biodiversity in Lebanon and future challenges. *Gene Conserve.*, 10(39): 23–41.
- Chalak, L.** 2015. *National strategy for conservation and management of plant genetic resources for food and agriculture in Lebanon* (in English). 38 p.
- Chehade, A.** 2011. *Country report on the implementation of the International Treaty on Plant Genetic resources for Food and Agriculture*. 21 p.
- FAO.** 2011. *Second Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture*. Rome.
- FAO.** 2016. *ABS elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture*. Rome. 32 p.

- Greiber, T., Moreno, S.P., Åhrén, M., Carrasco, J.N., Kamau, E.C., Medaglia, J.C., Oliva, M.J. & Perron-Welch, F.** 2012. *An explanatory guide to the Nagoya Protocol on Access and Benefit-sharing*. IUCN, Gland, Switzerland. XVIII +372 p.
- ITPGRFA/FAO.** 2013. *International Treaty of Plant Genetic Resources for Food and Agriculture* (available at <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>). 68 p.
- Ministry of Agriculture/FAO.** 2012. *Global Agricultural Census in Lebanon for 2010*. 186 p.
- Ministry of Agriculture/Rural Development Program.** 2015. *Ministry of Agriculture Strategy 2015-2019*. 71 p.
- Mouterde, P.** 1966. *Nouvelle flore du Liban et de la Syrie*. Beyrouth, Imprimerie Catholique.
- Stephan, J.** 2012. *First Country Report on the State of Forest Genetic Resources for Food and Agriculture*. 34 p.
- Tohme, G. & Tohme, H.** 2014. *Illustrated flora of Lebanon*. CNRS Publication. ISBN 978-9953-0-2890-3.
- UNDP/IBSAR.** 2005. *Thematic report on access and benefit sharing: the Republic of Lebanon*. 22 p. (available at <https://www.cbd.int/doc/world/lb/lb-nr-abs-en.pdf>).
- UNEP/GEF/Ministry of Environment.** 2015. *Fifth National Report of Lebanon to the Convention on Biological Diversity*. 106 p.
- UNEP/GEF/Ministry of Environment.** 2015. *Lebanon NBSAP*. 113 p.
- UNEP/CBD.** 2011. *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*. 25 p.

# Regulating Access and Benefit-sharing in Australia

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## **EXECUTIVE SUMMARY**

As a Federation, law making powers in Australia are divided between the Commonwealth Government and the State and Territory Governments. While the Commonwealth Government has the power to enter into international treaties, the Commonwealth only has power to pass biodiscovery laws in relation to Commonwealth land and waters (that only make up a small part of Australia). It is up to the State and Territory Governments to pass laws for their respective territories. As a result, biodiscovery practices in Australia are controlled by a combination of Commonwealth laws (for Commonwealth areas) and State or Territory laws (for their respective land and waters).

There are a number of problems with the schemes designed to regulate the collection, use and reuse of native biological resources in Australia. While Australia ratified the Convention on Biological Diversity in 1993, only the Commonwealth (2000), Queensland (2004) and the Northern Territory (2006) have enacted biodiscovery laws. None of the other five States or the one remaining mainland Territory have passed biodiscovery laws. Moreover, while the Commonwealth and Northern Territory schemes apply to all areas that could potentially be covered within their jurisdictions, the Queensland scheme is limited to State land and waters: it does not apply to private or aboriginal lands. As a result, there are many parts of Australia that are not covered by biodiscovery laws. Another problem with the existing schemes is that they have been under-resourced. When combined with a high turnover of administrative staff and (sometimes) unrealistic expectations on the part of access providers about the benefits that they are entitled to, this has undermined the uptake and effectiveness of the biodiscovery schemes. These problems create a perverse situation whereby biopirates are able to avoid the remit of the biodiscovery laws by collecting (or claiming to collect) on areas not covered by relevant laws. At the same time, parties who want to conduct ethical biodiscovery work are forced to deal with schemes that are often cumbersome, inconsistent and under-resourced.

## **INTRODUCTION**

The aim of this paper is to provide an overview of the legal schemes that regulate the collection, use and reuse of native biological resources in Australia. It is important to note that as a Federation, law making powers in Australia are divided between the Commonwealth Government and the State and Territory Governments. The Commonwealth is able to invoke the external affairs power of the Australian Constitution to pass laws that implement its

international treaty obligations (something that it did when Australia ratified the Convention on Biological Diversity (CBD) in 1993).<sup>1</sup> As the Constitution of Australia does not vest power to make environmental laws in the Commonwealth Parliament, the Commonwealth Government only has the capacity to pass laws in relation to Commonwealth lands and waters (that are limited). This means that the States and Territories retain sovereignty over the natural resources on their land and waters. As a result, biodiscovery practices in Australia are regulated by a combination of Commonwealth laws (for Commonwealth areas) and State or Territory laws (for their respective land and waters).

In order to overcome some of the problems that potentially arise as a result of the Australian Federal system (particularly forum shopping and inconsistency), the Commonwealth, State and Territory Governments came together in 2002 to develop a nationally consistent approach to how access and use of Australia's native genetic resources was to be regulated (Australian Government, 2002). The resulting *Nationally Consistent Approach* provides scope for the biodiscovery entity and the resource provider to negotiate terms of a private contract, rather than mandating certain benefit-sharing conditions (Lawson, 2006). Despite concerted intergovernmental efforts, only the Commonwealth (2000), Queensland (2004) and the Northern Territory (2006) have enacted biodiscovery laws. After looking at each of these schemes in turn, we will then turn to examine some of the problems with the schemes and how they may change in the future.

## **ACCESS AND BENEFIT-SHARING IN COMMONWEALTH AREAS**

Australia ratified the Convention on Biological Diversity on 18 June 1993.<sup>2</sup> In accordance with its obligations under the Convention, the Commonwealth Government enacted the *Environment Protection and Biodiversity Conservation Act 1999* (Cth), which commenced on 16 July 2000. While the Act set out a general framework for the establishment of a scheme to regulate biodiscovery research, it did not provide details of how the scheme would operate in practice. The Government subsequently conducted a public inquiry, chaired by John Voumard, which culminated in a report in July 2000 entitled *Access to biological resources in Commonwealth areas* (Voumard, 2000). The purpose of the inquiry was to propose an access scheme that could be incorporated into regulations under the Act. The Voumard inquiry was followed by an inquiry by the Commonwealth Parliament Standing Committee on Primary Industries and Regional Services, to examine the development of high technology industries in regional Australia based upon bioprospecting. The inquiry commenced on 4 October 2000 and released its report in August 2001, entitled *Bioprospecting: discoveries changing the future*. The submissions to the inquiry, and the report itself, echoed the imperative for all the governments in Australia to develop an access and benefit-sharing scheme with greater clarity and consistency (Australian Parliament, 2001). Many recommendations in the Voumard report and the Standing Committee report were adopted in the amended *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth), which set out more detailed guidelines for access to biological resources.<sup>3</sup>

<sup>1</sup> *Commonwealth v Tasmania* (1983) 158 CLR 1, 121.

<sup>2</sup> Convention on Biological Diversity, *List of Parties* (available at <https://www.cbd.int/information/parties.shtml>).

<sup>3</sup> *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth), Part 8A.

The *Environment Protection and Biodiversity Conservation Regulations 2000* created a system that allows “biological resources” to be collected from “Commonwealth areas” with a permit.<sup>4</sup> “Biological resources” are defined to include genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity.<sup>5</sup> The Commonwealth scheme applies to Commonwealth areas, which are defined as land owned or leased by the Commonwealth or a Commonwealth agency. This includes the continental shelf, the waters and seabed of the exclusive economic zone (200 nautical miles out) and national parks.<sup>6</sup> It does not include, however, the coastal waters of the States and Territories.<sup>7</sup>

To access biological resources in Commonwealth areas, it is necessary to apply for a permit from the Commonwealth Department of the Environment and Heritage. For a permit to be granted, the Department needs to be satisfied that:

- (i) where relevant, benefit-sharing negotiations involving owners of indigenous land were conducted on a fair and equitable basis, with informed consent by the access providers, and on mutually agreed terms;
- (ii) an environmental assessment was undertaken and completed; and
- (iii) the proposed access is ecologically sustainable and consistent with Australia’s conservation of biodiversity.

Notably, the Commonwealth scheme draws a distinction between collecting for commercial or potentially commercial purposes and collecting for non-commercial purposes. In relation to collecting that is motivated or potentially motivated by commercial goals, the party collecting the materials must enter into a benefit-sharing agreement with the access provider. In order to reduce transaction costs, the Commonwealth Government issued model agreements that set out the Commonwealth’s standard terms and conditions for access to biological resources in Commonwealth areas. Notably, these agreements do not interfere with existing property rights, including intellectual property rights, that arise from access to biological resources. They do, however, require the party seeking access to the biological resources to agree to give the access provider a fair and equitable share of the monetary and non-monetary benefits arising from that access. It also specifies that those benefits should continue to flow to the access provider, notwithstanding any agreement between the original party that accessed the material and a third-party engaged to further develop or commercialize it. Since 2006, only three commercial permits have been granted.

For non-commercial permits, applicants are only required to obtain written permission from access providers to enter onto the Commonwealth area in order to collect and remove biological resources. To date, the vast majority of the permits that have been granted have been non-commercial.

<sup>4</sup> Reg. 8A.07, *Environment Protection and Biodiversity Conservation Regulations 2000*.

<sup>5</sup> Genetic resources are defined as “any material of plant, animal, microbial or other origins that contains functional units of heredity and that has actual or potential value for humanity”. Section 528, *Environment Protection and Biodiversity Conservation Act 1999*.

<sup>6</sup> Section 525, *Environment Protection and Biodiversity Conservation Act 1999*.

<sup>7</sup> Section 227, *Environment Protection and Biodiversity Conservation Act 1999*. Coastal waters are defined as “the part of parts of the territorial sea that are within three nautical miles of the baseline of the territorial sea and adjacent to the State or Territory” and “any marine or tidal waters that are inside that baseline and adjacent to that State or Territory but are not within the limits of that State or Territory”.

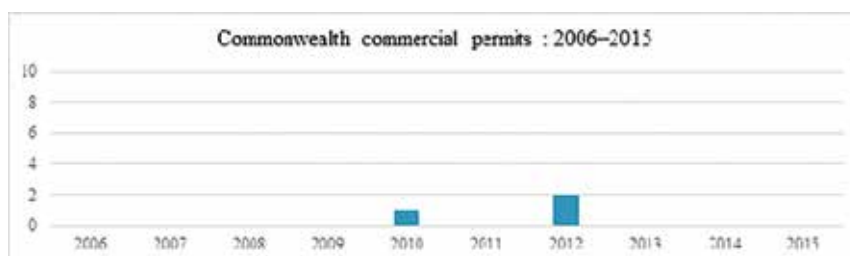


Figure 1. Number of commercial permits issued for Commonwealth areas.

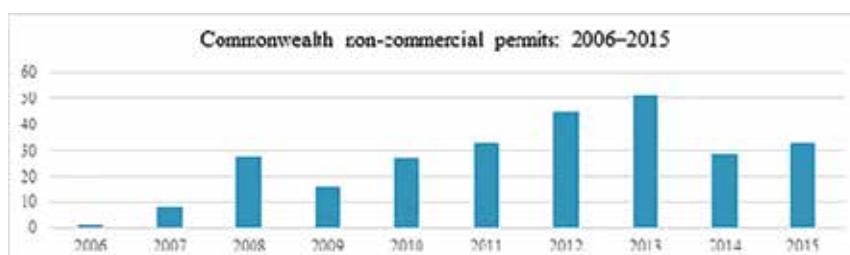


Figure 2. Number of non-commercial permits issued for Commonwealth areas.

## ACCESS AND BENEFIT-SHARING IN QUEENSLAND

In an attempt to encourage the growth of the biotechnology industry in Queensland during the late 1990s, the Queensland Government promoted the State's diverse biodiversity, particularly in the rainforests of North Queensland and the Great Barrier Reef, as a potential source of novel pharmaceuticals, cosmetics and foods. To promote biodiscovery research, the Government felt that it was necessary to provide potential researchers and investors with legal certainty.<sup>8</sup> To this end, the *Biodiscovery Act* was passed in 2004. As well aiming to establish a market for the conservation and sustainable use of native biological resources, the Queensland legislation also aimed to give effect to Article 15 of the CBD: namely, to set out how the State intended to exercise its authority over the use of native biological resources, particularly in relation to the fair and equitable sharing of benefits gained from access to those resources. The 2004 *Biodiscovery Act* also aimed to ensure that the State captured some of the benefits that were expected to flow from biodiscovery research.

The 2004 *Biodiscovery Act* applies to "native biological material" sourced from State land and waters. Native biological material is defined as non-human living organisms or viruses (or samples thereof) that are indigenous to Australia and sourced from State land or Queensland waters. It also includes substances sourced, whether naturally or artificially, from a native biological resource, or soil containing a native biological resource.

While the Queensland Government has the ability to legislate in relation to biodiscovery activities on freehold land, the Act is confined to State land and waters. This means that the

<sup>8</sup> Section 3, *Biodiscovery Act* 2004 (Qld). Lawson (2006).

scheme does not apply to material collected on either private or aboriginal land. As a result, if a biological resource exists on both State land and on aboriginal or private land, there is nothing to stop a party from evading the operation of the *Biodiscovery Act* by confining their collecting to non-State land. While there was a commitment made at the time the Act was passed to revisit the issue at some time in the future, the Act still does not address the protection of traditional knowledge under Article 8(j) of the Convention.<sup>9</sup>

With the commencement of the *Biodiscovery Act 2004* (Qld), the previously fragmented permit requirements, administered by multiple government departments under numerous statutes, were replaced by a single collection authority<sup>10</sup> (which are kept on a publicly accessible register).<sup>11</sup> Queensland law uses the grant of a single permit to collect biological resources as a trigger point to regulate the manner in which those resources are subsequently used. This is done by specifying that the collection of native biological resources on Queensland land and waters is only permitted if a relevant “collection authority” has been granted. According to the Act, a holder of a collection authority is permitted “to take minimal quantities of native biological material from, on or in, State land or Queensland waters, and keep the material, for biodiscovery”.<sup>12</sup> Three conditions are imposed on an applicant for a collection authority. Applicants must: (i) comply with any conditions imposed on the collection of materials; (ii) supply a “biodiscovery plan”; and (iii) enter into a “benefit-sharing agreement” with the State government.<sup>13</sup>

- (i) To ensure that the collection of native biological resources is done in an environmentally sensitive and sustainable manner, all collection permits specify the manner and amount of material that may be collected.<sup>14</sup> In exceptional cases, collection protocols may be issued, primarily when the collection occurs in environmentally sensitive areas, or where the material collected is particularly sensitive or endangered.
- (ii) An applicant for a collection permit is also required to supply a *biodiscovery plan*, which is effectively an overview of the scope of the proposed research. The biodiscovery plan will include things such as expected timelines, potential commercialization activities, any activities that are proposed to be carried on outside of Queensland, and the benefits the entity reasonably considers it will provide to the State under a benefit-sharing agreement. The *Biodiscovery Plan Guidelines* stipulate that the applicant must detail their commercialization plans, proposed investments,

<sup>9</sup> Section 4(4) *Biodiscovery Act 2004* (Qld). Lawson (2011).

<sup>10</sup> See, for example, *Forestry Act 1959*, *Land Act 1994*, *Nature Conservation Act 1992*, *Fisheries Act 1994*, *Marine Parks Act 1982*, *Native Title (Queensland) Act 1993*, and *Wet Tropics World Heritage Protection and Management Act 1993*. See P. Allen and A. Rush, *Biodiscovery Act 2004: Biodiscovery in Queensland*. 2004. *Australian Health Law Bulletin*, 13(3): 31.

<sup>11</sup> Sections 27–28, *Biodiscovery Act 2004* (Qld).

<sup>12</sup> Section 10, *Biodiscovery Act 2004* (Qld).

<sup>13</sup> Collection cannot take place unless a benefit sharing agreement is in place (section 17(2) *Biodiscovery Act 2004* (Qld)); and a collection authority (which run for a maximum of three years) will lapse if a “benefit-sharing agreement” is not entered into one year after the authority is issued (section 16(4) *Biodiscovery Act 2004* (Qld)).

<sup>14</sup> Section 16, *Biodiscovery Act 2004* (Qld). The legislative requirements are supplemented by the guidelines in a Compliance Code, issued by the Minister for the Department of Environment and by Collection Protocols. The Queensland Government issued the first collection protocol on 7 March 2017 to the Dugalunji Aboriginal Corporation in northwestern Queensland for the collection of spinifex foliage and resin. The collection protocol sets out detailed guidelines for the method and frequency of collection, labelling techniques and monitoring zones to ensure that the collection is ecologically sustainable.

intellectual property protection, product development and marketing strategies (Queensland Government, 2016). The *Guidelines* provide a table of potential benefits that may be provided to the State, such as technology transfer, collaborative agreements, employment opportunities and knowledge about the State’s biodiversity. Although the legislation makes no mention of traditional knowledge, the *Guidelines* state that a biodiscovery plan must disclose any use of traditional knowledge and the existence of a benefit-sharing agreement with relevant aboriginal community (Queensland Government, 2016). The Queensland *Biotechnology Code of Ethics* also requires researchers to enter into benefit-sharing agreements if they use traditional knowledge. It also mandates that research organizations must not undertake “biopiracy”, which is defined as “the appropriation of developments or discoveries involving biological resources by another party without consent” (Queensland Government, 2006). However, the *Biotechnology Code of Ethics* is only binding on entities that receive State Government funding.

- (iii) An applicant for a collection permit is also required to supply a benefit-sharing agreement. Unlike the biodiscovery plan – that is in effect a roadmap of the planned research and commercialization – the benefit-sharing agreement must provide specific details about the benefits to be provided by the biodiscovery entity to the State. This includes when the benefits are to be provided and where the benefits include financial payments, the amount to be paid or a way of working out the amount to be paid.

### Post-collection obligations

A party that collects material under a collection authority is under a number of obligations once the material has been collected. The 2004 *Biodiscovery Act* requires that when materials are transferred to a third party the material is subject to the same conditions as were imposed on the collecting entity. This is done in an attempt to ensure that parties do not avoid their

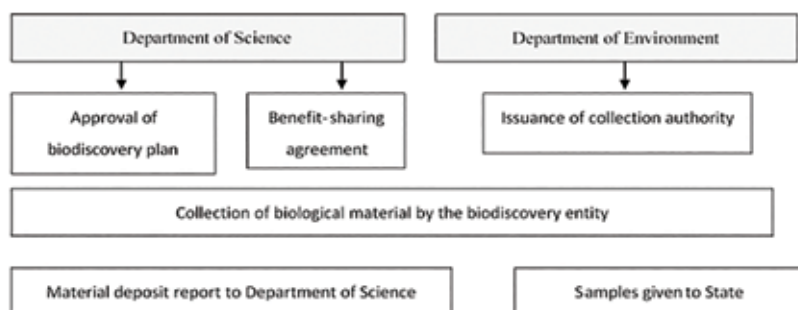


Figure 3. Process for the approval of biodiscovery research in Queensland.



access obligations by transferring biological material to third parties. The problem with these provisions, however, is that they are ineffective where the party granted the collecting authority is outside the jurisdiction, ceases to trade or becomes bankrupt. In the absence of some type of intellectual property right in the material or a binding contract with a third-party recipient, there is little that can be done where the material is transferred to a third party. Parties are also under an obligation to classify the material taxonomically and to deposit samples with the relevant collecting authority. The *Biodiscovery Act* also requires parties to label collected materials with information about the history and provenance of the material that has been collected. This is done so that the movement and utilization of native biological resources can be traced. In the absence of equivalent interstate provisions, a labelling system has not been adopted in Queensland.

The 2004 *Biodiscovery Act* was subject to an independent statutory review in 2009. The report concluded that Indigenous Land Use Agreements and private benefit-sharing contracts were sufficient to meet the objectives of the law, and recommended that Queensland continue to exclude private land and aboriginal land from the scope of the Act (DLA Phillips Fox, 2009). In 2016, a further review of the biodiscovery scheme was undertaken.<sup>15</sup> The review considered a number of shortfalls and problems with the scheme – one of which was that, to date, only five collection authorities have been issued since the Act came into operation in 2004 (Bosse, 2016).

The review also found that there was a need for “subsequent use agreements” – i.e. agreements that attempt to control downstream use – to be addressed in more detail. It was also accepted that there has been inadequate guidance about the biodiscovery plans and benefit-sharing agreements, which had contributed to the regulatory uncertainty. While there has been an increase in applications from university researchers, there remains an opportunity to improve engagement from other biodiscovery entities. As such, the Department of Science is developing communication and compliance plans, with the intention to publish a set of biodiscovery guidelines and a departmental regulatory strategy. While the guidance will only improve engagement and compliance from virtuous actors, it is an important starting point for the enforcement of the Queensland *Biodiscovery Act*, which has essentially been dormant in recent years.

The “soft law” changes are being supplemented by long-term substantive legislative reforms. On 10 May 2017, the Queensland Parliament introduced the *Gasfields*

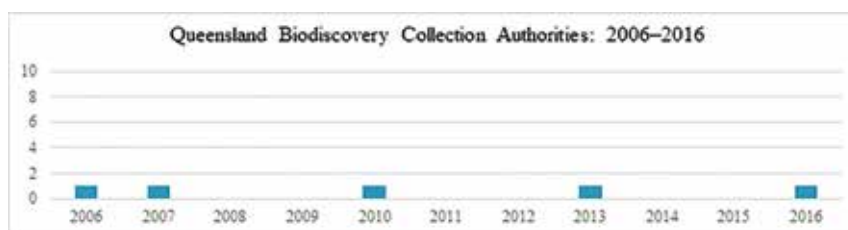


Figure 4. Number of collection authorities issued for Queensland land and waters.

<sup>15</sup> Explanatory Notes, *Gasfields Commission and Other Legislation Amendment Bill 2017* (Qld), 2.

*Commission and Other Legislation Amendment Bill 2017*. The Bill proposes to amend the *Biodiscovery Act 2004* (Qld) to introduce an alternative contractual framework for more efficient administration of biodiscovery benefit-sharing agreements. Under the proposed amendments, a “head biodiscovery entity”, which has a benefit-sharing agreement with the State, would be able to enter into “subsequent use agreements” with other entities along the commercial chain.

## **ACCESS AND BENEFIT-SHARING IN THE NORTHERN TERRITORY**

The Northern Territory passed the *Biological Resources Act 2006* (NT) on 14 February 2007. The drafting of the *Biological Resources Act 2006* was motivated by a number of factors, one of which was that the Government had received visits from members of the Japanese Bioindustry Association, who expressed the need for a clear framework that would allow research and development companies to inoculate themselves against downstream accusations of illicit collection or biopiracy.<sup>16</sup> At the time, the Northern Territory Government had a strong policy of being “open for business” in relation to the commercial use of natural resources, and the implementation of bioprospecting legislation was seen as a necessary incentive for industry.

The Northern Territory Government was also under pressure to control access to biological resources following well-publicized cases of unregulated biodiscovery research that occurred in relation to the native Kakadu plum (*Terminalia ferdinandiana*), which had attracted corporate interest, primarily because of its very high vitamin C content. This issue came to a head after the public became aware that the Amway and Mary Kay corporations had obtained patents over derivatives of the Kakadu plum (Robinson, 2010a).<sup>17</sup> What was particularly problematic was that it was reported that Amway and Mary Kay had collected the native Kakadu plum samples without having obtained prior informed consent or having entered into benefit-sharing agreements with the access providers (Robinson, 2010b). Interest in regulating biodiscovery research was also triggered in 2002 when marine biologists at the Museum and Art Gallery of the Northern Territory received funding from the United States National Cancer Institute to collect samples and send them to the National Cancer Institute to be screened for anti-cancer or anti-HIV properties. It would appear that the US National Cancer Institute had learned from the controversy it had experienced over the smokebush biodiscovery research in Western Australia, as the United States organization had developed a Model Letter of Collaboration and insisted that the Museum researchers sign it before the project could proceed.<sup>18</sup> Since the Museum is a government-owned entity, the letter was elevated through the Northern Territory Department of Business, Industry and Resource Development for approval, but which raised concerns that the letter was not meaningful for commercial research on marine genetic resources under Australian law. The Government solicitors made several amendments and the contract was ultimately signed.

<sup>16</sup> Interview with Executive Director, Northern Territory Biodiversity Conservation Commission (2 June 2017).

<sup>17</sup> See, for example, Patent US 7175862 B2: Method of preparing Kakadu plum powder, owned by Amway's sister company, Access Business Group International.

<sup>18</sup> US National Cancer Institute, *Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (and a Source Country Government/Source Country Organization(s))* (February 2002).

The *Biological Resources Act* 2006 (NT) was drafted over several years by an interdepartmental working group, comprising the Department of Primary Industry, the Department of Business, and the Parks and Wildlife Commission. The working group undertook significant consultation with stakeholders, especially aboriginal communities, the Northern Land Council and the Northern Territory Museum and Art Gallery. While a change of government caused delays, the *Biological Resources Act* 2006 (NT) ultimately passed the Legislative Assembly and came into force on 14 February 2007. The Northern Territory Natural Resources Management Board subsequently undertook the “Indigenous Cultural and Intellectual Property Protocols for Indigenous Ecological Knowledge Management” programme to develop guiding principles for the Act, although the outcomes are unclear (Holcombe and Janke, 2012).

While the scope of the biological resources governed by the Northern Territory scheme is much the same as in Queensland, there are a number of differences. One importance difference relates to the territorial scope of the biodiscovery laws. Unlike the position in Queensland, which only applies to State land and waters, the Northern Territory scheme applies *throughout* the Territory (including the air above, the water and the seabed or riverbed below the water).<sup>19</sup>

Another point of difference is that, unlike the case in Queensland, the Northern Territory legislation does not create a new permit system for the collection of biological materials. Instead, bioprospectors must apply for a permit from the relevant ‘permit issuing authority’ such as the Parks and Wildlife Commission or the Fisheries Division.<sup>20</sup> When the permit application is assessed, that authority must determine whether the activity may involve bioprospecting, at which point the matter is referred to the Department of Primary Industry to determine whether a benefit-sharing agreement is required (see Figure 5).

The Northern Territory Government scheme distinguishes between collections made on Crown (or Territory) land, and collections made on non-Crown land (private land or aboriginal land). As in Queensland, the legislation requires that a benefit-sharing agreement be made with the Territory Government if the biological resources are obtained from Crown land. The schemes differ in relation to non-Crown land, however, in that a bioprospector must enter into a benefit-sharing agreement with the resource provider, such as the owner of private land or aboriginal land.<sup>21</sup> In this context, the Department acts as a gatekeeper to ensure that the resource provider has given prior informed consent and that the benefit-sharing agreement contains equitable and mutually agreed terms, although the latter is presumed since the benefit-sharing contracts are confidential. The Department has a template benefit-sharing agreement available for organizations that request advice on the appropriate terms for the contract. The Northern Territory legislation has no counterpart to the Queensland biodiscovery plans.

<sup>19</sup> Excluding Commonwealth areas in the Territory, which are governed by the *Environment Protection and Biodiversity Conservation Regulations* 2000 (Cth).

<sup>20</sup> Section 11, *Biological Resources Act* 2006 (NT).

<sup>21</sup> Sections 27–29, *Biological Resources Act* 2006 (NT).

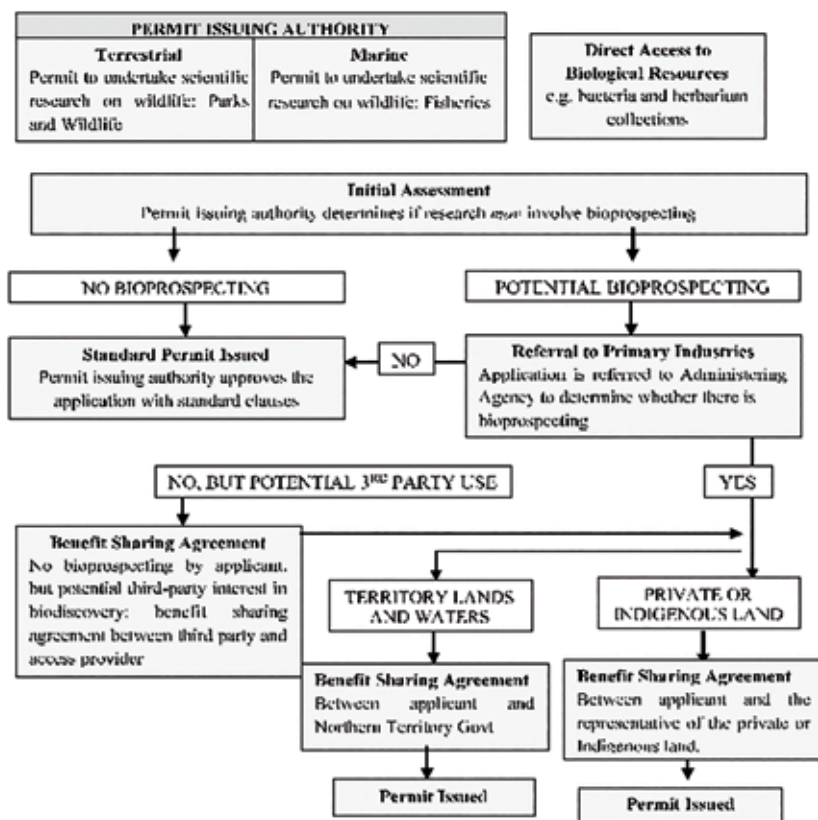


Figure 5. Process for approval for biodiscovery research in the Northern Territory.

While it is difficult to obtain accurate figures, it seems that only a limited number of benefit-sharing agreements have been negotiated in the Northern Territory to date (with reports of less than ten benefit sharing agreements in total). Anecdotal evidence suggests that gaps in staff to administer the scheme (particularly from 2012 to 2015) and problems in negotiating benefit-sharing agreements deterred bioprospectors from engaging with the scheme.

## ACCESS AND BENEFIT-SHARING IN WESTERN AUSTRALIA

Western Australia has been slow to enact effective biodiscovery laws. Towards the end of 2008, the Department of Industry and Resources produced an internal draft report entitled *Bioprospecting in Western Australia: a proposed framework*.<sup>22</sup> In August 2011, the Department of Commerce was approved to develop drafting instructions for a Western Australian bioprospecting Bill, with the intention of introducing the legislation in 2012.

<sup>22</sup> Western Australia, *Parliamentary Debates*, Legislative Council, 7 March 2012, 682 (Helen Morton).

However, progress was halted for several years.<sup>23</sup> While the *Biodiversity Conservation Act 2016* (WA) empowers the government to implement a bioprospecting licensing scheme, the provision has not come into operation.<sup>24</sup> As a result, Western Australia currently has no mechanism to ensure that benefits of bioprospecting are shared with the State.

### **ACCESS AND BENEFIT-SHARING IN TASMANIA**

The only regulation of access to biological resources in Tasmania is in relation to the collection of materials in environmental legislation, such as the *Living Marine Resources Management Act 1995* (Tas) and the *Nature Conservation Act 2002* (Tas). However, there is no legislation that requires the sharing of benefits with Tasmania. The Tasmanian Department of Primary Industries recognized the regulatory gap and released a position paper in 2009, *Bioprospecting: sharing the benefits for Tasmania*. As the paper noted, “[w]ithout strong policies and regulation biological resources may be taken from Tasmania without permission and/or without an obligation to share the benefits. A policy and regulatory framework also provides certainty to legitimate organizations seeking to invest in Australia’s research and development capabilities” (Tasmania. Department of Primary Industries and Water, 2009).

While some *ad hoc* biodiscovery contracts have been made in Tasmania, problems with them have highlighted the need for legislative intervention in relation to access and benefit-sharing in the State. For example, in 1996 the Herbarium in the Tasmania Museum and Art Gallery entered into a contractual biodiscovery partnership with Cerylid Biosciences (formerly ExGenix, and AMRAD). Under the agreement, the Herbarium would collect, identify, process and voucher plant material, with each voucher linked to a permanently preserved plant specimen (Kantivilas and Kashiwadani, 2006). The Herbarium managed the provenance data and provided advice on specimens that might have preliminary biopharmaceutical interest. The contract did not require the Herbarium to conduct research. As the collecting authority in the State, the Tasmanian Herbarium had permits for collecting flora specimens from the Tasmania Parks and Wildlife, Forestry Tasmania and the Wellington Park Trust. Under the contract, Cerylid provided lump sum funding to the Herbarium, but there were no provisions about royalties or other benefits from downstream applications of the research. The contract expired in mid-2002 and it was expected that the agreement would be renewed in early 2003.<sup>25</sup> However, the partnership was ultimately terminated. Without clear legislative requirements to the contrary, the plant extracts held at the Cerylid facility in Melbourne were never returned to the Herbarium, nor did the researchers know what became of the samples when the company ceased.

### **PROBLEMS WITH THE BIODISCOVERY SCHEMES IN AUSTRALIA**

There are a number of problems with the legal schemes designed to regulate the collection, use and reuse of native biological resources in Australia. The problems

<sup>23</sup> Western Australia, *Parliamentary Debates*, Legislative Assembly, 18 February 2015, 334 (William Johnston).

<sup>24</sup> *Biodiversity Conservation Act 2016* (WA) s 256(3).

<sup>25</sup> *Tasmanian Museum and Art Gallery Annual Report* (2003), 20.

with the biodiscovery schemes are reflected in the fact that neither the Commonwealth, Queensland, nor Northern Territory schemes have seen the high levels of uptake that were envisioned when the laws were passed.

One of the first problems with the existing schemes is that the legislative responses across the Commonwealth, States, and Territories are fragmented and incomplete. As mentioned, only the *Biological Resources Act* 2006 (NT) applies to the whole jurisdiction, including private land and aboriginal lands. In contrast, the *Biodiscovery Act* 2004 (Qld) and the *Environment Protection and Biodiversity Conservation Act* 1999 (Cth) are limited to Crown lands (such as national parks and marine reserves) and other State-owned lands. These problems are exacerbated by the fact that there are no access and benefit-sharing laws in New South Wales, Victoria, Tasmania, South Australia, Western Australia or the Australian Capital Territory. In contrast to the general principles of public international law, which have a “gap-filling” role for cases falling outside the scope of a specialized regime,<sup>26</sup> there is no equivalent “general law” to fill the gaps in Australian access and benefit-sharing legislation.

At the same time, the existing schemes are often difficult to navigate, cumbersome and slow. Benefit-sharing agreements can also be difficult to negotiate, particularly where expectations about returns are unrealistic and commercially unviable. Researchers have also complained about the difficulty of having to specify what the benefits of a biodiscovery research project are *before* they have collected the materials, let alone undertaken preliminary research on those materials. The need to enter into a benefit-sharing agreement that explains how benefits are to be distributed before material is collected makes it difficult to take account of serendipitous or unexpected discoveries (such as the discovery that Kakadu plum is useful to extend the shelf-life of prawns). At best, it leads to generalized claims, or at worst to claims that are unrealistic.

The fact that there are places in Australia where biodiscovery is unregulated allows people to obtain native biological materials from jurisdictions where there are no access and benefit sharing-laws. At the same time, parties who wish to comply with the legal schemes, who want to collect biological materials in a sustainable manner and to share benefits with access providers, are forced to navigate inconsistent legislative frameworks in order to conduct biodiscovery research. They may also be faced with cumbersome and slow bureaucratic regimes. This creates a perverse situation. On the one hand, biopirates are able to evade the laws by engaging in forum-shopping; they are able to collect biological resources from a jurisdiction or area of land where access and benefit-sharing laws do not apply. At the same time, parties who want to conduct ethical biodiscovery work and as such are willing to embrace the legal schemes are forced to navigate the inconsistent and under-resourced frameworks: a problem that has led at least some researchers to abandon their research plans. Rather than meeting the policy goal of facilitating scientific research and the sharing of the resulting benefits, access and benefit-sharing laws that are fragmented,

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<sup>26</sup> See, for example, Panel Report, *Korea - measures affecting government procurement*. WTO Doc WT/DS163/R (19 January 2000) [7.96]: “to the extent that there is no conflict or inconsistency, or an expression in a covered WTO agreement that applies differently, we are of the view that the customary rules of international law apply to the WTO treaties and to the process of treaty formation under the WTO”.

cumbersome and under-resourced simultaneously allow biopirates to evade the law while creating regulatory uncertainty and hurdles for organizations that seek to conduct ethical biodiscovery research.

If the collection, use and reuse of native biological resources is to be regulated effectively in Australia, the scheme must extend to all of Australia. The schemes also need to be resourced and staffed appropriately. While Australia signed the Nagoya Protocol on 20 January 2012, not only has it not yet ratified the agreement,<sup>27</sup> there is no indication that this is likely to happen in the near future. Australian biodiscovery entities that wish to commercialize in countries that have ratified the Protocol may face requirements to prove that the original biological samples were obtained pursuant to an access permit and benefit-sharing agreement. Without a clear permit system and an effective scheme for benefit-sharing agreements, there is a chance that biodiscovery entities may face downstream accusations of biopiracy.

Despite the problems with the existing biodiscovery schemes in Australia, there have been a number of notable developments. One of these is the possibility of the development of a national registry of benefit-sharing agreements, which would document compliance with the principles of the Nagoya Protocol, even in Australian jurisdictions without access and benefit-sharing laws. The creation of such a database remains at an embryonic stage. Another important development is that there has been a change in the research culture in Australia over the last decade or so, which can be attributed, at least in part, to the Convention on Biological Diversity and the debates and discussions that have circulated around it. In particular, there has been an increase in the use of benefit-sharing and access agreements even when there is no law in place that mandates their use (Bosse, 2016). While this will not help where parties do not wish to engage with the process, it does mark a positive move that goes towards (but not far enough) making up for the failure to address aboriginal and Torres Strait islander interests.

## REFERENCES

- Australian Government.** 2002. *Nationally consistent approach for access to and the utilisation of Australia's native genetic and biochemical resources* (11 October 2002). Department of the environment and Heritage (available at <http://www.environment.gov.au/system/files/resources/bbfbde06-d13a-4061-b2f9-c115d994de2d/files/nca.pdf>).
- Australian Parliament.** 2001. *Inquiry into development of high technology industries in regional Australia based on bioprospecting*. House of Representatives Standing Committee on Primary Industries and Regional Services.
- Bosse, J.** 2016. Biopiracy in Queensland: a broken record that needs repair. *Trade Insight*, 12(2): 35-38.
- DLA Phillips Fox.** 2009. *Statutory Review of the Biodiscovery Act 2004* (available at <http://www.parliament.qld.gov.au/Documents/TableOffice/TabledPapers/2009/5309T1532.pdf>).

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<sup>27</sup> *Parties to the Nagoya Protocol*, Convention on Biological Diversity (available at <https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml>).

- Holcombe, S. & Janke, T.** 2012. Patenting the Kakadu plum and the Marjarla tree: biodiscovery, intellectual property and indigenous knowledge. In M. Rimmer & A. McLennan, eds. *Intellectual property and emerging technologies: the new biology*, pp. 293-319. Edward Elgar.
- Kantvilas, G. & Kashiwadani, H.** 2006. The Tasmanian Herbarium and its role in biodiversity research, land management, conservation and economic development. In Y. Tomida *et al.*, eds. *Proceedings of the 7th and 8th Symposia on Collection Building and Natural History Studies in Asia and the Pacific Rim National Science Museum Monographs*, 34: 25-35.
- Lawson, C.** 2006. Patents and biological diversity conservation, destruction and decline? exploiting genetic resources in Queensland under the Biodiscovery Act 2004 (Qld). *European Intellectual Property Review*, 28(8): 418.
- Lawson, C.** 2011. Patents and access and benefit-sharing contracts: conservation or just more red tape? *Biotechnology Law Report*, 30(2): 197-206.
- Queensland Government.** 2006. *Queensland Biotechnology Code of Ethics* (available at <https://www.qld.gov.au/dsiti/assets/documents/qld-biotechnology-code-of-ethics.pdf>).
- Queensland Government.** 2016. *Guidelines for preparing a biodiscovery plan* (available at <https://publications.qld.gov.au/dataset/biodiscovery-plan-guidelines-and-template/resource/4fca0512-6eb9-4e13-bdf3-dbd242335230>).
- Robinson, D.** 2010a. *Traditional knowledge and biological product derivative patents: benefit-sharing and patent issues relating to camu camu, Kakadu plum and açai plant extracts*. Trade, Intellectual Property and the Knowledge Assets of Indigenous Peoples: The Developmental Frontier. Conference at Victoria University of Wellington.
- Robinson, D.** 2010b. *Confronting biopiracy: challenges, cases and international debates*. Earthscan. 190 p.
- Tasmania. Department of Primary Industries and Water.** 2009. *Bioprospecting: sharing the benefits for Tasmania*. Hobart.
- Voumard, J.** 2000. *Access to biological resources in Commonwealth areas*. Commonwealth Public Inquiry (available at <http://www.environment.gov.au/system/files/resources/dof84da6-eb69-4053-8d96-ec294da649bc/files/abrca.pdf>).