CGIAR

Science for a food-secure future

Guidelines on the Nagoya Protocol for CGIAR Research Centers

Approved by the Directors General of CGIAR's Article 15 Centers with effect from 26 February 2018. Approved by the CGIAR System Management Board with effect from June 2018.

Aknowledgements:

These guidelines were developed with financial support from the CGIAR System Organization, CLIPNet, CGIAR Research Program on Climate Change, Agriculture and Food Security, and the CGIAR Genebank Platform. They were written by a core team comprising Michael Halewood, Isabel López Noriega, Brendan Tobin and Gerald Moore. David Ellis, Lena Fey, Kathryn Garforth, Selim Guvener, Hartmut Meyer, Thomas Payne, Carolina Roa, Ruaraidh Sackville Hamilton and Rodrigo Sara commented on earlier drafts.

The views expressed in these guidelines are those of the authors, and do not necessarily reflect the opinions of the CGIAR Genebank Platform.

The CGIAR Genebank Platform supports the core activities of the CGIAR genebanks: conserving and making available crop and tree diversity. It ensures that the genebanks meet international standards, improve efficiency and ensure more effective use within an enabling policy environment.

https://www.genebanks.org/

Note: this is a 'rolling document' which will be updated occasionally. The present version focuses on plant genetic resources. It will be expanded to address animal and microbial genetic resources. It is available at
https://www.cgiar.org/how-we-work/accountability/legal-documents/

CGIAR Scientists may address questions or comments concerning these guidelines to:
GRPolicy-helpdesk@groups.cgiar.org

Document to be cited as: CGIAR Genebank Platform (2018) Guidelines on the Nagoya Protocol for CGIAR Research Centers. CGIAR, Montpellier, France.

CGIAR | Genebank Platform

Table of Contents

List of acronyms

ABS	access and benefit-sharing
ABS	Clearing-House Access and Benefit-Sharing Clearing-House
COP	Conference of the Parties
CBD	Convention on Biological Diversity
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
IRCC	internationally recognized certificate of compliance
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
multilateral system	multilateral system of access and benefit-sharing
MATs	mutually agreed terms
NGOs	non-governmental organizations
PGRFA	plant genetic resources for food and agriculture
PIC	prior informed consent
SMTA	Standard Material Transfer Agreement
TAC SMTA	Ad Hoc Technical Advisory Committee on the SMTA and multilateral system

Article 15 CGIAR Centers

All 11 CGIAR Research Centers that host germplasm collections in CGIAR Genebanks (termed Article 15 Centers) have agreements with the Food and Agriculture Organization of the United Nations (FAO) placing these collections within the purview of the Multilateral System of Access and Benefit-sharing of the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty). Pursuant to these agreements, Article 15 Centers hold and manage these collections in trust, for the benefit of humanity.

The Article 15 Centers are:

Center (short name)	Center (full name)
AfricaRice	Africa Rice Center
Bioversity	Bioversity International
CIAT	International Center for Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
ICARDA	International Center for Agricultural Research in Dry Areas
ICRAF	World Agroforestry Center
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute
IRRI	International Rice Research Institute

Introduction

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) came into force in October 2014.[1] As of January 2018, the Nagoya Protocol had one hundred and four Contracting Parties, including the European Union. The Nagoya Protocol deepens and extends member states' commitments under the Convention on Biological Diversity (CBD) to put operable systems in place to regulate access to genetic resources and associated traditional knowledge, and to monitor and enforce compliance by users with access and benefit-sharing legislation in provider countries. It also stablishes an international infrastructure – the ABS Clearing-House – which is a key component of international monitoring and enforcement efforts.

By way of introduction, it is important to underscore that most of the CGIAR Research Centers' activities related to the conservation, research and development and distribution of plant genetic resources are governed by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) [2] and not by the Nagoya Protocol. However, there are some situations where the CGIAR Centers will need to comply with regional, national and sub-national mechanisms that implement the Nagoya Protocol, for example, when accessing plant genetic resources that are not available through the ITPGRFA's multilateral system of access and benefit-sharing (multilateral system). As more countries ratify and implement the Nagoya Protocol, an increasing proportion of the genetic resources that the CGIAR Centers want to collect and use could be affected by access and benefit-sharing (ABS) laws developed under the Protocol. It is also important to highlight that many countries have ABS laws developed prior to their ratification of the Nagoya Protocol, which CGIAR Centers will need to continue to comply with when collecting genetic resources. Over time, countries that ratify the Nagoya Protocol will revise or replace their existing ABS laws to reflect their commitments under the Nagoya Protocol.

These guidelines are meant to help the CGIAR Centers understand which areas of their plant genetic resources-related activities could be affected by the Nagoya Protocol, and what their options are in terms of how they can comply with the legal obligations. The guidelines address situations where countries have national laws in place implementing the Nagoya Protocol as well as situations where the countries concerned have ratified or acceded to the Nagoya Protocol but do not yet have national laws and systems in place to implement it.

As of January 2018, few countries have put systems into place to fully implement the Nagoya Protocol. However, many countries and regions around the world are in the process of developing

[1] Nagoya Protocol on Access and Benefit Sharing and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, 29 October 2012, http://www.cbd.int/abs/text/ (accessed 18 December 2017) (Nagoya Protocol).
[2] International Treaty on Plant Genetic Resources for Food and Agriculture, 29 June 2004, http://www.planttreaty.org/texts_en.htm (accessed 18 December 2017) (ITPGRFA).

such systems. In the past, the CGIAR Centers have developed guidelines, [3] frequently asked questions4 and training materials for operating under the ITPGRFA framework. [5] As the CGIAR Centers have gained experience over time, these guidelines have been revised and updated. This first edition of guidelines concerning Centers' operations in compliance with the Nagoya Protocol addresses issues that have been highlighted in consultations with the CGIAR Centers – primarily the genebank managers and intellectual property focal points. These guidelines will also need to be updated on a rolling basis as the Nagoya Protocol becomes more widely implemented and the CGIAR Centers gain more experience operating in compliance with it. [6] These guidelines provide general introduction and guidance for Centers on relevant issues. It is understood that Centers have their own legal officers and access to independent legal advice to assist in addressing particular cases that arise in their daily work.

These guidelines focus primarily on the CGIAR Centers' access to, and distribution of, plant genetic resources for food and agriculture (PGRFA) and related traditional knowledge. Future iterations may be revised and expanded to include sections on how the Nagoya Protocol applies to the CGIAR Centers' use vis-à-vis animal, insect and microbial genetic resources and related traditional knowledge. A new issue that will be considered by the Conference of the Parties (COP) to the Nagoya Protocol is benefit-sharing in relation to the use of digital genetic sequence information. These guidelines will be updated in the future to reflect the outcome of those deliberations.

Following this introduction, these guidelines are divided into five sections. The first section provides an overview of the relationship of the Nagoya Protocol to the ITPGRFA, the CGIAR Centers' Article 15 agreements and their earlier 1994 In-Trust Agreement with the Food and Agriculture Organization (FAO). [7] This general overview will provide the context for more in-depth analysis in subsequent sections of how the Nagoya Protocol may apply to the CGIAR Centers and what their obligations are in those cases. The second section considers when the Nagoya Protocol could apply to CGIAR genebanks and breeders accessing new materials. The third section analyses how the CGIAR Centers' distributions of PGRFA could be affected by the Nagoya Protocol. The fourth section focuses on issues that the CGIAR Centers need to bear in mind concerning the operation of 'checkpoints' established within countries as part of the overall monitoring and enforcement apparatus established

[3] System-wide Genetic Resources Programme (SGRP), Guide for the CGIAR Centers' *Use of the Standard Material Transfer Agreement* (Bioversity International, Rome, Italy, 2009), http://cropgenebank.sgrp.cgiar.org/images/file/management/Guide_SMTA_updated.pdf (accessed 18 December 2017).
[4] *Frequently Asked Questions on the SMTA,* http://irri.org/images/downloads/smta_faq.pdf (accessed 18 December 2017).
[5] G. Moore and E. Goldberg (eds), *International Treaty on Plant Genetic Resources for Food and Agriculture: Learning Module* (SGRP, Bioversity International and the Generation Challenge Program, Bioversity International, Rome, Italy, 2010), http://treatylearningmodule.bioversityinternational.org/ (accessed 18 December 2017).
[6] CGIAR Scientists may send queries regarding issues raised in these guidelines to GRPolicyhelpdesk@cgiar.org
[7] Agreement with FAO to Place Center In-Trust Collections of Plant Genetic Resources under the Auspices of FAO, May 1994, http://hdl.handle.net/10947/149 (accessed 18 December 2017) (1994 InTrust Agreements).

by the Nagoya Protocol. This section is divided into two subsections. The first subsection focuses on the more common scenario in which the recipients and users of materials received from the CGIAR Centers will need to interact with national checkpoints. In the second subsection, we will consider those comparatively rare situations where the CGIAR Centers themselves may need to submit information to national checkpoints when their own use of a genetic resource triggers the need to provide a national checkpoint with information. In these two subsections, we will, among other things, focus on how recipients' due diligence requirements under EU Regulation 511/2014 implementing the Nagoya Protocol could impact on the CGIAR genebanks and breeders as providers of materials.[8] Finally, the fifth section considers how and when the Nagoya Protocol could apply to the CGIAR Centers accessing, using and distributing traditional knowledge.

[8] EU Regulation 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, (2014) OJ L150, establishes rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources in accordance with the provisions of the Nagoya Protocol. In 2016, the European Union Commission adopted a guidance document focusing on the scope of application and core obligations of Regulation 511/2014. In 2017, the Commission commissioned the development of a series of guidance documents to help different types of genetic resource users (including holders of genetic resource collections, researchers and breeders) to establish whether the activities they carry out fall within the scope of Regulation 511/2014. These sector-specific guidance documents also aim to assist users of genetic resources in identifying their due diligence obligations and in concluding how these obligations should be met.

1. The relationship of the Nagoya Protocol to the ITPGRFA, Article 15 agreements and the 1994 In-Trust Agreements

The objectives of the CBD and the ITPGRFA are basically identical – the conservation and sustainable use of genetic resources, access to genetic resources and the equitable sharing of benefits derived from their use. However, the ABS systems that these agreements require their member states to implement are very different. The ITPGRFA has created the multilateral system whereby countries agree to use a common approach to manage and share the genetic resources of 64 crops and forages listed in Annex 1 of the Treaty for agriculture and food-related purposes. The scope of the CBD is much broader than the ITPGRFA, covering all genetic resources and any potential use of those genetic resources, except human genetic resources and genetic resources beyond countries' jurisdictions – for example, in the deep sea and the Antarctic. The CBD provides for bilateral negotiation of ABS agreements between access seekers, and provider states and their constituents, subject to prior informed consent (PIC) and mutually agreed terms (MATs). Provider states may provide access to genetic materials for which they are the country of origin or for which they have acquired in accordance with the CBD. As stated above, the primary objective of the Nagoya Protocol is to promote the fair and equitable sharing of benefits derived from their utilization to support the conservation and sustainable use of biodiversity by extending and operationalizing the basic approach established under the CBD.

The ITPGRFA explicitly recognizes and provides a mechanism to incorporate the CGIAR Centers into the overall ITPGRFA framework. Article 15 of the ITPGRFA invites the Centers, as international institutions with independent international legal personalities (created through their establishment agreements and reinforced by the country hosting agreements), to sign agreements with the Governing Body of the ITGRFA, placing their 'in-trust' collections under the ITPGRFA's framework. Eleven CGIAR Centers signed such agreements with the Governing Body of the ITPGRFA, undertaking to make available the plant genetic resources they hold in accordance with the multilateral system and subjecting themselves to the overall policy guidance of the Governing Body. In this way, most of the CGIAR Centers' core obligations under the ITPGRFA have their source in the international agreement they executed with the Governing Body.

Of course, the CGIAR Centers' operations are also affected by the extent to which the Contracting Parties have implemented the ITPGRFA and the multilateral system, in particular. For example, on the one hand, it is certainly not required by the ITPGRFA for countries to pass new laws (for example, legislation, executive orders and so on) as part of their national implementation of the multilateral system. Indeed, the countries that have made the most progress implementing the multilateral system to date have been able to do so simply by relying on the exercise of existing powers and mandates to make requisite decisions, such as starting to use the Standard Material Transfer Agreement (SMTA)

when distributing materials from their national public collections.[9] However, on the other hand, in some countries, given the highly politicized nature of genetic resource issues, would be providers of materials do not feel they can 'take the risk' to provide materials under the SMTA without some kind of formal back-up in the form of law confirming the expectation that they should do so. In such cases, the CGIAR Centers will be directly affected if they cannot obtain materials from the countries, even though they are (most likely) in the multilateral system.

The situation is very different *vis-à-vis* the CBD and the Nagoya Protocol. These instruments do not explicitly mention the CGIAR Centers or create means by which international organizations like the CGIAR Centers can sign agreements to subject some or all of their operations to the policy guidance of the COP to the CBD or the Nagoya Protocol. Thus, as international organizations, the CGIAR Centers are not directly subject to the Nagoya Protocol. Instead, all of their concrete legal obligations pursuant to the Nagoya Protocol arise from the implementing measures of the countries from which they want to access plant genetic resources and associated traditional knowledge (and, in some cases, indirectly, where they want to provide these resources to others or to utilize them).[10] It is for this reason that the answer to the question: 'what do I have to do under the Nagoya Protocol in this case?' always starts with: 'you need to look at the national law.'

There is considerable potential for coordinated, mutually supportive implementation of the CBD, the Nagoya Protocol and the ITPGRFA. The boundaries between the two ABS systems (bilateral under the CBD and the Nagoya Protocol and multilateral under the ITPGRFA) are relatively clear, and they do not overlap. However, there is a close relationship between the two agreements. For organizations like the CGIAR Centers working with PGRFA, it is impossible to provide meaningful guidance with respect to operating under the Nagoya Protocol without simultaneously considering the application of the ITPGRFA's multilateral system.

The ITPGRFA was negotiated to be in harmony with the CBD, and it is explicitly based on the principle underscored in the CBD that all countries have sovereign rights over their natural resources, including their genetic resources. The Nagoya Protocol in turn was negotiated in full knowledge of the ITPGRFA and the multilateral system. The CBD's COP decision adopting the text of the Nagoya Protocol states that the ITPGRFA is a complementary instrument to the CBD and to the Nagoya Protocol. In its preamble, the Nagoya Protocol recognizes the ITPGRFA and recalls the existence of the multilateral system. Most importantly, while the ITPGRFA is not explicitly mentioned (nor is any other agreement) in Article 4 of the Nagoya Protocol, dealing with the 'relationship with international

[9] Standard Material Transfer Agreement, 16 June 2006,
http://www.fao.org/plant-treaty/areas-ofwork/the-multilateral-system/the-smta/en/
(accessed 18 December 2017) (SMTA).

[10] Some CGIAR Centers have raised questions about whether their operations as conservers and distributers of germplasm could be affected by systems that their host country could eventually put into place as part of their strategies to implement the Nagoya Protocol. In short, they should not, given the combined factors of each CGIAR Center's (1) international legal personality, (2) host county agreements, (3) 1994 In-Trust Agreements, (4) 2006 Article 15 agreements with the ITPGRFA, (5) genebank and breeding program distributions fitting so squarely under the ITPGRFA framework and the fact that (6) the Nagoya Protocol recognizes (and does not apply to) the ITPGRFA's Article 15 agreements and so on.

agreements and instruments', this article clearly recognizes, and leaves space for, the uninterrupted operation of the ITPGRFA, the Article 15 agreements and, even before them, the 1994 In-Trust Agreements. Subparagraphs 4.3 and 4.4 are the most important in this regard, stating:

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices 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.
4. This Protocol is the instrument for the implementation of the access and benefitsharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this 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.

In short, by virtue of these clauses, the CGIAR Centers' activities that fall squarely, and exclusively, under the framework of the multilateral system, their 2006 agreements with the Governing Body under Article 15 of the ITPGRFA, and their 1994 CGIAR–FAO In-Trust Agreements are not (or at least should not be) affected by the Nagoya Protocol. Examples of such activities by the CGIAR Centers are:

- Distributing 'in-trust' germplasm using the SMTA to recipients who will use these materials for the purposes set out in the SMTA
- Receiving plant genetic resources from the multilateral system under the SMTA.

However, as explained above, there are some activities that the CGIAR Centers engage in that would likely be governed by the Nagoya Protocol or the CBD. Examples of such activities are:

- Missions to collect plant germplasm that is not included in the multilateral system
- Collecting, using or distributing traditional knowledge associated with genetic resources
- Breeding new lines that incorporate plant genetic resources accessed under national laws that implement the CBD/Nagoya Protocol.

The MATs under which the CGIAR Centers acquire such plant genetic resources should incorporate provisions for their further distribution (or the new lines into which they are incorporated), ideally under the SMTA (that is, to manage them under the ITPGRFA framework). This is consistent with the CGIAR's mission as well as the Centers' commitments to conserving, creating and providing international public goods. Sections 2, 3, 4 and 5 of this document provide more detailed analyses of how the Nagoya Protocol may (or may not) apply to the CGIAR Centers' day-to-day uses of plant genetic resources and traditional knowledge and the Centers' options for complying with the letter or the spirit of the Nagoya Protocol when the Protocol is not fully implemented.

2. CGIAR genebanks and breeders acquiring PGRFA

The materials that the CGIAR Centers seek to acquire may be governed under the ITPGRFA's multilateral system or under national laws implementing the Nagoya Protocol. It is also possible that the uses for which genetic resources are sought are not regulated under either of the two agreements. This section is dedicated to helping the CGIAR Centers figure out what rules apply on a case-by-case basis and how to comply with them. The decision-making tree included in Annex 1 is meant to complement this section.

The CGIAR Centers acquire genetic resources of crops, forages, trees and wild relatives for inclusion in their genebanks and field collections and for incorporation in their breeding programs. They access these materials from a range of different sources in a range of different contexts. For example, working closely with national programs, they may organize or support new collecting missions to obtain materials from in situ conditions in farmers' fields or protected areas. In the context of joint research and breeding programs, they may receive genetic resources from national agricultural research organizations, universities, private companies, non-governmental organizations (NGOs) and farmers and other private individuals. They may receive materials from national programs in the execution of their role as the coordinators of international crop evaluation networks (for example, the International Network for the Genetic Evaluation of Rice) or genomics research consortia (for example, the Musa Genomics Consortium). In each case, the CGIAR Centers need to know the national law that applies to the Centers' acquisition of material and the particular terms and conditions under which they acquire it.

Where is it possible to get information about the laws in the countries where the CGIAR Centers would like to acquire material?

The CGIAR Centers' first steps in making sure that their acquisitions of PGRFA are in line with existing ABS laws may be (1) to find out whether the given country is a party to the ITPGRFA, the CBD and the Nagoya Protocol; if so (2) to get in touch with the focal points for these international agreements and (3) to obtain information about existing ABS measures. To find out if the country concerned has ratified these three agreements (and, thus, has become a Contracting Party to the agreements), one can consult the list of Contracting Parties maintained by the relevant secretariats of these agreements. All countries except for the Holy See and the United States are parties to the CBD (the list of Contracting Parties to the Nagoya Protocol is available at https://www.cbd.int/abs/nagoyaprotocol/signatories/; the list of Contracting Parties to the ITPGRFA is available at http://www.planttreaty.org/content/contracting-parties-treaty). The Contracting Parties undertake responsibility to implement the agreements they have ratified

To find out the actual state of implementation of these agreements in a country, the simplest thing (at least in theory) is to contact the national public authorities responsible for the implementation and administration of the ITPGRFA and the ABS-related provisions under the CBD and Nagoya Protocol (the list of national focal points under the Nagoya Protocol is available at https://absch.cbd.int/search/national-records/NFP; the list of national focal points under the ITPGRFA is available at http://www.planttreaty.org/nfp; it is possible (but by no means guaranteed) to obtain the text of the national laws and policies related to the implementation of the multilateral system through FAOLEX at http://faolex.fao.org/).

How can the CGIAR Centers know whether to apply for access to particular materials under the ITPGRFA or under the CBD and the Nagoya Protocol?

When countries that are parties to the ITPGRFA have notified the Treaty Secretariat about particular collections that are included in the multilateral system, the CGIAR Centers can safely assume that facilitated access to those collections will be provided subject to the SMTA for 'utilization and conservation for research, breeding and training for food and agriculture' (Article 12.3(a) of the ITPGRFA). However, for all other genetic resources, the CGIAR Centers, acting on their own, cannot know for sure which regime will apply. However, they can make informed predictions based on the basic rules of the multilateral system and the information they may be able to gather about the state of implementation of the relevant international agreements in the countries concerned. And, very importantly, they can check with the managers of the collections, the authorities managing protected areas, the high-level representatives of national programs and, ultimately, the national focal points.

A lot has already been written about the scope of the multilateral system and the plant genetic resources that are automatically included in this system.[11] Space does not permit repeating it here. In short, all PGRFA of the 64 crops and forages listed in Annex 1 of the ITPGRFA, found in a state that is a party to the Treaty and 'under the management and control' of the Contracting Party 'and in the public domain,' are automatically included in the multilateral system. The Ad Hoc Technical Advisory Committee on the SMTA and multilateral system (TAC SMTA) has opined that 'under the management' refers to a Contracting Party's 'capacity to determine how the material is handled and not to the legal rights to dispose of the PGRFA,' while control refers to the 'legal power to dispose of the material.' 'Contracting Party' refers to national governments, not to provincial or municipal

[11] See, for example, G Moore, W Tymowski, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture,* International Union for the Conservation of Nature, Gland, Switzerland, and Cambridge, UK, 2005; SGRP, 2009. Guide for the CGIAR Centers' *Use of the Standard Material Transfer Agreement.* SGRP, Rome (section 2 in particular); C Correa, Plant genetic resources under the management and control of contracting parties and in the public domain: how rich is the ITPGRFA's multilateral system, in M Halewood, I López Noriega, S Louafi, *Creating a global crop commons, Routledge, New York, 2013; and M Halewood et al. 2018. Decision-making tool for national implementation of the Plant Treaty's multilateral system of access and benefit sharing.* Bioversity International, Rome.

governments.[12] The TAC SMTA and numerous commentators have stated that materials should be considered in the 'public domain' if they are not subject to intellectual property rights.[13]

Typically, Annex 1 materials in national genebanks or held by national research organizations would be considered to fall within this definition. However, in most countries, materials managed or controlled by farmers or companies would not be included. PGRFA can also be placed in the multilateral system by legal and natural persons holding that PGRFA. PGRFA in the multilateral system can be accessed for the purposes of research, breeding or training for food and agriculture by natural and legal persons in other countries that are Contracting Parties to the International Treaty and by the CGIAR Centers and other international institutions that have signed Article 15 agreements with the Governing Body of the Treaty. Based on this information, the CGIAR Centers will usually be able to form a fairly clear idea about whether the materials they are interested in accessing should be available under the multilateral system. However, ultimately, this is a matter that will be determined by the competent national authorities. And it is also the case that many countries have not yet gone through processes of confirming what materials are included and available through the multilateral system.

When a plant genetic resource or use of a plant genetic resource does not fall under the multilateral system, it will often be covered by the national laws implementing the ABS provisions of the CBD and the Nagoya Protocol, assuming that the country concerned has decided to regulate access to genetic resources under the Protocol and they have had time to put such measure in place (a number of European countries for example have decided only to implement user enforcements measures and not access regulating measures). It can occur that a purported use of a genetic material may not be regulated under national laws implementing either the ITPGRFA or the Nagoya Protocol.

The scope of the Nagoya Protocol includes 'utilization' of all genetic resources (with the exclusion of human genetic resources and those located beyond national jurisdiction). The utilization of genetic resources 'means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology' (Article 2(c) of the Nagoya Protocol). Arguably, this scope covers most of the uses that the CGIAR Centers would make of the material in breeding programs and genebanks (bearing in mind the purposes for which materials can subsequently be made available under the SMTA). However, there may be cases in which it is not clear if the use of the germplasm by a CGIAR Center constitutes 'utilization' in the sense of the Nagoya Protocol and, therefore, if it triggers the application of access procedures in the provider country.

[12] *Report of the First Meeting of the Ad Hoc Technical Advisory Committee on the Standard Material Transfer Agreement and the Multilateral System,* Doc. IT/AC-SMTA-MLS 1/10/Report (18–19 January 2010), Appendix 3, http://www.planttreaty.org/sites/default/files/ac_smta_mls1_repe.pdf (accessed 24 October 2017).
[13] Ibid. Some scholars and civil society organizations have argued that this way of defining public domain is based on purely Western interpretations and does not reflect indigenous peoples' ways of managing, sharing and controlling biological resources. 'Public domain' has different meanings in different jurisdictions. The administrative and civil law of several countries uses the term 'public domain' to refer to things and goods that cannot be appropriated by anyone because they are for public use, such as rivers, lakes, beaches, public roads and for whose private use only the state can grant a permit.

Some of the activities which may or may not constitute utilization are: observing the performance of particular accessions in order to evaluate the presence of certain traits and then decide whether to include the accessions in a breeding programme; and conducting studies about genetic relationships and differences between geographically separated populations for understating variation and distribution of traits of interest. It is likely that when regulating access to genetic resources and putting in place monitoring mechanisms under the Nagoya Protocol, countries will interpret 'utilization' in different ways. Some countries may consider these activities to be 'utilization' in the sense of the Nagoya Protocol and therefore subject to national laws on ABS, while other countries may not. Even if there was consensus within the COP that these activities do not constitute 'utilization' as meant by the Nagoya Protocol, countries could still require PIC and MATs in order to grant access to genetic resources for these activities. CGIAR researchers should make sure that they meet access requirements of the provider countries even when they are not certain if they will use the genetic resources in a way that can be considered 'utilization' in the sense of the Nagoya Protocol. As stressed elsewhere in this document, it is essential that the Centers look to the actual law of the country concerned to make sure they know what kinds of materials, and uses of those materials, are regulated

In this context, it is noteworthy that the guidance documents developed by the EU Commission for the implementation of the EU Regulation 511/2014 on compliance measures under the Nagoya Protocol interpret 'utilization' to not include a range of uses of PGRFA, including the direct use of seeds for planting and harvesting, taxonomy studies and morphological characterization.[14] The sector-specific guidance documents being developed by the EU Commission to facilitate the implementation of the EU Regulation 511/2014 have identified various 'unresolved issues' (that is, situations in which it is not clear whether the use of the genetic resources can be considered 'utilization' according to the Nagoya Protocol). These unresolved issues include the screening of genetic resources for selecting accessions with desired traits, population genetic and phylogeographic analyses and the use of commercial varieties.

[14] The non-binding Guidance Document on the Scope of Application and Core Obligations of Regulation no. 511/2014 of the European Parliament and Council on the Compliance Measures for Users from the Nagoya Protocol, (2016) OJ C313, http://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX%3A52016XC0827(01) (accessed 18 December 2017) (EU ABS Guidelines) states that '[g]iven that the mere planting and harvesting of seeds or other reproductive material by a farmer does not involve research and development, this is outside the Regulation's scope' (at 8). The document developed under the auspices of the Food and Agriculture Organization's Commission on Genetic Resources for Food and Agriculture in 2015 adopts a similar interpretation and states: 'If the activities triggering access provisions are limited to "utilization" within the meaning of the Nagoya Protocol, certain typical uses of GRFA, for example the growing of seeds for subsequently using the harvested products for human consumption clearly do not qualify as utilization and therefore do not trigger the application of access provisions.' Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture,' Doc. CGRFA-15/15/Report (19–23 January 2015), para. 46, http://www.fao.org/3/amm660e.pdf (accessed 18 December 2017).

EU Regulation 511/2014 and its accompanying guidance documents focus entirely on establishing measures to monitor the 'utilization' of genetic resources in EU countries that are accessed from other countries that are Parties to the Nagoya Protocol and that have national ABS measures in place; the EU law does not establish standards for regulating access to genetic resources in the EU. Again, it is important to underscore that provider countries benefit-sharing will interpret 'utilization' more broadly than the EU in order to encompass a broader range of uses than are included in the EU's law.

The CGIAR Centers will be obliged to comply with these interpretations when seeking access to genetic materials in these countries. However, these provisions would not be enforceable in the EU pursuant to the user measures they have put in place to monitor 'utilization.' Thus, uses of materials in the EU that do not constitute utilization as defined by the EU would not be monitored by the national checkpoints. In these cases, therefore, users would not need to comply with (and compile and adduce evidence of) due diligence ascertaining that the materials they are using have been legally accessed. This does not mean that Centers can disregard their agreements with providers of genetic resources. They are still legally (and morally) binding on the Center that makes the agreements. It just means that the monitoring and enforcement mechanisms that are put in place in the EU would not apply to those aspects of those agreements.

Where the regime that applies to the access request is not clear, the CGIAR Centers may want to make enquiries directly with the national focal points or work through national partner organizations who can investigate with the competent national authorities on their behalf. Alternatively, the CGIAR Centers can find out by simply applying for access, thereby setting in motion the national processes for making a determination.

There is a long-standing tradition of informal exchanges between breeders. The international agreements adopted in the last decades – both the ITPGRFA and Nagoya Protocol – require changes to this modus operandi. Most of the time, the breeding materials being transferred from national programs to the CGIAR Centers will be in the multilateral system. However, the ITPGRFA will not always apply. Whereas researchers and breeders in national programs may have been able to say in the past that they had the ability to provide genetic resources on their own, national laws implementing the Nagoya Protocol will require providers to get additional sign-off from the competent national authorities (assuming the purposes of utilization fall within the scope of the national law).

How can the CGIAR Centers find out the process to follow to obtain access to genetic resources in accordance with the CBD and the Nagoya Protocol?

The Nagoya Protocol states that each party, by the time the Nagoya Protocol enters into force for that country, needs to appoint a national focal point and a competent national authority and to publicize their names and contact information through the online ABS Clearing-House maintained by the CBD's Secretariat (Article 13.4 of the Nagoya Protocol). The national focal point is to provide applicants with 'information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing' (Article 13.1 of the Nagoya Protocol). The competent national

authorities are responsible for granting access and issuing written evidence that the access requirements have been met (Article 13.2 of the Nagoya Protocol). In addition, the Nagoya Protocol requires parties to publish all 'legislative, administrative and policy measures on access and benefitsharing' on the ABS Clearing-House (Article 14.2 of the Nagoya Protocol). National ABS measures implementing the Nagoya Protocol are available at https://absch.cbd.int/search/national-records/MSR. Currently, 50 countries have published information about legal, administrative and policy measures on the ABS Clearing-House. Since a number of Contracting Parties have not published relevant information yet, it is advisable to get in touch with the national ABS focal point anyway.

In addition to addressing the actual holder of the resources, the CGIAR Centers should send their request for genetic resources to the competent national authorities designated by the countries of the Nagoya Protocol. If the names and contact details of the competent national authorities have not been made public, the CGIAR Centers can contact the national ABS focal point. Some countries may put in place processes for obtaining the PIC, or the approval and involvement, of indigenous peoples and local communities in the process to get access to genetic resources, in accordance with Article 6.3(f) of the Nagoya Protocol. In cases where countries have not put in place clear rules and procedures for access seekers to get the PIC from indigenous and local communities, the CGIAR Centers, as a good practice, should seek the involvement of these communities and get their approval when collecting genetic resources that indigenous and local communities conserve and manage.[15] Section 4 provides further guidance on how to deal with indigenous and local communities in the absence of national law.

What is required under the Nagoya Protocol to get access to genetic resources?

Article 6.1 of the Nagoya Protocol (and Article 15.5 of the CBD) states that access to genetic resources will be subject to the PIC of the Contracting Parties, 'unless otherwise determined by that Party.' Some countries have used this flexibility and decided not to require PIC for access to their genetic resources – for example, the Netherlands and the United Kingdom. Article 6.3 of the Nagoya Protocol states that those Contracting Parties that require PIC as a precondition for access 'shall take the necessary legislative, administrative or policy measures' to provide legal certainty with respect to

[15] Nagoya Protocol, Article 6.2 establishes that 'In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.' Some experts have interpreted that this article creates an obligation on all parties to the Nagoya Protocol to take measures to ensure indigenous and local communities' involvement in the access process. Based on this, if the CGIAR Centers want to operate in the spirit of the Protocol, they should always seek the approval of indigenous and local communities when accessing genetic resources over which those communities have rights, regardless of the existence of a national law (or lack of thereof) in this respect. This approach has been reflected in the Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets (IA Principles) in relation to Article 3.2 of the IA Principles, which provides that 'CGIAR seeks to be respectful of national and international efforts to protect and promote farmers' rights as envisaged by the Treaty and support the development of appropriate policies and procedures for their recognition and promotion.' Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets (14 June 2013), https://cgspace.cgiar.org/bitstream/handle/10947/4487/Implementation%20Guidelines%20for%20the%20CGIAR%20IA%20Principles.pdf (accessed 18 December 2017).

domestic ABS rules, clearly identify who to apply for access and how and so on. That said, the Nagoya Protocol does not actually set out any specific procedures that need to be put in place in countries to receive and consider access applications. The Contracting Parties have considerable flexibility in this regard. Based on several provisions of the Nagoya Protocol (Articles 6, 13 and 17), the CGIAR Centers can expect to be requested to do the following:

- To get the PIC of the competent national authority
- To agree on the terms and conditions for ABS
- To demonstrate the approval of the actual provider of the genetic resource in question
- To demonstrate the approval of, and the terms mutually agreed with, indigenous and local communities in case their genetic resources and related traditional knowledge is involved.

What is an internationally recognized certificate of compliance?

Once a permit is issued by the competent national authority/ies, the country providing access is required to publish information on the permit in the ABS Clearing-House. Information on a permit that is published in the ABS Clearing-House is used to constitute an internationally recognized certificate of compliance (IRCC) if it contains the following fields of information as specified in Article 17.4 of the Nagoya Protocol:

- Issuing authority
- Date of issuance
- Provider
- Unique identifier of the certificate
- Person or entity to whom the PIC was granted
- Subject matter or genetic resources covered by the certificate
- Confirmation that MATs were established
- Confirmation that PIC was obtained
- Commercial and/or non-commercial use.

The IRCC serves as evidence that the genetic resources that it covers have been accessed in accordance with PIC and that MATs have been established as required by domestic access and benefit-sharing legislation. It can be provided at checkpoints, described in Section 5 in this article, as proof that the genetic resources being utilized have been obtained in conformity with the national regimes on ABS. It is important to underscore that it is the responsibility of the country granting access to publish the information on access permits or their equivalent in the ABS Clearing-House. There is no mechanism for other entities (including CGIAR Centers) to make such reports. Another important aspect to bear in mind is that the IRCC is not the only document that users of genetic resources can submit to checkpoints. Competent national authorities may not publish IRCC for every access permit and material transfer agreement under their jurisdiction. In such cases, the actual agreements entered into by Centers, or information about them, can still be submitted to checkpoints as proof of compliance, subject to confidentiality obligations. .

Article 17.4 of the Nagoya Protocol does not prescribe to all of the fields of information that would ideally be included in a transfer agreement to address users' due diligence obligations under the Protocol. For example, it does not include an undertaking on the part of providers that they have the legal right, pursuant to national laws, contractual obligations, and so on, to provide the material for the purposes established in the agreement. It is advisable that the CGIAR Centers acquiring materials under agreements for genetic materials (other than the SMTA under the multilateral system) require such a statement to be included and perhaps even some of the details about when and how the provider legally obtained the materials being transferred. Future editions of these guidelines will include the text of such model clauses.

What should a CGIAR Center do if the provider country does not have the intention of requesting PIC and MATs?

Some Contracting Parties may decide not to require PIC and MATs as preconditions for access to genetic resources within their territories. Users of genetic resources accessed from those countries may be required by national checkpoints to show that they have acquired the materials legally. In such cases, it is advisable that the CGIAR Centers obtain from the competent national authority under the Nagoya Protocol or the CBD a written statement clarifying that PIC was not required by law in the provider country. Of course, it may be difficult to get such a document in many cases. In which case, the user should be prepared to provide information about the state of the law in the country of collection, the time of collection, and so on in order to satisfy the checkpoint.

What should a CGIAR Center do if a country from which it wants to acquire materials has ratified the CBD or the Nagoya Protocol but does not have the mechanisms in place to regulate access to genetic resources?

This is a relatively common scenario, given how long it takes most countries to pass implementing measures. In countries where there are no implementing measures in place, the CGIAR Centers, along with all other providers or users, will remain in a legal vacuum as far as the Nagoya Protocol and the CBD are concerned, without defined responsibilities or processes to follow. In such cases, as international organizations, the CGIAR Centers should not stop their enquiry regarding what they can or should do under the Nagoya Protocol by looking at the national implementing laws. They can and should proactively seek out ways to fulfil the spirit of these international agreements, to the extent possible, working with the partner organizations in those countries, the national focal points on ABS and the competent national authorities.[16]

[16] The CGIAR Centers' commitment to operate in line with the Convention on Biological Diversity and its implementing instruments in regard to access and benefit-sharing is expressed in article 4.2 of the CGIAR Principles on the Management of Intellectual Assets, which reads as follows: "Facilitated access to Plant Genetic Resources for Food and Agriculture within the purview of the Treaty shall be provided in accordance with the Treaty and these CGIAR IA Principles. In addition, the acquisition or transfer of any other genetic resources by the Centers shall be conducted in accordance with all applicable laws including those implementing the CBD, as well as these CGIAR IA Principles."

What can the CGIAR Centers do if they acquire genetic materials after the entry into force of the CBD without the requisite flexibility to (1) distribute them using the SMTA or (2) use them in the CGIAR Centers' breeding programs?

In such cases, they have to go back and seek such permission pursuant to the national laws. If there are not yet laws and procedures in place, the CGIAR Centers should follow the approach described in the preceding sections

3. CGIAR genebanks' and breeders' distributions of PGRFA

The CGIAR Centers distribute hundreds of thousands of samples each year from their genebanks and breeding programs. Pursuant to their Article 15 agreements with the Governing Body of the ITPGRFA, the CGIAR Centers are obliged to make Annex 1 PGRFA from their 'in-trust' collections available under the SMTA. The second session of the Governing Body decided that the CGIAR Centers (and other Article 15 organizations) should also use the SMTA to distribute non-Annex 1 materials from their collections that were acquired before the entry into force of the ITPGRFA. Furthermore, pursuant to Article 6.5 of the SMTA, improved materials developed through the CGIAR breeding programs that incorporate materials acquired from the multilateral system (known as 'PGRFA under development' in the lexicon of the ITPGRFA) must also be made available using the SMTA.

Under what circumstances could the CGIAR Centers' distribution of PGRFA using the SMTA be affected by the Nagoya Protocol?

Genebanks

When genebanks acquire new materials, they will want to be able to manage and distribute them under the same terms and conditions as the 'in-trust' materials. To this end, they need to make sure that they have acquire new materials under the Nagoya Protocol subject to MATs so that they can introduce them into their collections and distribute them using the SMTA. In the absence of such MATs, the genebank's management and distribution of the materials in question will be subject to different terms and conditions, creating unsustainable administrative burdens and transaction costs.

Breeders

It is possible that future CGIAR breeders may create improved lines derived not only from material accessed from the multilateral system but also from material accessed subject to MATs under the Nagoya Protocol. It would be crucially important to ensure that the MATs allow the CGIAR Center concerned to make the improved lines available using the SMTA. Otherwise, it would not be able to distribute them at all since the MAT requirement not to use the SMTA for derived breeding lines would conflict with the Treaty requirement to use the SMTA for the same lines. If the CGIAR Center concerned cannot make such an agreement with providers under the CBD/Nagoya Protocol,

the Center may choose not to accept the materials.[17] In this context, it is important to note that there is some flexibility when it comes to distributing CGIAR Center-improved materials than for in-trust germplasm. That is because when distributing Center-improved materials as PGRFA under development, the CGIAR Centers (or any provider for that matter) can add terms and conditions to those in the SMTA. In this way, the Center may be able to accommodate restrictions from the upstream providers of material.

A future revision of these guidelines will include model clauses for ABS agreements to be used by the CGIAR Centers to preserve the Centers' flexibility to distribute these materials, or derivatives of them, under the SMTA. These model clauses can be negotiated with national authorities in countries where the national measures for implementing the Nagoya Protocol have been, or have not yet been, adopted. Articles 19 and 20 of the Nagoya Protocol explicitly acknowledge the role that model contractual clauses can play. They are also recognized in EU Regulation 511/2014 (examples of model agreements and contractual clauses can be found at https://www.cbd.int/abs/resources/contracts.shtml; codes of conduct, best practices, standards and guidelines are available at https://www.cbd.int/abs/instruments/default.shtml).

Under what circumstances could the Nagoya Protocol affect the CGIAR Centers' ability to make material available for non-ITPGRFA purposes (for example, non-food/non-feed purposes or direct use by farmers)?

Like any other recipient of materials under the SMTA, the CGIAR Centers are obliged to use such materials only for the purposes set out in the SMTA. In the event that they want to use materials acquired under the SMTA for other purposes, they would need to get the provider's permission pursuant to the national laws implementing the CBD or the Nagoya Protocol. Such action will require developing a new ABS agreement. A future revision of these guidelines will include model clauses to include in an ABS germplasm acquisition agreement that would preserve the CGIAR Centers' flexibility to distribute materials for non-food/feed purposes. It is not expected that the use of this instrument will become widespread; the SMTA provides the requisite scope for most of the CGIAR Centers' purposes.

In this context, it is worth noting that the Ad Hoc Open Ended Working Group on the SMTA and multilateral system opined that, pursuant to their 1994 In-Trust Agreements, the CGIAR Centers have the discretion to make Center-improved materials and materials from their 'in-trust' collections available for agriculture-related non-food/non-feed purposes and for direct use by farmers.[18] The CGIAR Centers may use other material transfer agreements for such transfers, but these agreements must preclude the uses that are allowed under the SMTA.

To whom should the CGIAR Centers report their transfers of PGRFA when using the SMTA and when using other instruments?

Pursuant to paragraph 5.e of the SMTA, all providers, including the CGIAR Centers, must report their distributions of materials under the SMTA to the Secretariat of the ITPGRFA and through it to the Governing Body. This obligation is also set out in Article 2 of the CGIAR Centers' Article 15 Agreements with the Governing Body. There is no obligation under the Nagoya Protocol for international organizations to report any distributions of genetic resources to the ABS Clearing-House nor, to date, has there been any discussion at the COP/Meeting of the Parties for the Nagoya Protocol about international organizations making voluntary reports. That said, in the context of 'monitoring the utilization of genetic resources,' the parties to the Nagoya Protocol agree to '[e]ncourag[e] users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements' (Article 17.1(b) of the Nagoya Protocol). It is possible, over time, that providers of materials to the CGIAR Centers, or the Centers themselves, will voluntarily introduce reporting terms in material transfer agreements under the Nagoya Protocol in response to such 'encouragement.' Given the relatively early stages of implementation of the Nagoya Protocol around the world, this does not need appear to be a pressing issue at the time for the CGIAR Centers, but it should be monitored over time

[17] Occasionally, the genebanks make exceptions to this general approach if the material is unique and threatened and likely to disappear entirely unless the genebank agrees to conserve it under 'blackbox' conditions – that is to say, without permission to use it in any way and without permission to distribute it either under the SMTA or any other instrument. In such circumstances, the genebank will likely request the provider periodically for permission to make it available under the SMTA.

[18] Second Meeting of the Ad Hoc Advisory Technical Committee on the Standard Material Transfer Agreement and the Multilateral System (August 2010). See Opinions and Advice of the Ad Hoc Technical Advisory Committee on the Multilateral System and the Standard Material Transfer Agreement (2015), Opinion 10, https://www.geves.fr/wpcontent/uploads/OPINIONS_MLS_SMTA_v1.pdf
(accessed 18 December 2017).

4. Interacting with national checkpoints: information needed by the CGIAR Centers and the recipients of materials from the CGIAR Centers

Part of the agreed-to infrastructure for monitoring users' compliance with ABS measures and agreements under the Nagoya Protocol is the establishment of national checkpoints. Article 17 states that the Contracting Parties will designate one or more checkpoints to 'collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate.' The checkpoint will provide this information to 'relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House.' The Nagoya Protocol is silent with respect to what kind of organization should be designated as a checkpoint, beyond stating that they 'must be effective and should have functions relevant to' collecting or receiving relevant information related to the issues above. Presumably, the Contracting Parties will appoint organizations who can collect the requisite information in the course of the execution of their regular functions (for example, through a patent application in the case of a patent office, through notification of a new sample of an exotic species in the case of a botanical garden, through registration of a new plant variety under a national seed law or through project proposals involving genetic resources in the case of funding agencies).[19] This information will be passed onto the provider country of the material, which can then use the information to monitor utilization and as a basis for following up with the user if the national authorities of the provider country believe that the genetic resources are being used beyond the scope of the PIC that was granted and the MATs that were established. The requirements to monitor utilization are one of the innovations of the Nagoya Protocol so there is not yet a great deal of information or experience on how this will work in practice. Article 15 of the Nagoya Protocol provides that each party is to take the appropriate effective and proportionate legislative, administrative or policy measures to ensure that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC and that the MATs have been established as required by domestic ABS legislation and regulatory requirements in the provider country. It also provides that each party is to address situations of non-compliance. Similar requirements for traditional knowledge associated with genetic resources utilized in its jurisdiction are established under Article 16. Article 18 states that parties are to ensure that their legal systems provide opportunities to seek recourse in cases of disputes arising from the MATs.

[19] As of January 2018, 21 countries had shared information about their national checkpoints through the ABS Clearing-House. The information published by some countries through the ABS Clearing House specifies when and how the national checkpoints require users of genetic resources to show due diligence. For example, in Germany, Switzerland and Spain users of genetic resources are required to submit a due diligence declaration to the organ of the public administration who acts as competent national authority at different stages of the research and development process, namely when obtaining funding and prior to commercialization of the resulting product. Information available in the ABS Clearing House mechanisms about other countries' checkpoints does not include this level of detail and is therefore difficult to discern when and how checkpoints in these countries will monitor due diligence in practice.

Given the modus operandi of most CGIAR genebanks and breeding programs, which provide germplasm and improved lines to recipients who further develop and/or release them, it could be that CGIAR Centers will not often directly encounter, or be monitored by national checkpoints. Instead, depending upon the nature of the checkpoint, it could be that the recipients of germplasm from the CGIAR Centers will more frequently encounter the checkpoints – for example, patent offices, plant variety protection offices, variety registration authorities, national donor agencies supporting national research and development organizations, and so on. In the subsequent subsections, we address the question: how can information requirements for national checkpoints affect the CGIAR Centers directly (on the occasions when they are monitored by checkpoints) and indirectly (when the recipients of materials from the Centers are monitored by a checkpoint).

Information that is needed by recipients of materials from the CGIAR Centers vis-à-vis national checkpoints

> *For recipients of materials from the CGIAR Centers under the SMTA, what 'status' does the SMTA have if and when they need to interact with national checkpoints?*

As stated in Section 1, the Nagoya Protocol recognizes, works around and does not affect the operation of the multilateral system of ABS or the CGIAR Centers' Article 15 agreements under the ITPGRFA. As such, transfers of materials from the multilateral system or from Article 15 organizations – all under the SMTA – are outside the scope of systems to implement the Nagoya Protocol, including designated national checkpoints. That said, users of materials received by the CGIAR Centers under the SMTA that do encounter checkpoints could well be asked for information about the source of those materials, evidence of PIC in compliance with national laws, and so on. On the one hand, since the source is the multilateral system, the checkpoint system of the Nagoya Protocol does not apply to this material. On the other hand, unless the checkpoint understands that the materials were obtained under an SMTA through the multilateral system, it cannot know that this particular material is beyond the checkpoint's scope of application. To that end, it is in the interest of the user to provide evidence that she or he received the material under the SMTA from a CGIAR Center (or from any other provider in the multilateral system or Article 15 organization), thereby assuring the checkpoint that the material and its use, subject to the SMTA, does not fall under the regulatory framework under which the checkpoint is operating. In theory, once the user provides such evidence, the checkpoint should not require additional assurances or information. In this way, the two systems are complementary and mutually supportive.

Pursuant to the guidelines that the EU has adopted for the implementation of the Nagoya Protocol, plant genetic resources received under the SMTA by recipients in the EU from CGIAR Centers and other organizations that have signed Article 15 agreements are considered outside the scope of the regulation.[20] European states are in the early stages of putting systems in place to address this situation. Some are putting in place mechanisms for users to declare that they have received plant genetic resources under the SMTA, which suffices for the purposes of the checkpoint. The checkpoint will not be required to have them provide any additional information to demonstrate due diligence. This is a new area of practice, and most countries have still not defined the information that checkpoints may request about plant genetic resources obtained from the multilateral system. It is

impossible to know at this point what kinds of information/proof of due diligence checkpoints may request. With this uncertainty in mind, it is advised that all CGIAR Centers maintain records concerning the legal status of the different materials they hold and distribute under the SMTA (or other transfer instrument) in order to be able to provide additional information if necessary for the checkpoints. It would also be a good idea for the CGIAR Centers, if receiving materials under an instrument other than the SMTA, to include an undertaking from the provider that they have the legal right to provide the material, taking into account the Nagoya Protocol, the CBD and so on. While the Center may not be under any legally binding obligation to provide such additional information, and it will clearly add to the transactional burden for the CGIAR Centers to do so, recipients in countries where checkpoints require such information will appreciate the CGIAR Centers' assistance in this regard.

> *For recipients of materials from the CGIAR Centers under some other instrument (that is, not the SMTA), what 'status' does this instrument have if and when they need to interact with national checkpoints?*

As stated above, the CGIAR Centers may distribute Center-improved materials and 'in-trust' materials for direct use and for non-food/non-feed uses. However, they must not use the SMTA when doing so but, instead, use other instruments. National checkpoints will almost certainly not be familiar with the relevant background facts, so the CGIAR Center will need to be prepared to provide such information in a low-transaction, efficient manner. To this end, one option would be to include relevant background information in the recital of the legal instrument used so that a checkpoint can appreciate it is material from an international organization that has a legal right to hold and distribute the materials for the purposes set out in the agreements.

[20] EU ABS Guidelines, Section 5.2.1 states: 'There are various scenarios under which plant genetic resources for food and agriculture (PGRFA) can be obtained and utilized, depending on whether the country where genetic resources are accessed is a Party to the Nagoya Protocol and/or to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (24), and depending on the type of use. The overview below describes different situations and explains the applicability of the EU ABS Regulation in each of those situations: Out of the scope of the EU ABS Regulation

- PGRFA covered by Annex I of the ITPGRFA(25) included into its multilateral system and obtained from ITPGRFA Parties. Such material is covered by a specialised international instrument for access and benefit-sharing that is consistent with, and does not run counter to, the objectives of the Convention and the Nagoya Protocol (see Article 2(2) of the Regulation and p. 5 above).
- Any PGRFA received under a standard material transfer agreement (SMTA) from International Agricultural Research Centers such as those of the Consultative Group on International Agricultural Research or other international institutions that have signed agreements under Article 15 of the ITPGRFA (26). Such material is also covered by a specialised international instrument for access and benefit-sharing that is consistent with and does not run counter to, the objectives of the Convention and the Nagoya Protocol (see Article 2(2) of the Regulation and p. 5 above).'

CGIAR Centers' direct interaction with checkpoints

When might a CGIAR Center have direct interaction with, or be monitored by, a national checkpoint?

On occasion, as part of their strategy for ensuring the global public goods nature of their improved varieties and to promote their use within countries, the CGIAR Centers may utilize a plant genetic resource in such a way that brings them into direct contact with a national checkpoint. Examples of situations where this could occur include when a CGIAR Center:

- Seeks intellectual property rights over plant genetic resources and the related national authority is a designated checkpoint
- Seeks to include a new variety in a national variety registry pursuant to a national seed law and the relevant authority is a designated checkpoint
- Applies for funding from a national agency that has been designated as a checkpoint

In addition, CGIAR Centers may be required to demonstrate due diligence in other contexts, particularly when applying for funding to the EU Commission and possibly other donors and when submitting manuscripts for publication in scientific journals. Some journals require the authors to declare that the genetic resources that are the subject matter of the article have been obtained in accordance with national ABS legislation.

What kinds of information might the CGIAR Center have to provide?

Presumably, checkpoints will adopt approaches that are practical and do not create unreachable procedural requirements for genetic resource users. For example, it is unlikely that checkpoints will require users to show due diligence for all ancestors of an improved line or a released cultivar. In reality, it is likely that most of the materials used in the CGIAR breeding programs will not have been accessed under the Nagoya Protocol, either because they were accessed before the Nagoya Protocol came into force or because they came through the multilateral system or from other sources that are not regulated by the Nagoya Protocol. In those relatively rare cases where materials accessed from countries where the Nagoya Protocol applies, one practical approach would be to allow the CGIAR Centers to provide a statement confirming which materials were accessed and used after the entry into force of the Nagoya Protocol (October 2014) and that all other incorporated materials predate the entry into force of the Nagoya Protocol or are under the multilateral system. [21] Finally, for the remaining materials, which fall under the geographical and temporal scope of the Nagoya Protocol, the CGIAR Center could provide the requisite information.

[21] Should the CGIAR Centers be prepared to make statements about materials acquired after the CBD came into force but before the Nagoya Protocol came into force? Strictly speaking, the mechanisms that countries are obliged to put into place to monitor users' due diligence are meant to apply to Nagoya-related obligations (i.e., genetic resources acquired after the entry into force of the Nagoya Protocol), and everything else is outside the scope of that monitoring. On the other hand, in order to establish that materials were acquired before the Nagoya Protocol came into force, it will be useful for the CGIAR Centers to provide some details about when they received it, from whom and under what conditions or regulatory regime.

5. CGIAR genebanks and breeders acquiring, using and transferring traditional knowledge associated with genetic resources

Neither the CBD nor its Nagoya Protocol provide a definition of traditional knowledge. [22] Several definitions can be found in the literature and in voluntary codes of conduct developed by international organizations, but there is not a generally accepted definition. Usually, traditional knowledge is understood in a general sense (embracing the content of the knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with traditional knowledge) or in a narrow sense (referring to knowledge as such, particularly, the knowledge resulting from intellectual activity in a traditional context, including know-how, practices, skills and innovations). The Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization has traditionally adopted the narrower sense of traditional knowledge.[23]

The CGIAR Centers may acquire traditional knowledge through regular activities of their own scientists and consultants, by direct communication with traditional knowledge holders or through the research partners with whom CGIAR scientists work. The various kinds of research and development activities in which the CGIAR Centers could access and use traditional knowledge include:

- Gathering information on genetic resources from farmers from whom they are collecting
- Collecting information about farmers' practices associated with the management and uses of particular crops and varieties, including cultivation, seed selection, seed storage, culinary and medicinal uses, even when they are not collecting the associated resources
- Participating in plant variety selection and participatory plant breeding
- Collaborating with farming communities for on-farm and in situ conservation of genetic resources
- Collaborating with farming communities for the establishment and management of community seed banks
- Organizing, and participating in, seed fairs
- Preparing audio/visual recordings and publications pertaining to indigenous peoples' and local communities' agricultural practices and medicinal uses of plants and animals.

[22] CBD, Article 8(j) refers to 'knowledge … of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.' This is the citation used in the recital to the Nagoya Protocol.

[23] Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore, *List and Brief Technical Explanation of Various Forms in Which Traditional Knowledge May Be Found* (Secretariat of the Seventeenth Session of the Intergovernmental Committee, Geneva, 6–10 December 2010).

What are the CGIAR Centers' obligations generally under the CBD and, more recently, the Nagoya Protocol when seeking to access and use traditional knowledge associated with genetic resources?

Article 7 of the Nagoya Protocol requests the parties to take measures in accordance with domestic law and, as appropriate, to ensure that traditional knowledge associated with genetic resources that is held by indigenous peoples and local communities is accessed with PIC or the approval and involvement of these indigenous and local communities and that MATs have been established. According to Article 5.5 of the Nagoya Protocol, the parties commit to take measures 'in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge.' And Article 12 states:

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.
2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.
3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

    (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

    (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

    (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

Based on these three articles, the CGIAR Centers, working in countries where the Nagoya Protocol provisions on traditional knowledge have been implemented, can expect to be requested to get PIC from the farmers who share their traditional knowledge, to agree on MATs with them and to share the benefits arising from the use of traditional knowledge with the traditional knowledge providers. It may also be that community protocols have been established with which the CGIAR Centers will need to comply. It is also possible that the customary laws will apply.

Both the CBD and the Nagoya Protocol are agreements between states; they create rights and obligations for countries that are parties to them, and they are not of themselves binding upon the CGIAR Centers. Thus, as stated in Section 1, the concrete legal obligations for the Centers come from the national laws implementing these agreements.

How can the CGIAR Centers ascertain their specific obligations with respect to traditional knowledge and the Nagoya Protocol in particular countries?

Under the Nagoya Protocol, countries are required to make available information to the ABS ClearingHouse on relevant national legislation on ABS. This information will not always be up to date and, in many cases, may be incomplete due to the wide body of overlapping laws, policies and regulations associated with traditional knowledge. This is particularly true for the customary laws of indigenous peoples and local communities, which may be held only in oral form. To find out more about the obligations concerning access to traditional knowledge, the CGIAR Centers should make contact with the national focal points and, if necessary or appropriate, with the national and/or regional experts on ABS, the relevant indigenous and local community representative organizations and/or the NGOs working closely with these communities.

What if there is no national law implementing the Nagoya Protocol, or there is one, but it does not establish standards for accessing traditional knowledge?

In the absence of national law regulating access to traditional knowledge, the CGIAR Centers do not have any legal obligation under the Nagoya Protocol. Of course, there may be other laws in the country that establish standards, procedures and/or prohibitions with respect to accessing and using traditional knowledge. These could be laws put into place to implement other relevant international conventions or declarations such as the UN Declaration on the Rights of Indigenous Peoples and the Convention Concerning Indigenous and Tribal Peoples in Independent Countries, which were adopted under the auspices of the International Labour Organization, wherein the rights of indigenous peoples and local communities with respect to natural resources, and genetic resources, in particular, are recognized in various levels of particularity.[24]

[24] UN Declaration on the Rights of Indigenous Peoples, 12 September 2007, UN Doc. A/61/L.67/Annex (2007), Article 26 recognizes indigenous peoples' rights over their resources in general. Article 31 states that 'Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.' Article 32 establishes that '[s]tates shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free and informed consent prior to the approval of any project affecting their lands or territories and other resources, particularly in connection with the development, utilization or exploitation of mineral, water or other resources.' ILO Convention no. 169 Concerning Indigenous and Tribal Peoples in Independent Countries, 27 June 1989, 28 ILM 1382 (1989), Article 15 states that the rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded, and that these rights include the right to participate in the use, management and conservation of these resources.
25 CGIAR Principles on the Management of Intellectual Assets, 7 March 2012, http://hdl.handle.net/10947/4486 (accessed 18 December 2017).

Or there may be customary laws of indigenous peoples and local communities themselves that are relevant. In some countries, national laws recognize or create space for the operation of such customary laws. In other countries, these laws are not formally recognized, but the indigenous people or local communities concerned may nonetheless insist that the CGIAR Centers recognize them and make their ABS arrangements accordingly. Of course, these protocols will have to be consistent with the national laws of the country concerned. In situations where there appears to be a conflict between the two legal systems, the CGIAR Centers should try to work with both the local communities and competent national authorities for a mutually satisfactory process and agreement. Ultimately, if this is not possible, the Center may need to discontinue efforts to access the genetic resources or traditional knowledge concerned.

Furthermore, in the absence of any concrete obligations defined by national laws (and/or customary laws), as part of its overall research ethics, CGIAR is committed to operate with respect to internationally accepted principles and standards in relation to using traditional knowledge related to genetic resources and, more generally, working with indigenous peoples and local communities. These standards are generally established in the international human rights instruments referred to above as well as in the Nagoya Protocol, the CBD and the ITPGRFA. They are also established in the research and ethics protocols that have been developed by research communities, including CGIAR.

This commitment by CGIAR to observe international principles and standards has been reflected in Article 3.2 of the CGIAR Principles on the Management of Intellectual Assets, which provide that 'the CGIAR seeks to be respectful of national and international efforts to protect and promote farmers' rights as envisaged by the Treaty and support the development of appropriate policies and procedures for their recognition and promotion.' 25 With respect to situations where concrete legal obligations are not in force in certain countries, the Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets states that the CGIAR Centers should, when appropriate:

> When accessing PGRFA and/or associated traditional knowledge in the absence of access and benefit-sharing laws, ensuring that the prior informed consent of farmers providing them has been given. This implies taking into account community protocols, if any, and proactively engaging the farmers to ensure that they understand the proposed uses of the PGRFA and/or the knowledge collected. This can be done with or through partners in the national agricultural research systems or other organizations with whom work is being carried out and, where possible, drafting written agreements that reflect their prior informed consent and mutually agreed terms. [26]

[26] Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets, 14 June 2013, https://cgspace.cgiar.org/bitstream/handle/10947/4487/Implementation%20Guidelines%20for%20the%20CGIAR%20IA%20Principles.pdf?sequence=1 (accessed 18 December 2017).

The Guidelines include other practical actions that the CGIAR Centers could take, where appropriate, including:

- Proactively engaging farmers to ensure that they understand the proposed uses of the PGRFA and the knowledge collected
- Ensuring that research results are shared with the farmers from whom the PGRFA or associated information was accessed
- Ensuring that publications referring to traditional knowledge give all appropriate credits to the holders/providers of such knowledge and disclose the source of such knowledge
- Involving farmers in research and development projects.

1. These very same standards are included in a number of research ethics guidelines.[27] Perhaps the one that is most immediately relevant is the Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity, which was approved by the COP to the CBD in 2010.[28] It includes recommendations on ethical principles to be observed and methodological aspects to be taken into consideration.[29] Since the Code of Conduct was inspired by the CBD, was a result of the CBD's programme of work on Article 8(j) and was approved by the CBD's COP, it represents a reliable reference for the CGIAR Centers to guide their actions in the absence of applicable national law. In addition, the programme of work on Article 8(j) led to the development and adoption (in COP-13 in 2016) of voluntary guidelines for the development of mechanisms to ensure the PIC of indigenous peoples and local communities and other aspects involved in ABS.[30] While these guidelines do not apply to traditional knowledge associated with genetic resources under the Nagoya Protocol (as stated in paragraph 5 of the guidelines) Centers can use then as a reference when adopting measures for ensuring the PIC and agreeing on MATs with farmers and other local users in countries where the Nagoya Protocol is not implemented. Another useful reference is the FAO Manual for Project Practitioners entitled Free Prior and Informed Consent: An indigenous peoples' right and a good practice for local communities. [31]

[27] Some of these guidelines can be found on *Access and Benefit Sharing Clearing House: CBD,* https://absch.cbd.int/search/referenceRecords?schema=modelContractualClause (accessed 18 December 2017).
[28] Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity (2011), https://www.cbd.int/doc/publications/ethicalconduct-brochure-en.pdf (accessed 18 December 2017).
29 The code of conduct provisions on ethical principles refer to: respect for existing settlements, intellectual property, non-discrimination, transparency/full disclosure, prior informed consent and/or approval and involvement, inter-cultural respect, safeguarding collective and individual ownership, fair and equitable sharing of benefits, protection, precautionary approach, recognition of sacred sites, access to traditional resources, not being arbitrarily removed and relocated, traditional guardianship/custodianship, recognition of indigenous and local community social structures, restitution and/or compensation, repatriation of genetic resources and traditional knowledge, peaceful relations and supporting research initiatives of indigenous and local communities
[30] Mo'otz kuxtal voluntary guidelines. Available at https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-18-en.pdf
[31] FAO. 2016. *Free Prior and Informed Consent: An indigenous peoples' right and a good practice for local communities. Manual for Project Practitioners.* FAO, Rome. Available at: http://www.fao.org/documents/card/en/c/5202ca4e-e27e-4afa-84e2-b08f8181e8c9/ (last accessed 16 January 2018)

What practical measures can the CGIAR Centers take?

Based on all the above information, there are three basic measures that the CGIAR Centers should take to ensure that they are operating in line with the internationally recognized principles of those countries where ABS obligations are not defined by the existing legal regimes:

- Obtaining the approval of the providers of traditional knowledge
- Agreeing with them on the conditions that apply to the use of that knowledge
- Sharing the benefits, including research and development results, with the providers of traditional knowledge.

The CGIAR Centers can also take these three measures into those countries where there are national laws in place and where the adoption of these measures by the CGIAR Centers will not contradict the existing laws

The CGIAR Centers will have to approach these tasks in a practical and realistic way, depending on the history of collaboration with the communities providing the traditional knowledge and the context in which the exchange of information between scientists and farmers has taken place. The efforts by the CGIAR Centers to get the approval of the providers of traditional knowledge and to agree with them on possible conditions limiting the use of traditional knowledge should concentrate on research activities where scientists are obtaining information from farmers and farmers' communities within a formal research context, such as household surveys, focus group discussions, roundtables, workshops and so on.

Before farmers start sharing information with scientists, the scientists should follow a protocol to ensure that the farmers are fully informed and understand (1) what the scientists propose to do with the information they will receive; (2) what benefits the scientists are proposing to share and (3) that the famer can refuse to share his or her knowledge or do so subject to conditions suggested by the farmers. For the purposes of demonstrating that internationally recognized principles and standards have been followed, the process of obtaining the farmers' approval should result, ideally, in a document signed by the providers of the information. If obtaining the providers' signature is not viable or appropriate, scientists' written account of the process may be enough to show due diligence in the absence of procedures defined or required by national law.

Similarly, the CGIAR Centers may need to take into consideration the practical challenges involved in sharing the results of the CGIAR Centers' research and development activities with the providers of traditional knowledge and take measures to address those challenges. For example, if financial limitations do not allow the CGIAR Centers' scientists to organize feedback workshops and roundtables with farming communities, give them seeds of improved lines or distribute farmer-friendly publications at the end of a research project where the knowledge of those farmers has been used, the CGIAR Centers can explore ways for their national partners to facilitate, or take care of, these actions and/or adopt less resource-consuming, but still effective, measures to compensate farming communities.

Does the Nagoya Protocol apply the same monitoring measures to the utilization of genetic resources and traditional knowledge related to genetic resources?

The Nagoya Protocol treats genetic resources and associated traditional knowledge differently. According to Article 6 of the Protocol, Contracting Parties that regulate access to genetic resources are obliged to provide for a clear and transparent written decision by a competent national authority. If the decision is to grant access to the resources, the Contracting Parties must issue a permit as evidence of PIC and MATs. In the case of access to traditional knowledge, the Nagoya Protocol does not require countries to issue any official permit. However, some countries do require and issue permits for access to traditional knowledge.

Article 17 of the Nagoya Protocol on 'monitoring the utilization of genetic resources' limits the monitoring mechanisms of the Protocol to genetic resources. This means that internationally recognized certificates of compliance do not have to be issued to users of traditional knowledge in order to provide proof that they have obtained such knowledge in accordance with the domestic laws. It also means that when establishing national checkpoints countries do not have to include the utilization of traditional knowledge in the scope of their functions (but they can, if they wish to do so).

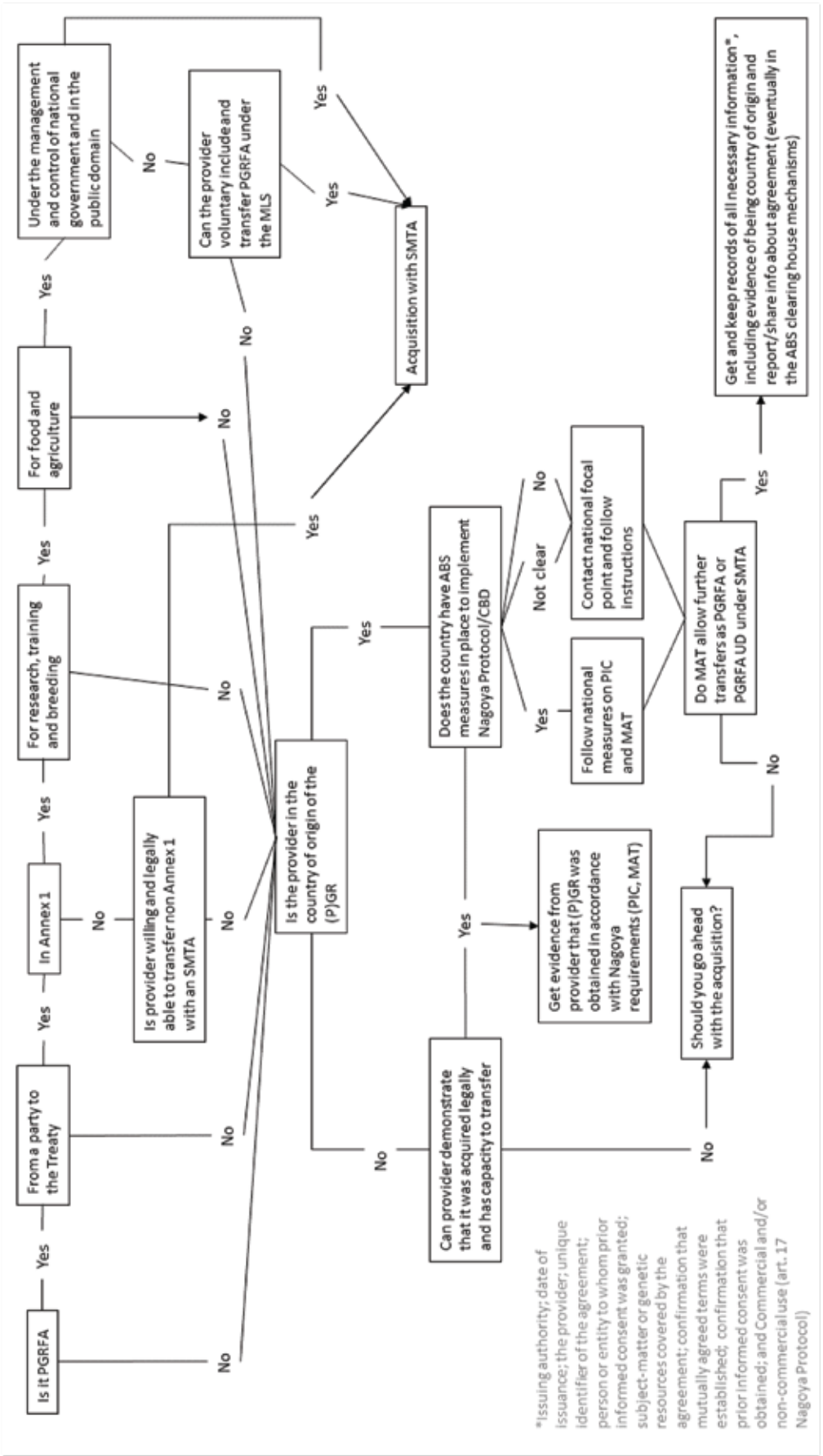
Article 16 of the Nagoya Protocol on 'compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources' does not require countries to put into place any particular monitoring mechanism but simply requires them to take measures 'to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities, as required by domestic access and benefit-sharing laws or regulatory requirements of the other Party where such indigenous and local communities are located.' Countries are therefore free to decide whether or not to establish checkpoints for monitoring the use of traditional knowledge. They have no such flexibility with respect to genetic resources, for which checkpoints must be established. If they wish, countries can apply similar, or the same, monitoring measures to both genetic resources and traditional knowledge, therefore requesting designated checkpoints to collect information on the origin and use of traditional knowledge, but, according to the Nagoya Protocol, they are not obliged to do so. The modus operandi of these possible checkpoints, such as patent and plant variety protection offices and funding agencies, will probably reflect this differentiated treatment in many countries that have ratified the Nagoya Protocol but not necessarily in all of them.[32]

What are the CGIAR Centers' obligations when transferring traditional knowledge associated with genetic resources?

The CGIAR Centers are obliged to respect the terms and conditions under which they have received the traditional knowledge. If the traditional knowledge accessed by a CGIAR Center is subject to restrictions, then it cannot be included in the information to which links are provided in the SMTA. Arguably, the situation is different if the genetic resources are transferred under the SMTA as PGRFA under development. In this case, there may be sufficient flexibility for the Center to pass on restrictions from the original traditional knowledge provider over the subsequent recipients' use of the related traditional knowledge. Of course, the original traditional knowledge provider would need to have agreed for the CGIAR Center to pass on the traditional knowledge in this way as one of the MATs.

[32] For example, Decision 486 of the Comunidad Andina de Naciones requests patent offices of Andean countries to collect information about the origin and circumstances of access to both genetic resources and traditional knowledge used in inventions described in patent applications and states that patent applications should be refused if the applicant does not present an appropriate access contract or the respective license or authorization for the use of traditional knowledge. However, this is a pre-Nagoya Protocol measure. In Peru, the implementing legislation of the Agreement on Commercial Promotion between Peru and the United States (Law no. 29316, 14 January 2007, in the Official Peruvian Diary) has amended the last requirement; a sanction exists to penalize the applicant if the requested documentation is not presented, but this is not a cause for annulment or invalidity of the patent application or the approved patent.

Annex 1: Decision-making diagram for CGIAR Centers acquiring PGRFA



Annex 2: Decision-making diagram for CGIAR Centers distributing PGRFA