ABS compliance in seven steps: guidance for organizations collecting, transferring, holding or using Genetic Resources

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INTRODUCTION TO BOOKLET

The Nagoya Protocol of the Convention on Biological Diversity (CBD) will impact users of Genetic Resources and Traditional Knowledge associated with Genetic Resources across many sectors: agriculture and food science, pharmaceutical and cosmetics, microbiology, marine biology, traditional medicine, biotech, and non-commercial research. "Genetic resources" is defined by the CBD as "genetic material of actual or potential value" (see Glossary in Annex 3 for definitions), and may be sourced from any organism: animals, plants, fungi, microbes or viruses (although human tissue is excluded). Users will need to develop tools and strategies to aid compliance with national legislation on access and benefit sharing (ABS). Building on their experience and lessons learned in developing toolkits for the non-commercial research, the authors suggest a checklist methodology for other sectors that focuses on common themes and key issues.

A seven step guide for developing a sectoral toolkit to aid compliance with the ABS provisions of the CBD

The Guide is set out as a series of seven steps (Fig. 1), each posing key questions to consider and with one or more worksheet to guide you through the process and help you cover all of the likely issues. Each of these is in the form of a checklist, building on your answers in the previous worksheet to enable you to develop systems that match your needs and fit with your workflows. The steps are as follows:

Step one: This is an initial audit of activities undertaken by your organization that might mean you have to manage ABS requirements. Having identified these, you will be able to consider in subsequent steps the legal context of these liabilities and to the means of managing compliance with these.

Step two: This enables you to review whether your work is likely to fall under the Nagoya Protocol, and what other legal frameworks covering access to and use of biological material potentially apply to your activities. It does not extend into the very many laws and agreements that cover details of handling biological and genetic resources (e.g. packaging, biosecurity, laboratory practices etc. Nor does it mention the Convention on Trade in Endangered Species (CITES), although this may apply in some cases. Steps focus specifically on tools to comply with ABS and the Nagoya Protocol.

Step three: Having broadly identified the work likely to incur ABS responsibilities this takes you further into your activities and workflows, to consider how you need each element to work to manage compliance. At this stage you are not developing tools, but simply developing a clear understanding of what you need such tools to achieve. This is the 'requirements' stage.

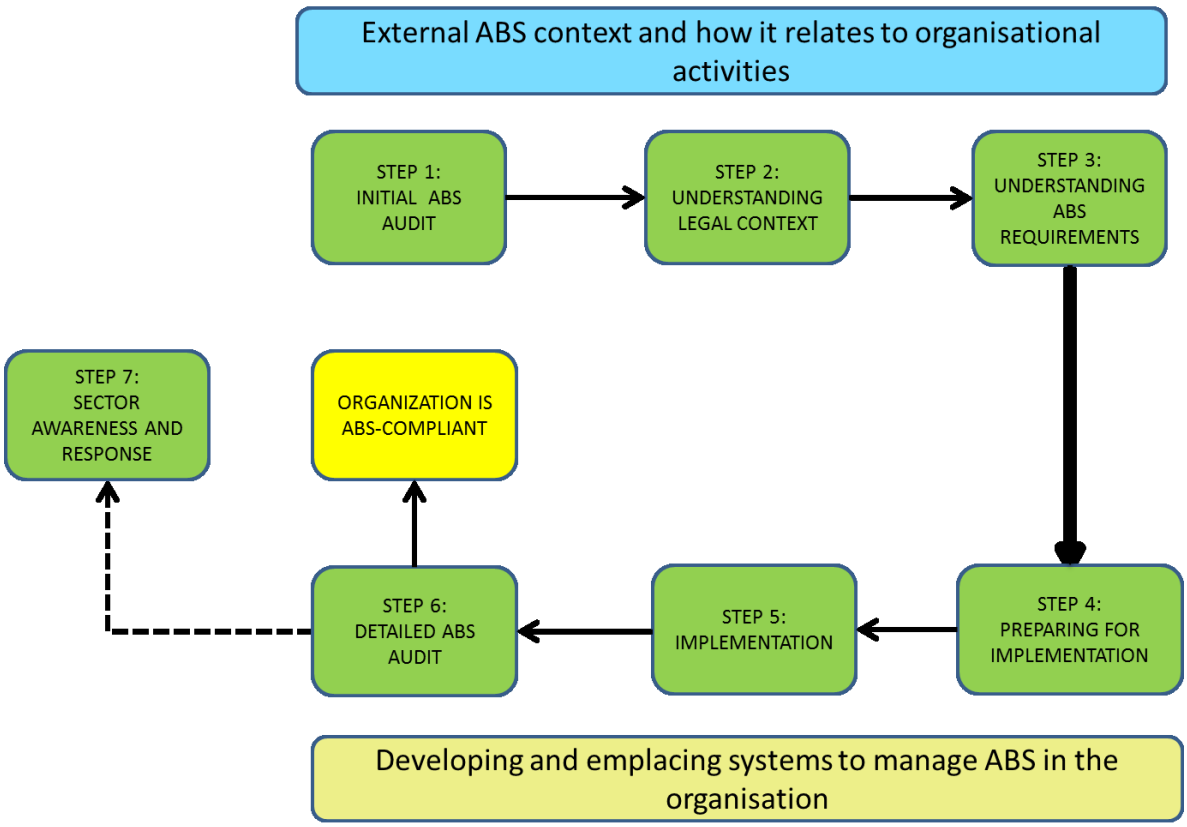


Fig. 1. Seven steps to ABS compliance. An outline of the process set out in this document. The outcome of the process should be ABS compliance of the organization, but an optional step 7 leads to wider sectorial best practice.

Step four: This takes you through the more detailed development of policies and procedures that you will need to have in place based on your identified requirements. The step does not prescribe exactly what you must do, since solutions have to match the requirements of the organization and other sectorial practices, but the information provided should enable you to develop them effectively.

Step five: Policies and Procedures will only be effective if personnel responsible for managing and implementing them have been identified, these individuals understand why the measures are in place, and are trained appropriately. This step takes you through the awareness raising and training process.

Step six: Once the systems are in place it will be helpful to test their efficacy in practice. This step takes you through that process. It will also be useful for periodic ABS audits in future to monitor performance. If any problems arise, they may be addressed by returning to the appropriate earlier step in the process.

Step seven: This optional step helps you share the policies and procedures with others in your sector, and build sectorial best practices and standards of operation.

Relevant resources are referenced at the end of each Step. A larger selection of references and other resources are provided in Annex 1.

The terminology applied to ABS can be confusing, and in some cases meanings are unclear even to experts. The Glossary in Annex 3 will provide some help. Relevant Acronyms are given in Annex 2.

In much of the document we refer to Genetic Resources (GR). In most if not all cases the statement will also apply to Traditional Knowledge associated with Genetic Resources (aTK), even if this is not stated. The statements should also be interpreted to apply to derivatives (see glossary).

Introduction to the ABS Regime

Prior to starting the process, the context of ABS and the Nagoya Protocol will be reviewed. The Convention on Biological Diversity came into force on 29 December 1993 and established the framework for a new more equitable approach to acquiring and using genetic resources. The Treaty's negotiators had been asked to take account of the need to share the costs and benefits of conservation more fairly between developed and developing countries. By recognising that states have sovereign rights over their resources, and requesting that users share benefits from the use of that biodiversity, the CBD created a mechanism whereby additional resources could be made available to support conservation and sustainable use. It also addressed a growing concern that the use of patents in biotechnology failed to adequately recognise or compensate the role of provider countries and indigenous and local communities' in the ownership and conservation of the resources used.

The provisions that establish the 'access and benefit sharing regime' of the CBD are laid out in Article 15 and set out the principle that access to genetic resources should be with the prior informed consent of the provider, on mutually agreed terms, and be granted in return for the fair and equitable sharing of benefits derived from their use. The idea is that if genetic resources are properly valued then this will give both an incentive and a means to their conservation. Following the CBD coming into force, many biodiverse countries developed new national legislation governing how genetic resources should be accessed and used. In many cases this continued to be largely through a permitting system, sometimes focussed on protected areas or species. In other cases it was through specific ABS legislation, or an agreement established with the relevant authority. As agreed by the CBD, Parties established national focal points to provide information, and competent authorities responsible for granting access. With over 190 Parties, access procedures varied widely, and calls for clarity and consistency, as well as a lack of any compliance mechanism to give providers security that terms of access would be followed, led to calls for, and the negotiation of, a legally binding ABS regime. In 2010 Parties to the CBD adopted what is now the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing (Full text in Annex 4 below). The Protocol gives more clarity to the access provisions Parties may implement, outlines how benefits should be shared from the 'utilization' of genetic resources, and, crucially, states that Parties must implement compliance mechanisms, such as checkpoints, to ensure that genetic resources are used legally, and institute penalties if they are not (see Table of Key Points of the Nagoya Protocol below).

Essentially, what this means is that users of genetic resources are working in a very different environment than twenty years ago. Many countries are working on or have introduced legislation governing how genetic resources can be legally accessed and, at the national level (for instance in all Member States of the EU), there are now measures in place to

ensure that these laws have been followed, and penalties if they have not. Organizations working with genetic resources, whether commercial or non-commercial in nature, will need to take steps to manage their procedures and workflows to ensure that they are accessing, using and supplying genetic resources legally, and sharing benefits fairly, or risk significant legal and reputational damage.

The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing – Key Points
Objective: The Nagoya Protocol's objective is the fair and equitable sharing of the benefits arising from the utilization of genetic resources (Article 1)
Scope: The Protocol covers benefit sharing from the utilization of genetic resources (and associated traditional knowledge) within the scope of Article 15 of the CBD. It does not apply to human genetic resources, commodities, genetic resources in 'areas beyond national jurisdiction' (such as the high seas). It is intended to be implemented in a *mutually supportive* manner with other relevant specialised ABS international instruments that are supportive of the CBD such as the ITPGRFA, and therefore may not apply to certain genetic resources in particular circumstances (Article 3). Subject to the legal interpretation of providing and user countries, the Protocol applies to GR accessed since it came into force (12 October 2014) and only to Parties to the Protocol. See Worksheet 2.1.
Access: The Protocol allows Parties to decide whether or not to require prior informed consent for access to genetic resources in their national boundaries. If Parties to the Protocol *do* decide to require consent for access, they must follow the detailed access standards laid out in Article 6, and set up ABS legislation that: • provides legal certainty and transparency • is time- and cost-efficient • provides information on how to apply for prior informed consent • sets out criteria for obtaining consent from indigenous and local communities • provides evidence (a permit or equivalent) of the decision to grant prior informed consent and the establishment of mutually-agreed terms (Article 6)
Benefit –Sharing: Under the Nagoya Protocol, benefits arising from the utilization of genetic resources *as well as subsequent applications and commercialization* shall be shared: • fairly and equitably with the provider Party (the country where plants are accessed) • upon mutually agreed terms • and with indigenous and local communities where appropriate Benefits may include monetary and non-monetary benefits (a list of some possible benefits is included in an Annex to the NP) (Article 5)
Compliance: Parties to the Protocol *must* introduce measures at a national level to ensure genetic resources and associated traditional knowledge utilized within their jurisdiction have been legally accessed. They also must introduce measures that address situations of non-compliance and monitor utilization through designating one or more checkpoints to collect or receive information on PIC, MAT, the source of the genetic resources and/or utilization. (Articles 15, 16, 17)
Traditional Knowledge associated with genetic resources is to be accessed with the prior and informed consent or approval and involvement of Indigenous and Local Communities (ILCs) that hold associated Traditional Knowledge (TK) (Articles 7 and 16)
Tools and Mechanisms to support implementation of the Protocol include: model contractual clauses (Article 19), codes of conduct, guidelines and best practices and/or standards (Article 20), awareness raising (Article 21), capacity building (Article 22)

STEP ONE: UNDERTAKE AN INITIAL ABS AUDIT

What is happening in your organization that might mean you have to manage ABS issues? What are you already doing?

Rationale

If your institution or company acquires, uses or supplies genetic resources (GR) it is likely to fall under ABS legislation or regulations in the country where the GR come from, the country where it is based, and countries to where it supplies genetic resources or their products. This is particularly so if these countries are Parties to the Nagoya Protocol. There are likely to be persistent legal responsibilities arising from its access to GR in the providing country, including obligations to share 'benefits' from any use of the GR. These obligations should be passed on to any future user (for instance for subsequent placing on the market), and as a supplier this will influence your management of those resources, as well as the information you acquire about them and supply with them.

STEP ONE outlines an INITIAL AUDIT to establish whether your organization does undertake any activities that bring it within the scope of regional or national ABS Regulations (this and other relevant legislation is addressed in Step 2). It also allows you to assess whether there are policies and procedures already in place, and where there may be gaps.

Handling GR may not be the major part of an organization's activities; for example a university may have only a few staff or students that operate in this field. However, if your organization accesses, uses or supplies GR in any way you will be liable for management of the legal responsibilities this work entails.

The initial Audit may be used at scheduled intervals to review against changing activities of the organization and external contexts.

Key Questions and information needed

Use the STEP ONE worksheet to frame your questions and record your results. Questions follow a generalised workflow (see diagram below in Figure 2) from access to the GR (or aTK) through to use or utilization, supply to third parties, commercialization of the results, and benefit-sharing. You or your organization may be involved in some, part or all of this process. The worksheet asks if you have procedures already in place to manage elements of the workflow. If you do, identify them for reference in Step 3.

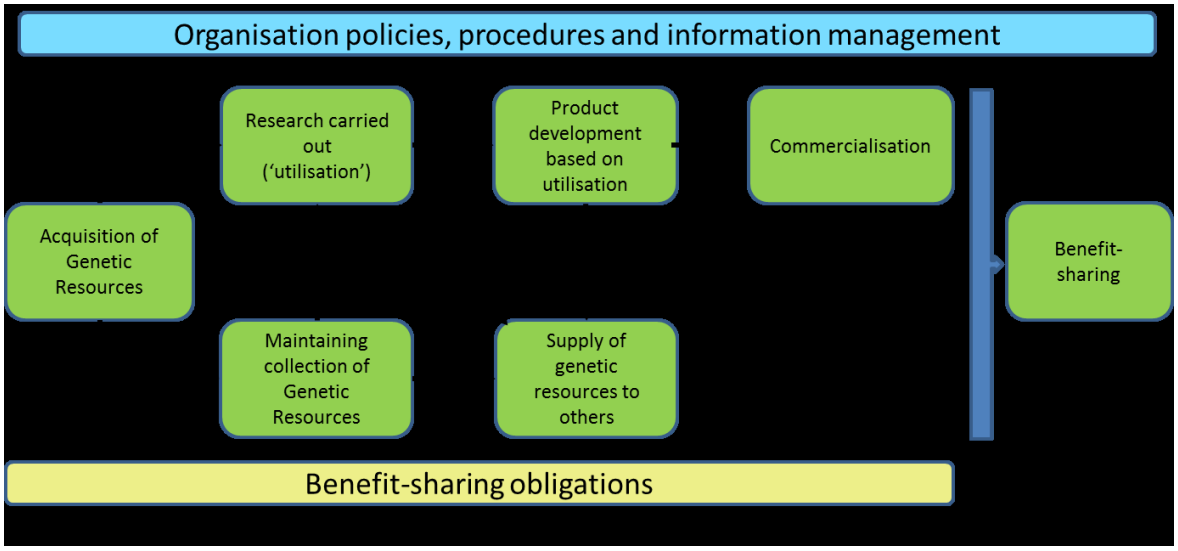


Fig. 2. Outline workflow of acquisition and use of genetic resources, which may be entirely within one organization or extend across several. Reporting requirements to national regulators are not included since they might be at different stages, according to the regulations of the country where utilization is taking place.

1.1. ***Acquisition of genetic resources and /or traditional knowledge associated with genetic resources***

Acquisition of GR and aTK may be directly from the country of origin, collected *in situ* or supplied by in-country third parties, or through sale, donation or exchange. Alternatively you may get new resources from another company or institution in your own or a third country. How GR are acquired, and under what conditions, will determine what ABS information or agreements need to be in place, and the nature of the legal responsibilities of the organization. An important part of acquisition is understanding and being able to manage these conditions.

1.2. ***Maintaining collections of genetic resources***

The collections you hold could range from living collections like plants, animals or seeds, herbarium, DNA and tissue cultures, bacteria or other microbes, preserved animals or other organisms, chemical extracts, traditional knowledge or artefacts. All of these other than traditional knowledge and artefacts are covered in this document by the term 'genetic resources'. For ABS / Nagoya Protocol purposes human tissues are not within scope, although pathogens in those tissues might be. As will be seen in Step 2, different collections may fall under the scope of different regulations.

Collections that you hold may have been acquired from the providing country or other third party supplier under particular terms and conditions. These will be set out in the national legislation of the providing country, in collecting permits, other bilateral contracts, or a combination of the three. These terms and conditions need to be kept linked with the genetic resource, abided by, and passed on to third parties to whom you supply the GR. There may be requirements under national ABS compliance legislation to obtain certain information regarding the provenance of the specimens when they are obtained, and to retain that.

1.3. ***Supply of Genetic Resources, extracts or derivatives to third parties***

There are often restrictions on transmission to third parties under the original terms of access from the provider. If the GR were accessed under conditions that prohibited certain uses (e.g. not to be used for commercial purposes), it may not be possible to supply them to some recipients without seeking new Prior Informed Consent with the providing country. When GR or extracts are passed on to another company or organization you will need to ensure that you also pass on all relevant information. Third party transfer will be possible only with clear conditions. This will be explored further in Step 2 and tools to assist the process discussed in Step 5.

1.4. ***Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)***

Research and development ('utilization') may trigger access agreements requiring reporting to the providing country and benefit-sharing. Use of GR that does not constitute 'utilization' can still be subject to benefit sharing obligations under the access or other bilateral agreements. Moreover, some types of research may have been prohibited under these agreements. Finally, records of the utilization may have to be retained under national legislation of the country where utilization is carried out to fulfil checkpoint and reporting requirements under national compliance measures. For all these reasons it is important to have effectively-managed institutional records of acquisition of the GR and the relevant agreements.

1.5. ***Non-commercial or commercial research involving traditional knowledge associated with genetic resources***

Organizations researching and using involving traditional knowledge associated with genetic resources need to be particularly careful to ensure that they have followed national, local and international procedures to obtain prior informed consent from all relevant stakeholders for the work they wish to do.

1.6. ***Research involving utilisation of GR on behalf of others***

Utilizing GR on behalf of other organizations or individuals will require clarity on which organization has reporting responsibilities under user-country legislation. You will also need to know that you are permitted to carry out the research under the access agreements covering the GR, and whether you are liable for any benefit-sharing.

1.7. ***Researchers not employed by your organization carry out utilisation of GR on your premises***

The Nagoya Protocol states that the Party having jurisdiction where utilization takes place should take action to ensure the GR have been accessed appropriately and address non-compliance (NP Articles 16 and 16). This suggests that you will take responsibility for any utilization on your premises, whether or not it is carried out by your staff.

1.8. ***Commercialization or sale to others the results of your research on genetic resources***

Commercial activity involving the utilization of GR or derivatives in natural product development may trigger reporting responsibilities under national or regional legislation (for instance under the EU Regulations) as well as benefit sharing obligations under access agreements; it may be specifically allowed or excluded under these agreements.

1.9. ***Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced***

Access legislation, permits or other bilateral contracts will outline how monetary or non-monetary benefits are shared with the providing country and relevant stakeholders. Benefit sharing may take place at any point in the process from access to utilization to commercialization, depending on the agreement. It is important that this benefit-sharing is recorded and managed, both to ensure that contractual agreements are being met and that third parties subsequently involved are aware of further requirements to share benefits down the workflow chain of use. This is discussed further in Section 3 below.

1.10. ***Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge***

You will need policies and procedures in place to ensure that both the organization and its staff are aware of their responsibilities and equipped to meet them. They may be combined as an overall ABS policy or ABS aspects placed wherever a policy area requires them. The level of detail may also vary, with some organizations making very general policy statements and detail being provided in the procedural documentation. At this stage it is important to know what is already in place, so it can be reviewed later in the process.

You may already have some policies and procedures which manage some or all of your ABS needs. There may also be best practices, codes of conduct or guidelines on ABS available for your sector, which will assist developing your own policy in in subsequent steps.

Guidance Notes

- Some organizations, like universities, cover a very wide range of activities only a minority of which involve ABS. Because ABS issues carry contractual and legal responsibilities for both the individual researcher and the organization it is important for the organization to develop systems to manage ABS.
- Be aware that some national legislation may use different definitions to those given in the Nagoya Protocol. As an example, the EU and its Member States use the same definitions as the Nagoya Protocol, with some uncertainty about the use of the term ‘Providing Country’. African Model Law differs in its definition of utilization.
- ABS agreements and obligations tend to be established or negotiated at the beginning of the supply chain, at the point when the GR are accessed from the providing country or otherwise acquired. Even if this is a comparatively small part of the organization’s workflow (compared, say, to the product development phase) the obligations persist and may be triggered by events at the end of the process, such as commercialization. Thus in Fig. 3, a workflow for identification, isolation and development of natural oils, ABS agreements made at the point of bioprospecting potentially give requirements to be met in all of the other activities in the workflow.

- For this step it will be helpful to develop a flow chart of how genetic resources enter your organization, how they are used, and how they exit, together with where ABS decisions need to be made, and the flow of information that needs to be maintained. You can use the model in Fig. 2 as a starting point, or use a more detailed approach as in Figs 4-6. Note that the policies and procedures you develop will need to guide staff and manage risk wherever an ABS decision is required.

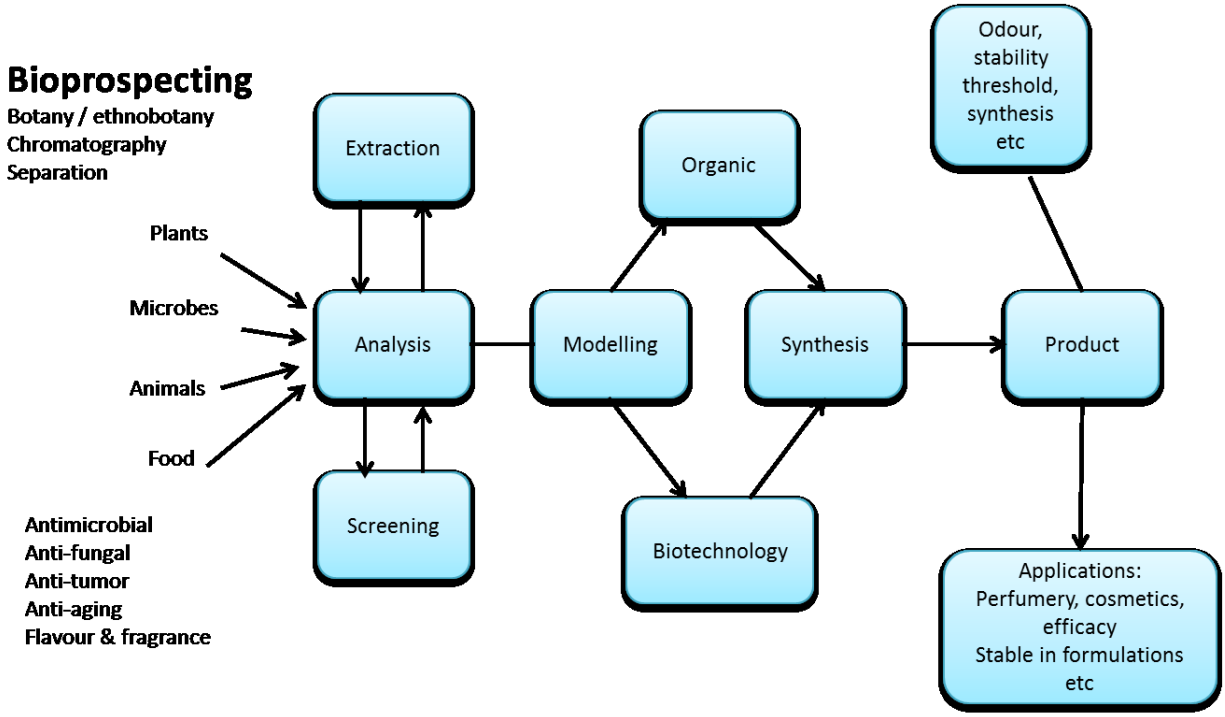


Fig. 3. Supply and Value chain example for the discovery and commercialization of Natural Aromatic Molecules, indicating the number of steps (and potential actors) between accessing a genetic resource (on the left) and marketing a product which might trigger benefit-sharing or reporting under user-country legislation (on the right). (diagram after Murray Hunter, Presentation on *Essential Oil Development* http://www.slideshare.net/Murray58/essential-oils-presentation)

STEP TWO: UNDERSTANDING LEGAL FRAMEWORKS

What ABS-related laws and regulations might affect the work of your organization?

Rationale

Countries may have national legislation on Access (obtaining genetic resources within their borders), and regulations on utilization (the research and development carried out within their jurisdiction on GR sourced from other countries, in particular Parties to the Nagoya Protocol). Even if a country from which a GR was sourced is not a Party to the Nagoya Protocol, or doesn't yet have specific legislation, the original access may have required granting of Prior Informed Consent (PIC) and agreement of Mutually Agreed Terms (MAT), or have been subject to contractual arrangements that govern the use of GR and might be the basis of civil cases in court.

While the focus of this manual is on the Nagoya Protocol and Access and Benefit-Sharing many countries have other legislation that governs what species can be collected, where from, and how they might be used. Other national and international regulations may also apply, such as the International Treaty on Plant Genetic Resources for Agriculture (ITPGRFA), the Convention on Trade in Endangered Species (CITES), phytosanitary regulations, exporting and import requirements, and regulations on the transport of dangerous goods. In addition, some countries also have specific legislation on traditional knowledge and working with indigenous and local communities. Patent and IPR legislation is clearly also of relevance, as are legislation or regulation specifically related to particular user sectors. Key regulatory areas as they relate to ABS are indicated below; take advantage of the Audit to consider whether actions need to be taken regarding other relevant legislation.

There are two aspects to consider under this heading: the source of the genetic resources and how they are being used in the workflow of the organization.

Key Questions for Step 2

2.1. What are the ABS-related legal frameworks under which you work?

Worksheet 2.1 focusses on the Nagoya Protocol, but will allow you to determine what other legislation or regulatory frameworks may in principle apply.

Regulations in user countries on compliance with the Nagoya Protocol are unlikely to be in place unless the user country is itself a Party to the Protocol. EU Member States are required to implement the EU regulations on ABS irrespective of whether they are a Party to the Protocol or not, because the EU itself is. The USA is neither a Party to the CBD nor to the Nagoya Protocol, but does exercise legal requirements on importers of genetic resources under the Lacey Act, and users of genetic resources in the USA are still subject to the national laws of the providing country, and any bilateral agreement they have entered into. Countries that are Party to the Nagoya Protocol are likely apply ABS regulations both to researchers from outside the country and to nationals working within the country.

Having identified the important legislation and regulatory frameworks you should acquire copies where possible, since detailed requirements will allow you to highlight areas for action in worksheet 2.2. and in Steps 3-5.

2.2. At what points do these legal frameworks require a response from the organization in terms of policy and procedure?

Worksheet 2.2 provides more focus on applicable legislation and regulations, and builds on the understanding developed in completing Worksheets 1 and 2.1. Having identified which of the legislative elements apply in Worksheet 2.1., you should consider where there are likely to be requirements of the relevant legislations to different aspects of your activities.

Guidance Notes:
There are a variety of laws, agreements and regulations that may apply. An exhaustive list cannot be provided here, but the most important to consider are given on Table 1. Some indication of the most important likely conditions and relevance is given.

In addition to the external legal framework, your organization may have committed to, or wish to commit to, sectoral guidelines, standards or best practices. Such standards may have regulatory significance (for example the EU has a system of recognised Best Practices which may be used by Member State regulators to assess risk). It will be helpful to add any such standards on worksheet 2.2. to guide development of management requirements in Step 4. Some examples are given below under 'Resources' but this is by no means a complete list, and more are being developed by different sectors.

Resources
Examples of sectoral guidelines, standards and best practice

ABS Clearing House provides access to Codes of Conduct and guidelines within the Reference Records, under the heading Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards https://absch.cbd.int/search/reference-records/

Botanic Gardens Conservation International (BGCI), ABS Learning Modules for Botanic Gardens: https://www.bgci.org/policy/abs_learning/

Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change Factsheets on Implementing the Nagoya protocol, The Agricultural sector, Botanicals, The Cosmetics Sector, The Food and Beverage Sector, Industrial Biotechnology and The Pharmaceutical Industry. https://www.cbd.int/abs/policy-brief/default.shtml/

CBD Website provides links to a number of Codes of Conduct, guidelines and best practices at https://www.cbd.int/abs/instruments/default.shtml

The Principles and Common Policy Guidelines on ABS for Botanic Gardens https://www.bgci.org/policy/abs_principles/

Consortium of European Taxonomic Facilities (CETAF), 2015, CETAF Code Of Conduct & Best Practices For ABS (Access & Benefit-Sharing) http://cetaf.org/taxonomy/publications

Davis, K., 2008, A CBD manual for botanic gardens. Botanic Gardens Conservation International, Richmond, United Kingdom ISBN: 978-1-905164-29-5 http://www.bgci.org/files/cbd_manual.pdf

Global Genome Biodiversity Network (GGBN), 2015, Best Practice for Access and Benefit-Sharing. Also GGBN Code of Conduct http://wiki.ggbn.org/ggbn/Documents

International Plant Exchange Network (IPEN) Code of Conduct
https://www.bgci.org/files/ABS/IPEN/IPEN%20Code%20of%20Conduct.doc (more information about IPEN can be found at https://www.bgci.org/policy/ipen/

Union for Ethical Biotrade (UEBT), 2012, STD01 – Ethical BioTrade Standard 201 -04-11. http://ethicalbiotrade.org/dl/STD01_Ethical%20BioTrade%20Standard_2012.04.11_Eng.pdf

Agreement, law, regulation etc	Scope	Information available at:	Significance
Convention on Biological Diversity (CBD)	International, legally binding	https://www.cbd.int/	Article 15 sets out the ABS framework
Nagoya Protocol (NP)	International, legally binding	https://www.cbd.int/abs/	If providing and user country are Parties to the Protocol the providing country is likely to have access legislation and the user country is likely to have regulations governing compliance with the Protocol
International Treaty on Plant Genetic Resources for Agriculture (TPGRFA)	International	http://www.planttreaty.org/	Potential exemption from ABS regulations for some plant species in some countries for set uses (Annex 1 species used for food or agriculture). National legislation in the providing country should be checked.
International Convention for the Protection of New Varieties of Plants (UPOV)	International	http://www.upov.int/portal/index.html.en	In some cases there may be an exemption from regulation. Check with your national legislation and the legislation of the providing country.
UN Convention on Law of the Sea (UNCLOS)	International	http://www.un.org/Depts/los/index.htm	When marine genetic resources are found in areas beyond national jurisdiction or on the continental shelf.
Antarctic Treaty System	International	http://www.scar.org/antarctic-treaty-system	To be considered for marine and terrestrial genetic resources from the area south of 60° South Latitude.
World Intellectual Property Organization (WIPO)	International	http://www.wipo.int/portal/en/index.html	Addresses IP issues that may be associated with traditional knowledge. If necessary, discuss issues with relevant people in providing country.
EU Regulations	Regional,	http://tinyurl.com/jz2oo4q[1]	Apply to all EU Member States for user

[1] http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

Agreement, law, regulation etc	Scope	Information available at:	Significance
	legally binding		compliance, and are implemented through national legislation. Access regulations are left to Member States to decide individually.
African Model Law	Regional, guidelines	https://www.cbd.int/doc/measures/abs/msr-abs-oau-en.pdf	
Andean Pact	Regional		Some Decisions are directly applicable to Andean Pact countries (Bolivia, Colombia, Ecuador, Peru), for example Decision 345 on a Common Regime on Plant Breeder's Rights
National ABS legislation and regulations in providing countries - Access	National	ABS Clearing House - https://absch.cbd.int/ under country profiles, provides information on the ABS Legislation and Regulations of Parties to the Nagoya Protocol and some others. Not all Parties to the Protocol have uploaded the relevant legislation, so absence of a record does not guarantee there is no legislation. If no legislation is shown, contact the National ABS Focal Point, whose contact details should be given. Further information might be available on the country profile at https://www.cbd.int/information/parties.shtml	Governs requirements for Access to GGR, and provides the legal framework for ABS permits, PIC and MAT. Legislation may be clearly related to the Nagoya Protocol if the country is a Party, or not. If the country is a Party to the Nagoya Protocol this will govern your legal responsibilities in the country where the GR are to be utilized (if that is also a Party to the Protocol). Note that ABS requirements may or may not be contingent on planned utilization and whether or not the results may be used for commercial purposes. Thus Access legislation may require conditions to be met even if the Genetic resources are not to be utilized under the Protocol. There may be limitations in the providing country agreements (PIC and

Agreement, law, regulation etc	Scope	Information available at:	Significance
			MAT) that restrict transfer to all third parties, or only those undertaking commercial research. These conditions may require the collection holder or third party to approach the providing country for a revised agreement. Some agreements prohibit certain activities. Sequencing may be prohibited or restricted under the permit conditions; some countries, for example, require it to be carried out only within their borders. In some cases a separate permit is required for sequencing. The research may or may not fall within scope of the user country ABS legislation. The possibility of commercialization depends on the provisions agreed with the providing country in MAT, or set out in the permit or equivalent. The provisions agreed with the providing country in MAT, or set out in the permit or equivalent, will govern benefits to be shared. This requirement is not dependent on whether or not provider or user country is a Party to the Nagoya Protocol.
Other National legislation and regulations in providing countries that	National	The ABS Clearing House will not provide information about other legislation or regulations in Providing Countries that may affect Access. The national ABS Focal Point may have the information, or	There may be legislation in the country of origin of the GR in addition to formal ABS legislation that restricts access in

Agreement, law, regulation etc	Scope	Information available at:	Significance
might affect obtaining GR		alternatively approaches might be made through the Embassy or scientific contacts.	some situations. This may arise from more than one government department. Such legislation may be, for example, wildlife laws or regulations regarding activities in Protected Areas. There may also be requirements for Export Permits or other permissions. If marine research is to be carried out within the EEZ or extended Continental Shelf (see Worksheet 2.1) permission may need to be sought from the Coastal Country.
National ABS legislation and regulations in countries where utilization and / or commercialization is being carried out – compliance	National	ABS Clearing House - https://absch.cbd.int/ under country profiles, provides information on the ABS Legislation and Regulations of Parties to the Nagoya Protocol and some others. Not all Parties to the Protocol have uploaded the relevant legislation, so absence of a record does not guarantee there is no legislation. If no legislation is shown, contact the National ABS Focal Point, whose contact details should be given. Further information might be available on the country profile at https://www.cbd.int/information/parties.shtml	If the country in which you are utilizing GR is a party to the Nagoya Protocol it is likely to have legislation on compliance. This is likely to include having put National Checkpoints in place and implementing reporting and compliance procedures. Countries which are not party to the Protocol are less likely to have done so. The user country legislation may require certain information about access conditions and circumstances to be transferred with the GR, which may be important if the GR is being sourced from a third party. (see step 3). The user country legislation may require certain information about access conditions and circumstances to be

Agreement, law, regulation etc	Scope	Information available at:	Significance
			transferred with the GR, particularly to a 'user' within the meaning of the relevant Regulation (see step 3). The national legislation may be subject to regional regulations, as is the case in EU Member States. The user country may require reports at set stages in the value chain leading to commercial products. The user country may have regulations to monitor compliance with benefit-sharing agreements, or not.
Legislation and Regulations that govern your sector	Sectoral		
Sectoral codes, best practices, guidelines, professional codes of conducts		See Resources for Step 2 for examples	Other members of the sector may have developed best practices or have identified key legislation that will be of relevance. Best practices can assist in obtaining agreements with providing countries, and may be called for under the user country legislation and have a role in compliance monitoring (e.g. within the EU). They are also called for in the Nagoya Protocol Article 20.

Table 1. Conventions, laws and regulations that may have relevance to access and use of genetic resources and traditional knowledge associated with genetic resources

STEP THREE: UNDERSTANDING ABS REQUIREMENTS

What do these requirements mean for my workflows? What tasks are affected and how?

Rationale

Regulatory and legal framework requirements can only be met through appropriate safeguards and actions being placed in your organizational workflows. This means examining the outline workflow considered in Step 1 in more detail and identifying the policies and procedures that need to be present at each critical point to ensure that legal requirements can be met and risks managed. Step three should allow you to develop knowledge of access and benefit sharing requirements and what these mean in practice for your institution or company. The understanding gained in this step will be used to develop appropriate tools and mechanisms in Step four. You will need to consider each question and record what properties your system will need to have for its day-to-day running: at what level in the management does there need to be responsibility? What action will be needed and by which posts? Are there recording and databasing requirements? If so, in what detail? Are there legal requirements that require regular specialised advice? Do procedures need to be created and managed? Will policies need to be created?

Key Questions for Step 3

3.1 Acquisition of genetic resources and /or traditional knowledge associated with genetic resources

How can you ensure that the Genetic Resources you acquire are legal in their provenance, that the necessary agreements been entered into, and you can monitor and record matters relevant to legal and contract compliance?

Guidance Notes:

- GR may be acquired in a number of ways, as shown in the flowchart in Fig. 4. Your organization should only acquire GR legally, and only GR that have been legally accessed from their source. It needs to ensure that its policies and practices support this. There are some possible cases where GR might be accepted even if it was not accessed according to the legal requirements of the country of origin or where the requirement to check the legal provenance might be relaxed:
    - Official sources such as quarantine interceptions or identifications from official agencies with a mandate to deal with potentially illegal specimens may request identification, origin research or voucher storage.
    - Systems should be cost-effective and manage risks effectively. For example, an insect museum collection that receives large number of specimens from many locations in a purchase or bequest, most if not all of which are unlikely to be utilized within the meaning of the Nagoya Protocol, may not find it cost-effective to seek permit information for all of them. However, if subsequently a specimen from such a collection is selected for utilization or commercialization it would then be appropriate to determine the provenance of the specimen and contact the providing country to seek PIC and negotiate MAT.
- If staff of the organization, or anyone acting in the organization's name, acquire GR or aTK from a third party, they should be equipped to do so in line with the organization's

policies and in surety that the organization can fulfil any conditions associated with the acquisition.

- When acquiring GR or a TK, irrespective of the use to which they are to be put, the appropriate documentation and data should be acquired and retained. These documents may include Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), Material Transfer Agreement (MTA), contracts, research permit, export permit, import permit, phytosanitary certificate, CITES permit; this is not an exhaustive list, and the full range of documents needed should be established as part of the process on a case by case basis.
- If staff of the organization, or anyone acting in the organization's name, access GR or aTK from the country of origin, they should be equipped to discover and abide by the country's relevant laws and regulations. They should be empowered to negotiate MAT for use and benefit-sharing, and have sufficient information to know that the organization can meet any conditions agreed.
- Staff should operate ethically (and if working with communities, follow available customary laws/protocols/codes of conduct).

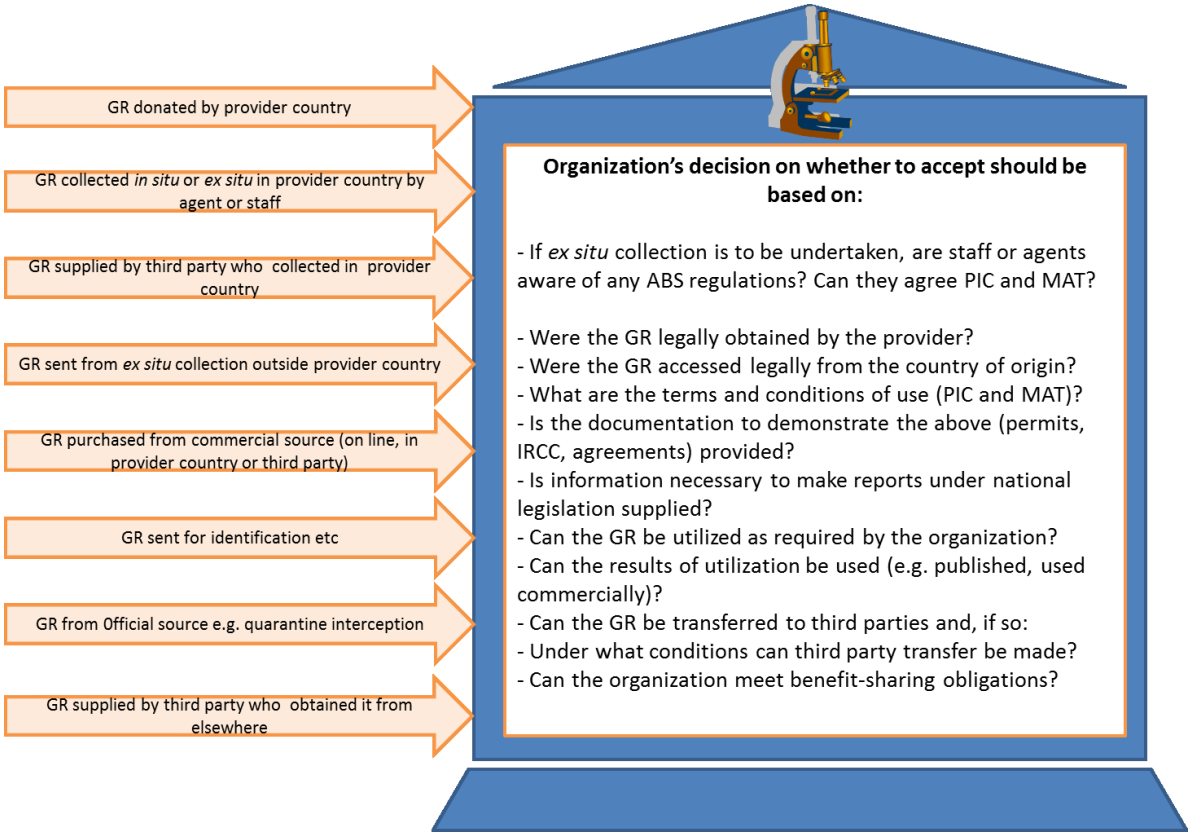


Fig. 4. Processes of acquisition of genetic resources by an organization (Section 3.1.). Arrows indicate different means whereby GR might be supplied to the organization. Third parties providing GR may be the entities that originally accessed them, or an intermediary. Supply includes permanent and temporary transfer and being brought in by external researchers for utilization within the organization's premises.

3.2 Maintaining collections of genetic resources

Collection management; how can you ensure you are compliant with legal and contractual requirements?

Guidance Notes

- This section addresses the management of GR while in the custody or ownership of the collection, its use (See Fig. 5). Managing its availability for utilization in the context of the Nagoya Protocol and its supply to others, is discussed in following sections.
- If there is more than one collection in an organization, for example research collections managed by individual scientists, the ownership and legal status of these needs to be established. ABS responsibility for each collection (and associated data and document management) will need to be assigned (see Step five). Decisions should be taken on whether to keep collections with uncertain ownership or provenance and, of they are retained, how they are managed.
- Where an organization holds more than one type of collection (for example a preserved and living collection, or a tissue collection and culture collection), policies, management and record keeping protocols across all collections and research groups in the organization should be harmonised.
- Organizations must manage their collections and associated information so that GR are only used in a way consistent with the terms and condition under which they were acquired from the Providing Country. This requires that both organization and individual staff can rapidly and easily locate appropriate information on requirements and restrictions, that appropriate benefit-sharing takes place if agreed, and that reports required under national legislation in a user country can be generated efficiently. Relevant legal documentation might be most effectively held at one central point (e.g. with a registrar), especially if subsamples of a single organism or sample are stored separately or dispersed out of the collection. Systems may need to be put in place to enable specimens and samples, and their use, to be tracked through the organization.
- aTK will need to be managed sensitively and distinguished from other similar information;
- Procedures should be in place to ensure staff, visiting researchers, students and other external users of the collections are aware of the terms of use of the genetic resources held.
- A monitoring or audit system is helpful in order to determine if the organization is managing its ABS documentation effectively and complying with agreements.

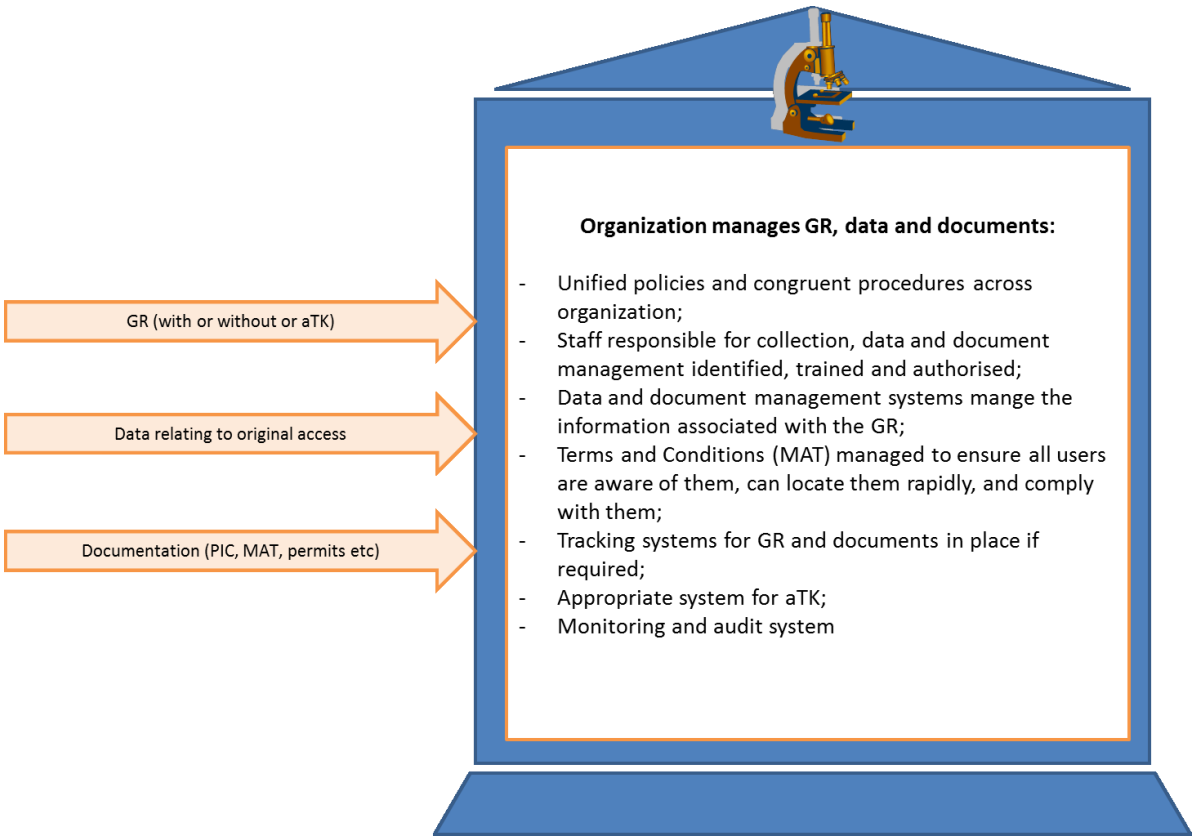


Fig. 5. Organization's management of collections, together with the associated data and documents (Section 3.2.).

3.3 Supply of Genetic Resources, extracts or derivatives to third parties

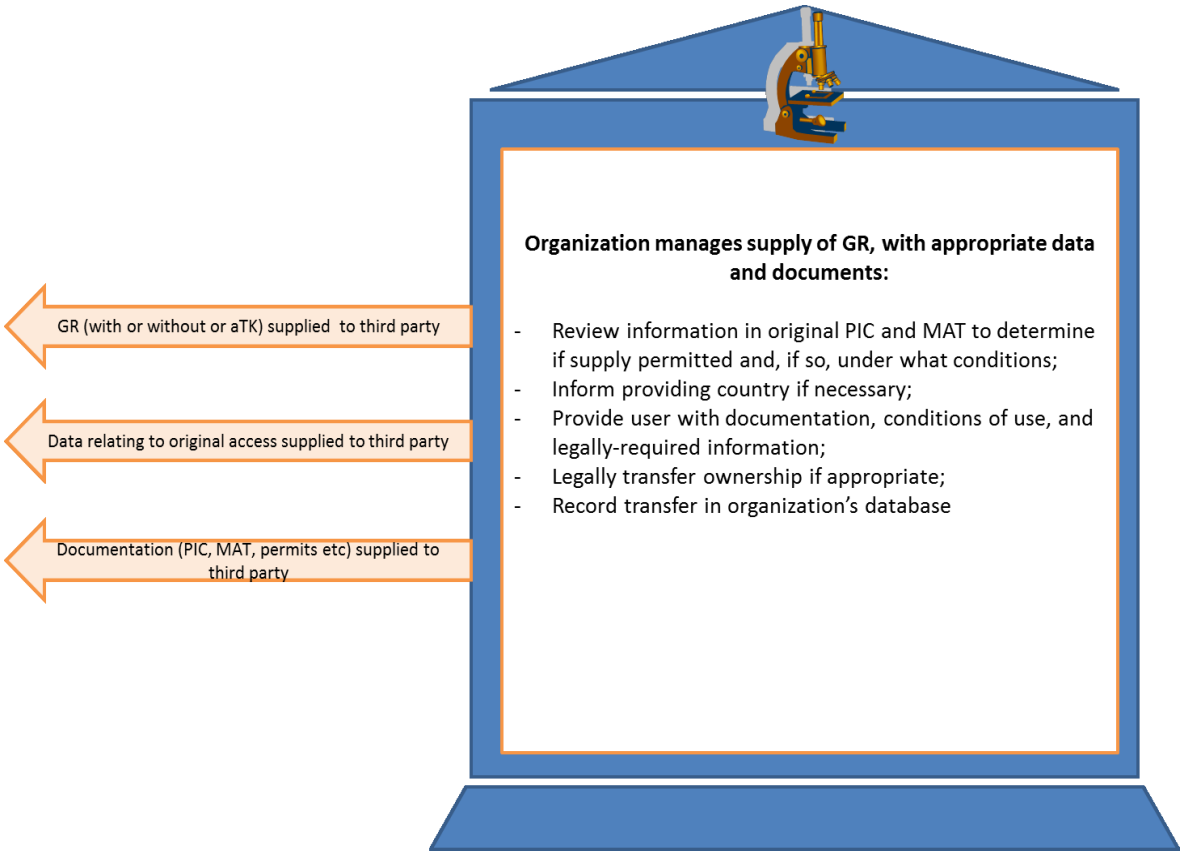
How can you ensure you are compliant with legal and contractual requirements?

Guidance Notes

- In addition to the 'value chain' in which every step involves some development step leading to a product arising from utilization of genetic resources there is a 'supply chain' which may or may not involve utilization. At its simplest it involves GR being transferred between owners or custodians, either permanently or temporarily (Fig. 6).
- GR should only be transferred to a third party if this is permitted in the PIC and MAT or permit, and according to conditions therein. In some cases the providing country will require to have a separate agreement with the recipient. As supplier, you will need to be aware of such conditions and ensure you can abide by them. This has added significance if the GR are to be used in a way by the third party that is not covered by the PIC and MAT.
- You will need to manage your legal responsibilities to the providing country and both you and the provider may need to have clarity when these have ceased. In some cases it will be helpful to inform the provider when GR have been transferred to a third party and legal responsibility has been transferred.
- If GR are transferred to a third party for utilization the recipients need to know that the GR have been legally transferred to them, must understand the conditions which are attached to the material in the original PIC and MAT, and be aware that they will need to

go back to the provider to renegotiate PIC and MAT if the intended use contravenes existing PIC and MAT. This information will need to be transferred to them in an appropriate form to provide legal certainty.

- The third party recipient, if they are in a Party to the NP and utilizing the GR, may be required to make a report to the national regulator of their country on the results of their utilization. To do this they may require particular information or documents as specified in the regulating legislation. This information will need to be transferred to them in an appropriate form to provide legal certainty, at the time the GR are transferred.



- **Fig. 6.** Management of supply of genetic resources by an organization (Section 3.3.). Prior to any supply the organization must be confident that such supply is legally-compliant and permitted by the original agreement with the providing country. It may decide or be required to inform the providing country of the transfer.

3.4 – 3.7. Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties) or involving traditional knowledge associated with genetic resources

Use and utilization: are you compliant with legal and contractual requirements? How do you ensure this?

Guidance Notes

- This section addresses research undertaken on GR and aTK, particularly 'utilization' (Fig. 7). Utilization in the sense of the Nagoya Protocol means "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the

Convention", where "Biotechnology" means "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" and "Derivative" means a "naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity". Other uses will not fall under the regulatory responsibilities in the country in which use is taking place, but may be covered by the PIC and MAT or permit issues at the time the GR were originally accessed.

- A simplified workflow is given in Fig. 7.
- Before further steps, you will find it helpful to:
    - Analyse how GR are used in your organization, and what requests for use are made by those inside and outside;
    - Develop and understanding who are the users of the GR, both within and outside the organization;
- Any use or utilization of GR should only be undertaken if it is permitted under the conditions agreed with the providing country (permits, ABS legislation, bilateral contracts etc). Information on such conditions needs to be made available efficiently and in a timely manner to staff and others wishing to utilize the GR.
- If the proposed use or utilization is not allowed under the original conditions, or there is doubt and associated risk, you will need to seek revised PIC and renegotiate MAT to cover the intended change in use. Institutional mechanisms are needed to ensure this is recognised and implemented, and to halt utilization until renegotiation has taken place.
- If the organization is carrying out research involving utilization of GR on behalf of others the responsibilities and legal position of the organization need to be understood and documented. The responsibilities may differ if the utilization is carried out as a joint research project with the owners of the GR or if the utilization is being carried out on a contractual basis. Receipt of GR for utilization and return of the results to a third party should not be an accidental by-passing of protocols covering acquisition of GR by the organization or entry into the organization's premises.
- Under the Nagoya Protocol Parties are responsible for ensuring that GR utilized under their jurisdiction have been accessed in accordance with PIC and take action to address non-compliance. This will cause them to monitor all utilization under their jurisdiction, whoever is carrying it out. Consequently, if researchers who are not members of staff of your organization utilize GR using its the facilities you may have legal obligations to ensure the research is in compliance with PIC and MAT, and that any reports required by your national regulator are made. You will need to ensure that any such reports are made, put in place mechanisms to manage the activities of all individuals using the organization's facilities in this way.

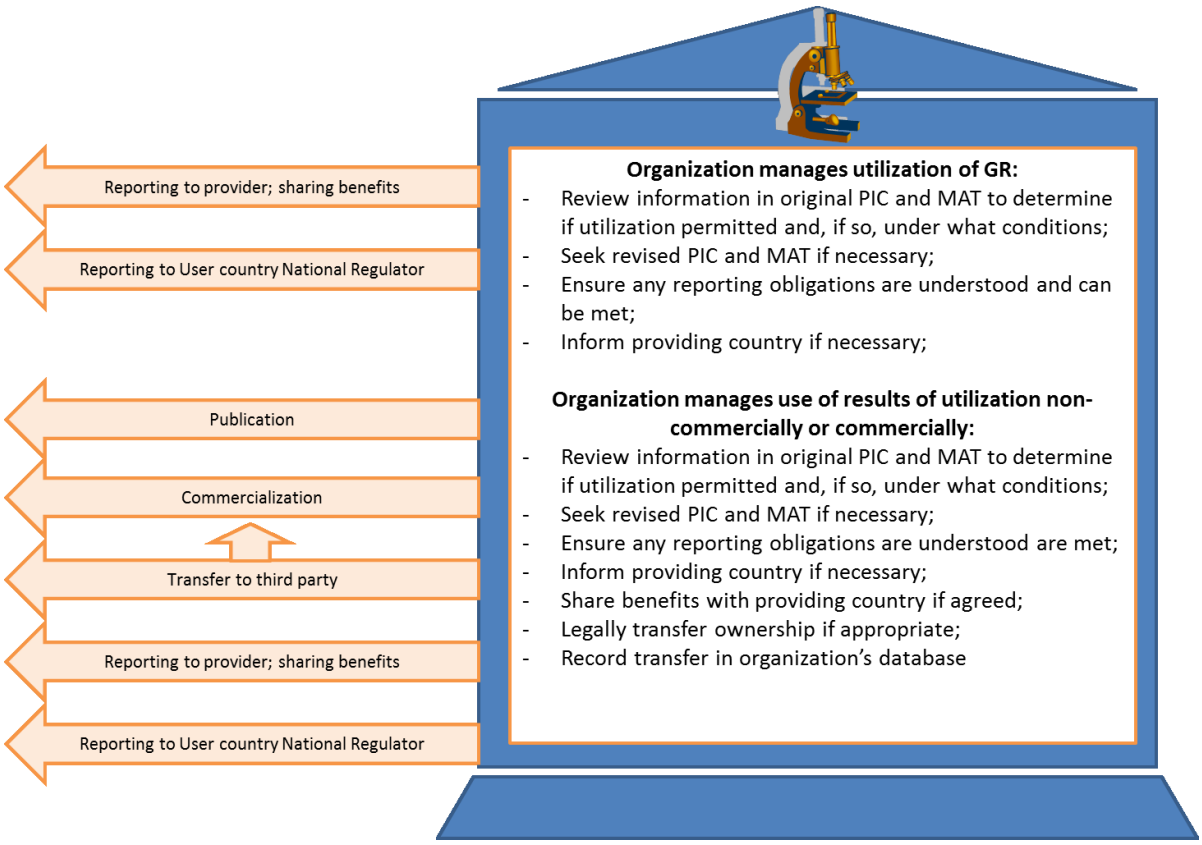


Fig. 7. Management of utilization of genetic resources by an organization and the publication or commercialization of the results of that utilization, including possible transfer to third parties, benefit-sharing and reporting. (Sections 3.4., 3.5 and 3.6)

3.8 Commercialization or sale to others the results of your research on genetic resources

Commercialization or transferring the product of commercialization to others in the value chain. How do you ensure legal compliance?

Guidance Notes

- Towards the end of the value chain a product is developed and either commercialized directly or passed to a third party for further development or placing on the market (see Fig. 3).
- This step may require making a report to the national regulator, or providing information to a third party recipient as discussed above. Procedures will need to be in place to ensure that reports are created and submitted as required, and that the information to enable this is available to staff in a timely manner and to fit with their workflows most efficiently.

3.9 Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced

How do you share benefits, and ensure that this is done?

Guidance notes

- Benefits to be shared may have been agreed with the providers when the GR were accessed. These may have been monetary or non-monetary (see the Annex to the

Nagoya Protocol for an indicative list) (Annex 4 below). Benefit-sharing may be linked explicitly to utilization or some other point in the value chain, such as placing on the market. Alternatively, benefits may have been agreed simply in the context of access, and some benefits may have been delivered at that time (e.g. field training, sharing of specimens).

- It is important to know and manage:
  - Whether benefit-sharing has been agreed;
  - if benefit-sharing was required under the providing country legislation this was included in any agreement;
  - what has been delivered against benefit-sharing agreements, and what is still expected.

  The trigger for benefit-sharing may be far down the value chain from access, and may occur in a different part of the organization. Staff must know when a benefit-sharing trigger has been reached and how to address it. Record keeping and access to agreements must therefore be managed effectively to ensure all of these aspects.
- The complexity of research and development, especially if a very large number of GR from different sources being used, may make it very difficult to assign benefits in any rigorous way. In such situations it is important to ensure that initial agreements with providers reflect this and do not make it impossible for contracts to be met. In due course the Global Multilateral Benefit-Sharing Mechanism (Article 10 of the Nagoya Protocol) may form part of a solution to this problem, but it is not yet in place.
- Because benefit sharing will be a part of what is effectively a contract, legal oversight of the process and documents may be required.

Resources for Step Three

Botanic Garden Policies on benefit-sharing - https://www.bgci.org/policy/case_studies_policies/

Public Interest Property Advisors, 2013, Bioprospecting Resource Guide, 2nd Edition, http://www.piipa.org/images/PDFs/PIIPA_Bioprospecting_Resource_Guide_2013_Final.pdf

Secretariat of the Convention on Biological Diversity (2008). Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors. Montreal, Technical Series No. 38, 140 pp.

Union for Ethical Biotrade (UEBT), 2013, Fair and equitable benefit sharing. Manual for the assessment of policies and practices along natural ingredient supply chains. http://ethicalbiotrade.org/dl/benefit-sharing/ABS_manual_ENG.pdf

STEP FOUR: PREPARATION FOR IMPLEMENTATION - WORK FLOW ANALYSIS AND TOOLKIT PREPARATION

What will your organization have to do to manage ABS requirements and meet legal and ethical obligations?

This step will help you identify what tools you will need to take the requirements identified in step 3 to practical implementation.

Rationale
This Step enables you to apply the ABS requirements set out in Step 3 to the work of the organization. It will enable appropriate tools to be developed, policies to be written, staff responsibilities identified and the results of these activities to be implemented. The more aligned these are to the existing ways in which the organization operates, the more effective they are likely to be and the more readily applied by staff. The aim is to become ABS READY.

Key Question for Step 4

What procedures and tools do you need to put in place?

The Worksheet for Step four details elements that will need to be considered, as identified in Step three. Delete any that do not apply and then use this as a checklist to ensure you have developed policies and procedures to cover everything that you need.

Procedures and tools will need to address the following areas:

- Acquisition of new specimens (4.1)
- Managing the collection/s, including record keeping and disposal (4.2)
- Supply to third parties (4.3)
- Use of GR, including by others on your premises (4.4-4.6.)
- Commercialization (4.7.)
- Benefit sharing (4.8)

Developing a suite of ABS Policies at organizational level and, depending on the organization structure, of subsidiaries of the organization, will help manage ABS compliance and how the organization and its staff manage the requirements identified in Step 3. These policies must be developed in the context of the existing policy structure, and may be in the form of a single ABS policy covering in appropriate detail all relevant parts of the workflow, or with the various ABS elements distributed among separate policies. Some organizations have a simple policy but address the detail in well-documented procedures.

In developing policies and procedures it will be helpful to work with your Key stakeholders. These could include clients, customers, indigenous people and government representatives. It is often helpful to contact others in your sector to share ideas and experiences.

4.1. Acquisition of genetic resources and /or traditional knowledge associated with genetic resources

Step Three helped you identify from where your organization acquires GR: field (*in situ*) conditions, or donation from, exchange with, or sale by, another *ex situ* collection or private company. Depending on the source, you will have different issues to consider.

Acquisition from *in situ* conditions (wild or field collected)

Before ABS-compliant field (*in-situ*) collection can take place by anyone acting in the name of the organization they will need to establish:

- What legislation applies in the country and area where access is going to take place (see Table 1);
- Any relevant legislation in the country where the GR will be taken (see Table 1);
- Whether the acquisition will fall under the Nagoya Protocol;
- Key official contacts (see Table 1);
- What permits and permissions are needed to ensure PIC has been granted.

They will then need to obtain:

- Permits and permissions needed to demonstrate PIC has been granted;
- Mutually agreed terms (MAT) for use and benefit-sharing, set out in a written agreement. This may be set out in national legislation, agreements or permits, or you may need to negotiate a new bilateral agreement.

If the providing country is a Party to the Nagoya Protocol it may publish the permit or equivalent on the ABS Clearing House and through this process generate an Internationally Recognised Certificate of Compliance (IRCC). This publicly-available document may be used to demonstrate legal acquisition of the GR. In negotiating MAT it is sometimes appropriate to agree elements which should be confidential (see Article 17 of the Nagoya Protocol); this will be reflected in the contents of the IRCC.

If your organization has an active field collecting programme you may consider developing a Fieldwork collecting policy and tools. This will ensure that members of staff are equipped to go through the above process, and that the organization has managerial oversight.

Acquisition from *ex situ* conditions

For ABS-compliant acquisition of genetic resources from an *ex situ* collection (e.g. from another institution or private company) you will need to establish:

- That the GR are held legally by the provider;
- That the provider has permission to pass/sell the GR to your organization;
- Whether, if the provider is situated within the country of origin of the GR, it is acting on behalf of its country to provide access to the GR under its ABS legislation;
- What regulations apply to the GR, including whether the Nagoya Protocol applies;
- The terms and conditions under which the GR are transferred to you;
- What the reporting requirements are for your organization or a subsequent user, and ensure that you have the necessary documentation and information.

In both cases (*ex situ* and *in situ* acquisition) the elements above will establish legal certainty of ownership and terms of use. To ensure this process is carried out effectively:

- Individuals involved in negotiation of the Terms will need training (see Step 5) for example:
  - negotiation skills
  - to understand key terms under which GR can be accepted, including any red lines (e.g., where the conditions are incompatible with the operation of the organization, or would be too costly, or impossible, to meet).

- You can develop and use model clauses for agreements, Material Transfer Agreements, or donation letters (of particular use when acquiring from *ex situ* sources). Model agreements and clauses need to clarify;
  - What the GR are to be used for. Written documentation as an annex to PIC setting this out in appropriate detail has proved valuable - see Resources to this section): CETAF *Use of Biological Material statement for negotiating Prior informed Consent*. And text box 1.
  - Whether the use is commercial, non-commercial or either;
  - Triggers for seeking revised PIC and renegotiating MAT if there is a change in the intended use
  - Ownership of all GR collected under an agreement.

Such model agreements have been developed in many sectors which can be used as a starting point to develop suitable model agreements for your needs. (See Resources for Step four)

Text Box 1: Elements to include in a model agreement might include:

- Parties to the agreement
- Nature /purpose of agreement
- Genetic material covered – seeds, herbarium specimens, DNA, data/TK/information
- Sampling places and amounts, if access taking place and information relevant
- Legal documentation (permits etc, ideally attached to the document as annexes), including IRCC number if available
- Whether the agreement covers PIC/legal access from provider
- Special conditions if aTK are included
- Use of material (including whether non-commercial or commercial)
- Steps to take if change of use anticipated
- Terms of transfer and supply of material and results to third parties, if allowed
- Storage/disposal of the material
- Record keeping and reporting
- Publication of results of utilization
- Commercialization of results of utilization
- Benefit sharing (monetary/non-monetary; short term/long term; sharing of knowledge)
- Intellectual property aspects
- Mutually agreed confidential elements
- Liabilities and warranties
- Legal clauses
- Dispute resolution
- Termination of agreement
- Governing legal framework
- Definitions of key phrases and terms (utilization, commercialization etc)

4.2. Maintaining collections of genetic resources

You will need to ensure that you have collection management procedures in place so that your organization, and all persons handling GR, can and will comply with any terms of use and share benefits, and renegotiate PIC if there is intent to change the agreed use. To achieve this you will need to establish:

- workflows to ensure conditions are met and benefits shared;
- systems of monitoring and recording the use of specimens or samples. This might require reporting on any movement or use of the samples, or only reporting on one of a set of key events, such as sequencing, biochemical analysis, splitting to subsamples, transfer to third parties etc.

Where there are collections or samples for which the ownership or provenance is uncertain you will need to decide whether to retain them and, if they are retained, how they should be managed. Developing criteria based on legal and reputational risk might be helpful. For example, GR accessed prior to 1993 will not fall under the Nagoya Protocol and their utilization is less likely cause legal problems than more recently-accessed GR (although for ethical and reputational reasons PIC and MAT might still be sought.

Many of the necessary activities are related to data and information management. An information management system will need to:

- Keep records of terms and conditions, ideally with a controlled vocabulary to facilitate use and flagging of key conditions;
- track specimens and samples in the collection, including when sent to third parties permanently or temporarily, and when subdivided and stored in different places;
- record the use of specimens or samples, such as sequencing, biochemical analysis, and publication of results;
- record transfer to third parties;
- enable document management, with simple association of documents to the specimens covered;
- Hold and generate reports of information required for compliance with national regulations e.g. reporting to national regulators on utilization where appropriate – ideally this will be a semi-automatic process.

- A single database used across the organization may be most efficient, or a system of transferring information between databases (and staff training to do this) put in place;
- Unique identifiers should be associated with the GR, and applied appropriately to subsamples, progeny etc. References related to tracking and tracing GR are listed in Resources for Step 4.
- For exchange of information appropriate standard data elements may be required. The Global Genome Biodiversity Network has developed a data standard including a vocabulary for permits. This is intended to be used with ABCD or Darwin Core and is not a stand-alone solution. (See Resources for Step 4).

4.3. Supply of Genetic Resources, extracts or derivatives to third parties

You need to ensure that you only supply GR to third parties according to original or renegotiated terms of use and permitted by them. You should develop and use Material

Transfer Agreements (MTAs) (alternatively Material Supply Agreements – MSAs) to manage legal requirements in this process. These will inform the recipient of their responsibilities, transmit the information and documents they require for compliance (with both the conditions of the original PIC and MAT and the user country regulations), document the transfer of the GR, and act as a useful checklist for the process.

If you regularly supply to commercial organization, special consideration should be given to ensuring the original or subsequently renegotiated conditions of access allow commercial activity and, if so, under what conditions. If they do not, the third party should be made aware that they are responsible for renegotiating terms. A procedure for notifying the National Competent Authority in the providing country of such transfer may be appropriate.

Text Box 2: Elements of a MTA / MSA

- Parties to the agreement
- Definition of genetic material covered – seeds, herbarium specimens, DNA, data/TK/information
- Legal documentation (permits etc, ideally attached to the document as annexes), including IRCC number if available
- Purpose of supply (Use of material (non-commercial/commercial)
- Steps to take if change of use anticipated by recipient
- Terms of transfer and supply to third parties, if allowed
- Storage/disposal of the material
- Benefit sharing (monetary/non-monetary; short term/long term)
- Intellectual property aspects
- Mutually agreed confidential elements
- Any stricter terms from provider
- Dispute resolution
- Governing legal framework
- Definitions of key phrases (utilization, commercialization etc)

4.4. – 4.7. Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties) or involving traditional knowledge associated with genetic resources

This section includes utilization by your own staff, either on your behalf or for external organizations or individuals, and external individuals utilizing GR on your premises for their own purposes.

GR in your organization and on its premises must be used legally and ethically, and all staff and visitors must be made aware of any restrictions. This will involve:

- Putting in place procedures to ensure potential users are aware of any restrictions of use and their responsibilities in this regard. Restrictions should be recorded in databases, and may be printed on labels of specimens or samples or their containers. In addition policies for staff, visiting researchers and students should be drawn up, and individuals may be required to sign use agreements. Training for staff will be important (Step five);
- Developing a policy for when terms of use are unclear. In many situations the conditions agreed are silent on whether utilization is permitted. This is particularly

the case for pre-Nagoya GR. You will need to develop a risk based policy on how such GR can be used. You may decide that basic research is acceptable, but if the intention is to commercially develop the GR PIC and MAT should be sought from the country of origin.

- Procedures for requesting revised PIC and renegotiating MAT if proposed use of a GR changes, or an unexpected commercial opportunity arises.

Data and information management systems to support utilization will be important, as discussed above under 4.1. Note that some reporting requirements in your country may require information that may not be held in databases concerning GR; in particular, reporting within the EU may be triggered by the funding of the research and development by a grant. Ensuring that the requisite information is transmitted within the organization from work areas focussed on the GR to work areas focussed further down the value chain may require particular attention.

4.8. Commercialization or sale to others the results of your research on genetic resources

Commercialization of the results of utilization, or selling them on to another organization to market, may require making a report to a national regulator in your country, and trigger benefit-sharing with the providing country. At this point your procedures should:

- Enable a final check on conditions to ensure that commercialization is allowed under the original PIC and MAT
- Generate any reports required by the Regulator;
- Trigger benefit-sharing if required.

4.9. Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced

You need to ensure that you have the procedures in place to track how genetic resources have been used and ensure that benefits agreed in MAT are shared, and the policies to ensure this is implemented.

It is important to document what benefits have been shared and when this is has done.

Resources for Step Four:

Workflow developed in Step 3

BGCI Case studies on MTAs: www.bgci.org/resources/case_studies/

Bonn Guidelines: www.cbd.int/abs/bonn/

CBD, 2013, Survey of Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and Standards - http://www.cbd.int/doc/meetings/abs/icnp-03/information/icnp-03-inf-02-en.doc

CBD, Codes of conduct, guidelines and best practices and/or standards: www.cbd.int/abs/instruments/default.shtml

Consortium of European Taxonomic Facilities (CETAF), 2015, Use of Biological Material statement for negotiating Prior informed Consent – Annex within CETAF Code Of Conduct & Best Practices For ABS (Access & Benefit-Sharing) http://cetaf.org/taxonomy/publications

Consortium of European Taxonomic Facilities (CETAF), 2015, Standard MTAs for provision and receipt of biological material http://cetaf.org/taxonomy/publications

European Commission Glossary of Terms in ABS - http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Glossary%20for%20Europa.pdf

Garrity, G.M., Thompson, L.M., Ussery, D.W., Paskin, N., Baker, D., Desmeth, P., Schindel, D.E. and Ong, P.S., 2009, Studies on Monitoring and Tracking Genetic Resources: An Executive Summary. Standards in Genomic Sciences 1: 78-86 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3035216/

Garrity G, Thompson L, Ussery D, Paskin N, Baker D, Desmethe P, Schindel D, Ong P, 2009, Studies on Monitoring and Tracking Genetic Resources. United Nations Convention on Biological Diversity; 2009. Report No. UNEP/CBD/WG-ABS/7/INF/2. 1 - 100 p. http://www.cbd.int/doc/meetings/abs/abswg-07/information/abswg-07-inf-02-en.pdf

Global Genome Biodiversity Network (GGBN), 2015, Standard Material Transfer Agreements for receipt and provision of genomic material http://wiki.ggbn.org/ggbn/Documents

Global Genome Biodiversity Network Data Standard, 2015, http://terms.tdwg.org/wiki/GGBN_Data_Standard

Latorre Garcia, F., Williams, C., ten Kate, K. and Cheyne, P., 2001, Results of the Pilot Project for Botanic Gardens – Booklet sets out all aspects of developing policies and procedures on ABS for botanic gardens: https://www.bgci.org/files/ABS/Principles_on_ABS.pdf

Micro B3 Model Agreement on Access to Marine Microorganisms and Benefit-Sharing https://www.microb3.eu/sites/default/files/pdf/MICRO_B3_ABS_model_agreement_17122013%20explanatory%20notes.pdf

Model Access and Benefit Sharing Agreement between Australian Government and Access Party http://www.wipo.int/tk/en/databases/contracts/texts/australiaprovider.html

Model ABS Agreements and Contractual Clauses on CBD website: www.cbd.int/abs/resources/contracts.shtml

Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC) - http://bccm.belspo.be/projects/mosaicc Includes:
MOSAICC Code of Conduct, with annexes Model MTA, Model PIC application form
http://bccm.belspo.be/documents/files/projects/mosaicc/code2011.pdf

Public Interest Property Advisors, 2013, Bioprospecting Resource Guide, 2nd Edition. This useful guide provides comprehensive and position-neutral lists and links to IP resources, from publications to tools, focusing on bioprospecting transactions. http://www.piipa.org/images/PDFs/PIIPA_Bioprospecting_Resource_Guide_2013_Final.pdf

Swiss Academy of Sciences Biber-Klemm S, Martinez SI, Jacob A, & Jetvic A., 2010, Sample Agreement on Access and Benefit Sharing for Non-Commercial Research. Swiss Academy of Sciences, Bern, Switzerland. http://www.naturalsciences.ch/organizations/biodiversity/abs/publications

ITPGRFA Standard Material Transfer Agreement: www.planttreaty.org

Union for Ethical Biotrade (UEBT) Tools - http://ethicalbiotrade.org/resources/uebt-tools/

Union for Ethical Biotrade (UEBT), 2010, Principles on Patents and Biodiversity http://ethicalbiotrade.org/dl/public-and-outreach/UEBT_principles_on_patents_biodiversity_EN.pdf

Union for Ethical Biotrade (UEBT), 2013, Fair and equitable benefit sharing. Manual for the assessment of policies and practices along natural ingredient supply chains. http://ethicalbiotrade.org/dl/benefit-sharing/ABS_manual_ENG.pdf

WIPO Contracts Database and Draft Guidelines: http://www.wipo.int/tk/en/databases/contracts/index.html

STEP FIVE: IMPLEMENTATION

How can these new policies and procedures be embedded in the existing workflows of the organization?

Rationale

Policies and procedures only operate effectively if they are understood, accepted and adopted by the people implementing them. To ensure such understanding is in place, the process of implementing the tools developed in Step 4 must be accompanied by a programme of awareness-raising and training in your organization. This is important to manage the legal, contractual and reputational risks that arise if there is insufficient ABS awareness.

Key Question for Step 5

How can you take the procedures and tools developed in Step 4 and make sure they are *embedded in organizational practices?*

The introduction of new systems needs to be carefully structured. It will, of course, depend on what is already in place and the existing level of staff understanding. The process below assumes starting from a position of nothing in place and no understanding, so will need to be adapted for other situations. However, the tools and methodologies are likely to be of value even where some systems are already emplaced. In many cases ABS is simply a context in which existing practices take place. ABS implementation should not be thought of as an additional burden, but rather as factors which need to be mainstreamed into organization policies and procedures to ensure that the work of the organization is legally compliant and follows best sectoral practice with benefits to the organization. Emphasising benefits such as legal clarity and stronger collaborations can assist the change management process. The notes below can be read against worksheet 5.2 to help you document your progress.

1. Factor staff time into the process

The process will inevitably need time from all staff if it is to be successful. This time should be understood before the start of the process and factored into staff job descriptions and expectations. In the case of most staff this will be limited to workshops and training but, depending on the size of the organization, you may wish to identify one or more people with set responsibilities and thus a higher time allocation.

2. Identify staff member or members with ABS responsibility.

It is helpful in most cases to give overall ABS responsibility for the organization to a single person. This individual would be the contact point for external bodies such as regulators, and oversee implementation across the organization. The individual may be assisted by representatives from relevant departments who would also act as local focal points or ABS managers.

Activities undertaken internally by the responsible individual or team might include:

- Organizing training seminars and materials for staff to provide information on ABS implementation within the organization and key issues;
- Developing a staff manual on ABS implementation in the organization. This could be in paper form, be online, or link to online resources;

- Acting as a resource for staff on issues of access and benefit-sharing, and other related policy matters;
- Facilitating development and processing of ABS applications and agreements;
- Facilitating communication with potential collaborators;
- Acting as sector focal point for national Regulators
- Ensuring reports to regulators or others are delivered as required;
- Ensuring compliance within the institution and by institutional policies;
- Monitoring activities with ABS dimensions across the organization and managing ABS audits.
- Supporting the development of an ABS Policy for the organization

Activities undertaken externally by the responsible individual or team might include:

- Working with other institutions in the sector and country to share experiences and develop congruent policies and best practices (see Step 7);
- Organizing regional policy workshops for projects, universities, and research institutions;
- Following national and international policy developments that impact institutional policy, and participating on behalf of the institution in such policy processes;
- Working with and supporting your government (ABS Focal Point) in its development of access and benefit sharing consultations and measures.

3. Providing awareness-raising and staff training on ABS in your organization

Awareness-raising activities and training can be delivered through talks, posters, intranet guides and workshops, or a combination of all these. The first step is to bring understanding of the concept of and rationale for ABS – the context in which handling and use of genetic resources now takes place, and how this is relevant to the organization. Following this, more focussed training can be given on the implementation of the ABS policy and the procedures developed to implement it. This will also be an opportunity to obtain wider feedback on this implementation, including suggestions as to how it might be improved. Worksheet 5.1. can be used to help you ensure everything necessary is covered.

- **Awareness-raising**

  This element should include:

  - International and national legal frameworks that govern acquisition, use and disposal of genetic resources by your organization;
  - Background of the Convention on Biological Diversity and the international legal agreement that changed biodiversity from being the common heritage of humanity to falling under the sovereign rights of the state in which it occurs.
  - The concept of Access to genetic resources and sharing of the benefits arising from their utilization, the Nagoya Protocol and examples of national ABS legislation
  - The modes of benefit-sharing, including both monetary and non-monetary benefits
  - Benefits to the work of the organization

- **Organization policy and procedures**

This element should include the procedures and tools developed in Step 4. Some particular training may be needed to equip relevant staff for negotiation with provider countries and understanding terms and conditions imposed in national legislation and permits, and identifying the most appropriate modes of benefit-sharing.

4. Put in place a system for ongoing training

This will be important for staff, both new and existing, who need refresher courses. It is also important to have resources to inform visitors, clients, customers, students and other short-term users of the organization's facilities or genetic resources. The organization should establish clear internal procedures for ongoing and brief training for staff, visitors etc. This might make use of intranet resources, and also use induction talks or training, posters, and regular drop-in 'surgeries'.

Resource folders or an intranet site can be set up to ensure that necessary information is available for staff to refer to, to provide a resource for staff to refresh their understanding and revisit training modules, and to ensure continuity of information through staff changes. A set of hard-copy or digital resources should be created. This might include:

- Background information on ABS, the Nagoya Protocol and the significance to the institution (Awareness-raising materials, including presentations given);
- Codes of ethics and research guidelines
- National access and benefit-sharing measures (sample laws, etc.)
- Organization's ABS Policy documents;
- Organization's ABS procedures;
- Model contracts and contractual clauses;
- Relevant best practices;
- Key contacts and resources

5. Launch of policy and toolkit

A formal launch of the organization's new policies and procedures helps to raise wider public awareness and can be an opportunity to reinforce the importance of the issues with staff. It may also be an opportunity to engage with other key audiences to highlight the steps your organization is taking to be compliant, share benefits and support biodiversity. External audiences might then include local and national and trade press, the home country government (for example the National ABS Focal Point and the Regulatory Authority), and representatives for any particularly important partners. The ABS Clearing House, run by the CBD Secretariat, has a section for 'virtual library records', and it may be seen as appropriate to post copies of the procedures adopted there.

Resources for Step Five

ABS Capacity Development Initiative: audiovisual and print documents provide a good overview of Access and Benefit Sharing and the ABS Capacity Development Initiative. Resources include the Films 'ABS Simply Explained' (5 mins), 'People, plants and profit' (25 mins), 'making ABS work for you – a strategic partnership' (3 mins), a brochure and poster on ABS and the ABS Initiative, Interactive infographics 'Sectoral ABS cases – opportunities provided by the Nagoya Protocol' and a Poster, 'Sectoral ABS Cases - Opportunities Provided by the Nagoya Protocol'. http://www.abs-initiative.info/knowledge-center/multimedia/

Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change Factsheets on Implementing the Nagoya protocol, The Agricultural sector, Botanicals, The Cosmetics Sector, The Food and Beverage Sector, Industrial Biotechnology and The Pharmaceutical Industry. https://www.cbd.int/abs/policy-brief/default.shtml/

Botanic Gardens Conservation International (BGCI), ABS Learning Modules for Botanic Gardens: https://www.bgci.org/policy/abs_learning/

Nagoya Protocol factsheets https://www.cbd.int/abs/factsheet/

The ABS Information Kit (updated to include information on the Nagoya Protocol). The information kit is available in the six UN languages (Arabic, English, Spanish, French, Russian and Chinese) and in Portuguese, and contains the following:
A brochure,
Factsheets on Access and benefit; Uses of genetic resources; Traditional knowledge; The Bonn Guidelines; National implementation; and The Nagoya Protocol.
PowerPoint slides: English, French and Spanish

STEP SIX – DETAILED ABS AUDIT

How did that go?!

Rationale

Once the mechanisms to ensure the organization can manage ABS requirements is in place it is necessary to monitor and evaluate its performance. This can be done with a more detailed ABS audit. It takes the methodology from Step one but based on the far more detailed analysis done in Step three. If the requirements of step three are not being met steps four and five need to be re-examined.

Key Questions for Step 6

6.1. Is the organization handling ABS matters appropriately?

Worksheet 6 requires you to review the requirements identified in Step 3 against actual performance. You may wish to select trial questions to test the efficacy of the implementation, e.g. 'What are the restrictions and requirements for this specimen? Have benefits been delivered against this agreement?

6.2. What still needs to be done?

Any failing may be due to insufficient implementation or identification of workflow issues, or it may be a capacity problem.

- Identify gaps in capacity (e.g. more staff needed, staff time in curation, database capacity etc.) to implement
- Review how you can effectively close these gaps, if possible! Develop a plan for improvement. Even if resources are currently lacking, how gaps could be filled.
- Review Steps

STEP SEVEN – DEVELOP SECTOR STANDARDS AND AWARENESS

Rationale

If all members of a sector develop and adopt a set of guidelines, best practices, tools and procedures it has the following benefits:

- Increases rigour of analysis and understanding of problems
- Creates level of trust in that sector by both providers and users. In some circumstances it might be used as unofficial kitemark.
- Provides tools for all members of sector, reducing individual development costs
- Acts as awareness raising exercise for the sector.
- Can have a significant influence on development of legislation and policy.
- May be accepted as best practice by national ABS legislation (for instance EU Regulations and Australian access legislation) and facilitate access for users following such a code.
- May ease regulatory overheads

This step needs to be taken with others, perhaps through a sectorial association. It is optional, but carries benefits.

Key Question for Step 7

How can you benefit from working with other organizations within your sector?

Work with others in your sector to:

- develop common access standards for online information/databases etc.
- develop codes for online information sharing etc
- share information on ABS policies and procedures
- develop sector guidelines,
- develop best practice,
- develop common standards,
- develop common procedures,

Resources for Step seven

Consortium of European Taxonomic Facilities (CETAF), 2015, Code Of Conduct & Best Practices For ABS (Access & Benefit-Sharing) http://cetaf.org/taxonomy/publications

Global Genome Biodiversity Network (GGBN), 2015, Best Practice for Access and Benefit-Sharing. Also GGBN Code of Conduct http://wiki.ggbn.org/ggbn/Documents

International Plant Exchange Network (IPEN) Code of Conduct https://www.bgci.org/files/ABS/IPEN/IPEN%20Code%20of%20Conduct.doc (more information about IPEN can be found at https://www.bgci.org/policy/ipen/

Microbial Resource Research Infrastructure (MIRRI) Best Practice Manual on Access and Benefit Sharing

http://www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI_ABS_Manual_web.pdf

Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC) Code of Conduct http://bccm.belspo.be/documents/files/projects/mosaicc/code2011.pdf

Union for Ethical Biotrade (UEBT), 2012, STD01 –Ethical BioTrade Standard 201 -04-11. http://ethicalbiotrade.org/dl/STD01_Ethical%20BioTrade%20Standard_2012.04.11_Eng.pdf

The CBD Website provides links to a number of Codes of Conduct, guidelines and best practices at https://www.cbd.int/abs/instruments/default.shtml

The ABS Clearing House provides access to Codes of Conduct and guidelines within the Reference Records, under the heading Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards https://absch.cbd.int/search/reference-records/

Acknowledgements

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Annex 1. Useful references and resources

ABS Capacity Development Initiative: audiovisual and print documents provide a good overview of Access and Benefit Sharing and the ABS Capacity Development Initiative. Resources include the Films 'ABS Simply Explained' (5 mins), 'People, plants and profit' (25 mins), 'making ABS work for you – a strategic partnership' (3 mins), a brochure and poster on ABS and the ABS Initiative, Interactive infographics 'Sectoral ABS cases – opportunities provided by the Nagoya Protocol' and a Poster, 'Sectoral ABS Cases - Opportunities Provided by the Nagoya Protocol'. http://www.abs-initiative.info/knowledge-center/multimedia/

ABS Clearing House - https://absch.cbd.int/

Many resources, including:

- Codes of Conduct and guidelines within the Reference Records, under the heading Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards https://absch.cbd.int/search/reference-records/
- National Records, including the contact details of national Focal Points, the status of a country as a Party to the Protocol or not, links to national legislation, Internationally Recognised Certificates of Compliance
- Virtual library with increasing content.

Biber-Klemm et al, 2014, Access & Benefit-Sharing in Latin America & the Caribbean A science-policy dialogue for academic research http://www.diversitas-international.org/resources/outreach/abs-docs/ABS-Brochure_ENG.pdf

Botanic Gardens Conservation International (BGCI), https://www.bgci.org/

A number of valuable resources including:

- ABS Learning Modules for Botanic Gardens: https://www.bgci.org/policy/abs_learning/
- A CBD manual for botanic gardens. Botanic Gardens Conservation International, Richmond, United Kingdom ISBN: 978-1-905164-29-5 http://www.bgci.org/files/cbd_manual.pdf
- Botanic Garden Policies on benefit-sharing - https://www.bgci.org/policy/case_studies_policies/
- Case studies on MTAs: www.bgci.org/resources/case_studies/
- Results of the Pilot Project for Botanic Gardens – Booklet sets out all aspects of developing policies and procedures on ABS for botanic gardens: https://www.bgci.org/files/ABS/Principles_on_ABS.pdf

Bonn Guidelines: www.cbd.int/abs/bonn/

CBD Website on ABS https://www.cbd.int/abs/default.shtml

Many resources, including:

- Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change Factsheets on Implementing the Nagoya protocol, The Agricultural sector, Botanicals, The Cosmetics Sector, The Food and Beverage Sector, Industrial Biotechnology and The Pharmaceutical Industry. https://www.cbd.int/abs/policy-brief/default.shtml/

Codes of conduct, guidelines and best practices and/or standards: www.cbd.int/abs/instruments/default.shtml
Model ABS Agreements and Contractual Clauses on CBD website: www.cbd.int/abs/resources/contracts.shtml
Nagoya Protocol Text, https://www.cbd.int/abs/text/default.shtml
Nagoya Protocol factsheets https://www.cbd.int/abs/factsheet/
The ABS Information Kit (updated to include information on the Nagoya Protocol). The information kit is available in the six UN languages (Arabic, English, Spanish, French, Russian and Chinese) and in Portuguese, and contains the following:
A brochure,
Factsheets on Access and benefit; Uses of genetic resources; Traditional knowledge; The Bonn Guidelines; National implementation; and The Nagoya Protocol.
PowerPoint slides: English, French and Spanish

CBD, 2013, Survey of Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and Standards - http://www.cbd.int/doc/meetings/abs/icnp-03/information/icnp-03-inf-02-en.doc

Consortium of European Taxonomic Facilities (CETAF). Several very helpful documents, including:
CETAF Code Of Conduct & Best Practices For ABS (Access & Benefit-Sharing) (2015) http://cetaf.org/taxonomy/publications
Standard MTAs for provision and receipt of biological material (2015) http://cetaf.org/taxonomy/publications
Use of Biological Material statement for negotiating Prior informed Consent – Annex within CETAF Code Of Conduct & Best Practices For ABS (Access & Benefit-Sharing) http://cetaf.org/taxonomy/publications

Davis, K., 2008, A CBD manual for botanic gardens. Botanic Gardens Conservation International, Richmond, United Kingdom ISBN: 978-1-905164-29-5 http://www.bgci.org/files/cbd_manual.pdf

Elisa Morgera, Elsa Tsioumani, and Matthias Buck, 2014, Unraveling the Nagoya Protocol. A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity. (Martinus Nijhoff) ISBN 9789004217171 doi:10.1163/9789004217188

European Commission Glossary of Terms in ABS - http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Glossary%20for%20Europa.pdf

Garrity G, Thompson L, Ussery D, Paskin N, Baker D, Desmethe P, Schindel D, Ong P, 2009, Studies on Monitoring and Tracking Genetic Resources. United Nations Convention on Biological Diversity; 2009. Report No. UNEP/CBD/WG-ABS/7/INF/2. 1 - 100 p. http://www.cbd.int/doc/meetings/abs/abswg-07/information/abswg-07-inf-02-en.pdf

Garrity, G.M., Thompson, L.M., Ussery, D.W., Paskin, N., Baker, D., Desmeth, P., Schindel, D.E. and Ong, P.S., 2009, Studies on Monitoring and Tracking Genetic Resources: An

Executive Summary. Standards in Genomic Sciences 1: 78-86
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3035216/

Global Genome Biodiversity Network (GGBN). Several helpful resources, including:
GGBN Best Practice for Access and Benefit-Sharing (2015)
http://wiki.ggbn.org/ggbn/Documents
GGBN Code of Conduct (2015) http://wiki.ggbn.org/ggbn/Documents
Standard Material Transfer Agreements for receipt and provision of genomic material (2015) http://wiki.ggbn.org/ggbn/Documents
GGBN Network Data Standard, 2015,
http://terms.tdwg.org/wiki/GGBN_Data_Standard

International Plant Exchange Network (IPEN) Code of Conduct
https://www.bgci.org/files/ABS/IPEN/IPEN%20Code%20of%20Conduct.doc (more information about IPEN can be found at https://www.bgci.org/policy/ipen/

ITPGRFA Standard Material Transfer Agreement: www.planttreaty.org

Latorre Garcia, F., Williams, C., ten Kate, K. and Cheyne, P., 2001, Results of the Pilot Project for Botanic Gardens – Booklet sets out all aspects of developing policies and procedures on ABS for botanic gardens:
https://www.bgci.org/files/ABS/Principles_on_ABS.pdf

Micro B3 Model Agreement on Access to Marine Microorganisms and Benefit-Sharing
https://www.microb3.eu/sites/default/files/pdf/MICRO_B3_ABS_model_agreement_17122013%20explanatory%20notes.pdf

Microbial Resource Research Infrastructure (MIRRI) Best Practice Manual on Access and Benefit Sharing
http://www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI_ABS_Manual_web.pdf

Model Access and Benefit Sharing Agreement between Australian Government and Access Party http://www.wipo.int/tk/en/databases/contracts/texts/australiaprovider.html

Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC) - http://bccm.belspo.be/projects/mosaicc Includes:
MOSAICC Code of Conduct, with annexes Model MTA, Model PIC application form
http://bccm.belspo.be/documents/files/projects/mosaicc/code2011.pdf

These have been updated in TRUST (see below)

Public Interest Property Advisors, 2013, Bioprospecting Resource Guide, 2nd Edition. This useful guide provides comprehensive and position-neutral lists and links to IP resources, from publications to tools, focusing on bioprospecting transactions.
http://www.piipa.org/images/PDFs/PIIPA_Bioprospecting_Resource_Guide_2013_Final.pdf

Secretariat of the Convention on Biological Diversity, 2008, Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors. Montreal, Technical Series No. 38, 140 pp. https://www.cbd.int/doc/publications/cbd-ts-38-en.pdf

Swiss Academy of Sciences. http://abs.scnat.ch/ Useful resources including:

Biber-Klemm S, Martinez SI, Jacob A, & Jetvic A., 2010, Sample Agreement on Access and Benefit Sharing for Non-Commercial Research. Swiss Academy of Sciences, Bern, Switzerland. http://www.naturalsciences.ch/organizations/biodiversity/abs/publications

Biber-Klemm, S. and S. Martinez, 2012, Access and Benefit Sharing – Good practice for academic research on genetic resources. Swiss Academy of Sciences SCNAT, Bern Switzerland: 1-60. English version http://www.naturalsciences.ch/organizations/biodiversity/abs/publications

The Principles and Common Policy Guidelines on ABS for Botanic Gardens https://www.bgci.org/policy/abs_principles/

Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva Frederic Perron-Welch in cooperation with Natasha Ali and China Williams, 2012, An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing. IUCN, Gland, Switzerland. xviii + 372 pp. https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf

TRUST - TRansparent User-friendly System of Transfer, implementing the Nagoya Protocol in microbiology. The TRUST system comprises 4 elements:

- Updated MOSAICC features with administrative workflows adapted to the structure of the Nagoya Protocol.
- Refined Material Accession Agreement (MAA) and Material Transfer Agreement (MTA) models with standardized definitions.
- An automated powerful integrated data management and processing system able to provide for any information related to microbial material: the ground breaking Global Catalogue of Microorganisms (GCM).
- Cooperative structures within the WFCC where culture collections
  - make use of the latest ICT technology.
  - conduct and facilitate research in genomics and functional genomics, thus develop capacities of storage and processing of genomic, transcriptomic and metabolomic information.
  - conduct their efforts in networks, in conformity with NP provisions on Technology Transfer, collaboration and cooperation.
- Guidelines and a handbook are downloadable. http://bccm.belspo.be/projects/trust

Union for Ethical Biotrade (UEBT) Resources including

- UEBT Principles on Patents and Biodiversity http://ethicalbiotrade.org/dl/public-and-outreach/UEBT_principles_on_patents_biodiversity_EN.pdf
- Tools - http://ethicalbiotrade.org/resources/uebt-tools/
- STD01 –Ethical BioTrade Standard 201 -04-11. http://ethicalbiotrade.org/dl/STD01_Ethical%20BioTrade%20Standard_2012.04.11_Eng.pdf
- Fair and equitable benefit sharing. Manual for the assessment of policies and practices along natural ingredient supply chains. http://ethicalbiotrade.org/dl/benefit-sharing/ABS_manual_ENG.pdf

WIPO Contracts Database and Draft Guidelines: http://www.wipo.int/tk/en/databases/contracts/index.html

Annex 2. Acronyms

ABNJ Areas beyond national jurisdiction. Refers to the open ocean (see worksheet 2.1. for more detail)
ABS Access to genetic resources and benefit-sharing
aTK Traditional Knowledge associated with Genetic Resources
ATS Antarctic Treaty System (see worksheet 2.1)
BGCI Botanic Gardens Conservation International
CBD Convention on Biological Diversity
CETAF Consortium of European Taxonomic Facilities
CHM Clearing House Mechanism
GGBN Global Genome Biodiversity Network
GR Genetic Resources
EEZ Exclusive Economic Zone of a country, which extends 200 nautical miles from the coastline.
IPEN International Plant Exchange Network
IPR Intellectual Property Rights
IRCC Internationally Recognised Certificate of Compliance
ITPGRFA International Treaty on Plant Genetic Resources for Food and Agriculture
MAT Mutually agreed terms
MOSAICC Micro-Organisms Sustainable use and Access regulation International Code of Conduct
MSA Material Supply Agreement
MTA Material Transfer Agreement
NFP National Focal Point
NP Nagoya protocol
PIC Prior informed consent
TK Traditional Knowledge
TKaGR Traditional Knowledge associated with Genetic Resources
UEBT Union for Ethical Biotrade
UN United Nations
UNCLOS United Nations Convention on Law of the Sea
UPOV International Convention for the Protection of New Varieties of Plants
WIPO World Intellectual Property Organization

Annex 3. Glossary

Access – The acquisition of Genetic Resources or of Traditional Knowledge associated with Genetic Resources from a Providing Country. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations.
The EU Regulation defines access as 'the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol'.

Access and Benefit Sharing Clearing House – Information sharing mechanism developed under the Convention on Biological Diversity to make information available on national contacts, national legislation and other matters relevant to Access and Benefits-Sharing generally and the Nagoya Protocol in particular. It is on the internet at https://absch.cbd.int/.

Accession – The addition of specimens and samples to a collection, by which process they pass under the ownership or custodianship of the Institution, including long-term loans and Genetic Resources held in trust. See also *Object Entry*.

Benefits arising from the use of genetic resources – Not defined by the CBD or the Nagoya Protocol, but may include: (1) Monetary benefits when research and developments leads to a commercial product (e.g. royalties, milestone payments, licensing fees); (2) Non-monetary benefits (e.g. technology transfer, enhancement of research skills, sharing research results, research partnerships, Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies, etc.). Examples are given in the Annex to the Nagoya Protocol (attached in Annex 4 to this document).

Biological material – All specimens and samples of or subsamples from living or dead organisms, regardless of whether they contain 'functional units of heredity' or not. See also 'Genetic material' and 'specimen'.

Biotechnology – Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Collection – A group of specimens or samples that can be seen, studied, and kept together.

Competent National Authority – The body or individual in a country authorised by that Party to sign ABS agreements.

Country of origin – means the country which possesses those genetic resources in in situ conditions (CBD definition)

Data – unless otherwise stated, information, including locality and other collecting information, permits and other agreements, and any other information provided by the supplier with the Genetic Resources.

Derivative – a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity (NP definition)

EU Regulation on ABS – This refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, which entered into force for Europe on 6 Jun 2014.

Exchange – Also '*Transfer*', and '*Permanent supply*'. Permanent transfer of specimens to a Third Party to the original agreement; note that 'exchange' implies a receipt of items in return for providing or transferring items. This is somewhat different from a straight transfer.

Genetic material – Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Genetic Resources – Genetic material of actual or potential value (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Internationally Recognised Certificate of Compliance – A record generated when the Competent National Authority of a Providing Country publishes a permit or equivalent (e.g. PIC and MAT) on the ABS Clearing House. This is given a unique

identifier by the Clearing House and provides legal surety of the genetic resources covered. It may also be used to simplify reporting.

Material Transfer Agreement (MTA) – An agreement between two institutions stipulating the terms and conditions for transferring specimens or samples, including genetic material.

Memorandum of Collaboration (MoC) – An agreement between two or more institutions to cooperate. In the context of the CETAF Code of Conduct and Best Practice this will include reference to ABS.

Mutually Agreed Terms (MAT) – An agreement reached between the Providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

Object Entry – The point at which a specimen, sample or collection enters the institution or organization, whether temporarily as a loan or being carried by a visitor for study, or with the intention of it coming into ownership or custodianship of the institution. At this point decisions based on ABS compliance and responsibilities may be taken. See also *Accession*.

Prior Informed Consent (PIC) – The permission given by the Competent National Authority of a Providing Country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework; i.e. what a user can and cannot do with the biological material, Genetic Resources or Traditional Knowledge.

Providing Country – The country supplying genetic resources collected from *in situ* sources, including populations of both wild and domesticated species, or taken from *ex situ* sources, which may or may not have originated in that country (definition from Article 2 of the Convention on Biological Diversity). See also country of origin.

Research – The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. This does not include any development of commercial applications.

Research and development – There is no definition provided in the CBD or Nagoya Protocol. Interpretation of this term may differ between different legislations.

Samples – Any type of material including biological or genetic material. These may include one or many species, and often the composition is not known.

Specimen – This includes any type of biological material.

Track - follow movements of GR or aTK once they have left the country of origin, or within an organization. 'Trace' is also used for this concept.

Traditional Knowledge (TK) – There is currently no generally accepted definition of TK at an international level. WIPO defines it as "knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity." It also notes that "TK in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations." (http://www.wipo.int/tk/en/tk/).

Traditional Knowledge associated with Genetic Resources (aTK; TKaGR) - The Nagoya Protocol and EU Regulation only cover aTK, leaving terms of access and benefit sharing relating to TK as a separate element, to be established by national legislation or in bilateral contracts.

Use – The purposes to which samples and specimens (biological and genetic material) are put, including but not limited to 'utilization' in the sense of the Nagoya Protocol.

Utilization (of GR) – To conduct research and development on the genetic and/or biochemical composition of Genetic Resources, including through the application of biotechnology as defined in Article 2 of the Convention (definition from the Nagoya Protocol).

Workflow - A workflow consists of an orchestrated and repeatable pattern of business activity enabled by the systematic organization of resources into processes that transform materials, provide services, or process information.

Annex 4. TEXT OF THE Nagoya Protocol

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR IJTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and *recognizing* that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and *affirming* the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing "distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional know ledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

ARTICLE 1

OBJECTIVE

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

ARTICLE 2

USE OF TERMS

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "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 as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

ARTICLE 3

SCOPE

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

ARTICLE 4

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS
AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

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 benefit-sharing 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.

ARTICLE 5

FAIR AND EQUITABLE BENEFIT-SHARING.

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1. above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, 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. Such sharing shall be upon mutually agreed terms.

ARTICLE 6

ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. 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.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, In a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including In relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

ARTICLE 7

ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

ARTICLE 8

SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

ARTICLE 9

CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

ARTICLE 10

GLOBAL MULTILATERAL BENEFIT-SIIARING MECIIANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional know ledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

ARTICLE 11

TRANSBOIJNDARY COOPERATION

1. In instances where the same genetic resources are found *in situ* within· the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

ARTICLE 12

TRADITIONAL KNOWLEDGE ASSOCIATED WITII
GENETIC RESOURCES

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 know ledge 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.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

ARTICLE 13

NATIONAL FOCAL POINTS AND COMPETENT
NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and

involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

ARTICLE 14

THE ACCESS AND BENEFIT-SIIARING CLEARING-HOUSE AND INFORMATION SHARING

1. An Access and Benefit-sharing Clearing-house is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-house any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

(a) Legislative, administrative and policy measures on access and benefit-sharing;

(b) Information on the national focal point and competent national authority or authorities; and

(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;

(b) Model contractual clauses;

(c) Methods and tools developed to monitor genetic resources; and

(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

ARTICLE 15

COMPLIANCE WITH DOMESTIC LEGISLATION
OR REG-ULATOR'Y REQUIREMENTS ON ACCESS
AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph I above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 16

COMPLIANCE WITH DOMESTIC LEGISLATION OR
REGULATORY REQIJIREMENTS ON ACCESS AND BENEFITSHARING
FOR TRADITIONAL KNOWLEDGE ASSOCIATED
WITII GENETIC RESOURCES

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, 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 and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 17

MONITORING THE UTILIZATION OF GENETIC RESOURCES

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

(i) Designated checkpoints would 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;

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

(iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, to the collection of relevant information at, *inter alia,* any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging 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; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

ARTICLE 18

COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with

genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

ARTICLE 19

MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

ARTICLE 20

CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

ARTICLE 21

AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia:*

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

ARTICLE 22

CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia,* the following key areas: (a) Capacity to implement, and to comply with the obligations of, this Protocol;

(a) Capacity to negotiate mutually agreed terms;

(b) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(c) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia:*

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools. and Internet based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional know ledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

ARTICLE 23

TECIINOLOGY TRANSFER, COLLABORATION AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

ARTICLE 24

NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-house.

ARTICLE 25

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for

consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities. 4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

4. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis,* to the provisions of this Article.

5. The 'developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 26

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat; it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 27

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

ARTICLE 28

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis,* to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the

Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

ARTICLE 29

MONITORING AND REPORTING

Each Party shall monitor the Implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

ARTICLE 30

PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCEWITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or -assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

ARTICLE 31

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

ARTICLE 32

SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations I-headquarters in New York, from 2 February 2011 to 1 February 2012.

ARTICLE 33

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 34

RESERVATIONS

No reservations may be made to this Protocol.

ARTICLE 35

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:

(a) Access fees/fee per sample collected or otherwise acquired;

(b) Up-front payments;

(c) Milestone payments;

(d) Payment of royalties;

(e) Licence fees in case of commercialization;

(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

(g) Salaries and preferential terms where mutually agreed;

(h) Research funding;

(i) Joint ventures;

(j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

(a) Sharing of research and development results;

(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

(c) Participation in product development;

(d) Collaboration, cooperation and contribution in education and training;

(e) Admittance to *ex situ* facilities of genetic resources and to databases;

(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including

biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

(g) Strengthening capacities for technology transfer;

(h) Institutional capacity-building;

(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

(1) Contributions to the local economy;

(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;

(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(o) Food and livelihood security benefits;

(p) Social recognition;

(q) Joint ownership of relevant intellectual property rights.

Worksheet 1 – What do you do with Genetic resources?

Organization activity	*Questions to consider* - *Will identify Requirement outlines in Worksheet 3*	*Y/N*
1.1 Acquisition of genetic resources and /or traditional knowledge associated with genetic resources	Are any genetic resources or derivatives acquired by your organization?	
	Do your staff access genetic resources from *in situ* sources in the countries where they originate?	
	Does your organization obtain genetic resources from collections or other *ex situ* sources in the countries where they originate?	
	Does your organization obtain genetic resources from third parties in countries outside the country of origin as a permanent transfer (e.g. collections, collectors, commercial suppliers, internet sellers, donations)	
	Does your organization obtain genetic resources as commodities in country of origin from 3rd parties e.g. purchasing fish in a market, and put them into a workflow where they may be utilised	
	Does your organization obtain genetic resources from third parties as a temporary transfer (e.g. identification requests, on loan)	
	Does your organization have an internal supply system operating between different countries? (for instance, does your company own collections based in different countries which exchange material between them)	
	Does your organization access traditional knowledge associated with Genetic Resources (aTK)?	
	Do visitors or researchers not employed by your organization bring genetic resources or aTK into your organization to utilise or undertake research? (see also 1.7)	
1.2 Maintaining collections of genetic resources	Does your organization hold collections of any of the following types?	
	Living collections (e.g. plants, seeds, animals, insect cultures, microbial or fungal cultures)	
	Herbarium materials, preserved animals and other organisms	
	DNA and tissue cultures	
	Biochemical extracts (derivatives)	
	Artefacts containing biological or botanical materials e.g. feathers	

Organization activity	*Questions to consider* - *Will identify Requirement outlines in Worksheet 3*	*Y/N*
	Traditional knowledge or artefacts	
	Human tissues	
1.3 Supply of Genetic Resources, extracts or derivatives to third parties	For non-commercial research only	
	For research that may lead to commercialization (e.g. Pharmaceutical, botanicals, cosmetics, agricultural and horticultural sectors)	
	For unspecified purposes	
1.4 Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)	Does it involve sequencing genetic material?	
	Does it involve research and development on the biochemical composition of genetic resources?	
	Do you obtain grants to support your research?	
1.5 Non-commercial or commercial research involving traditional knowledge associated with genetic resources		
1.6 Research involving utilisation of GR on behalf of others		
1.7 Researchers not employed by your organization carry out utilisation of GR on your premises		
1.8 Commercialization or sale to others the results of your research on genetic resources	Are you involved in any natural product development?	
1.9 Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced	Do you share benefits with provider countries?	
1.10 Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge	Does your organization have policies that address ABS requirements?	
	Are there agreed best practices, codes of conduct or guidelines on ABS within your sector that could help you?	

Worksheet 2.1 – Is the genetic resource your organization uses covered by the Nagoya Protocol?

Resource type	*Does this fall under the Nagoya Protocol?*	*Does your organization use this resource? (Y/N)*	*Steps to take (to consider under Step 4)*
Human tissues	Human tissue does not fall under the Nagoya Protocol		Ensure no pathogens are included or, if they are, take steps to manage them in the case of proposed utilization. See step 3.
Human pathogens	Human pathogens fall within the scope of the Nagoya Protocol, although there may be special consideration under Article 8(b) in the legislation of the user country or providing country.		Check regulations of providing country and user country, and act accordingly.
Commodities	The text of the Protocol makes no explicit mention of commodities. Generally biological material exported and used as commodities falls outside Access regulations. However, such material if acquired as a commodity in a user country and utilised within the meaning of the Nagoya Protocol may come under the Protocol.		National / regional regulations in the user country should be examined for clarity. Ensure PIC and MAT are established for any utilisation of genetic resources.
Material transferred under the International Treaty on Plant Genetic Resources for Agriculture (ITPGRFA)	Under Article 4 of the Nagoya Protocol addresses relationships with other international agreements and requires a mutually supportive manner for implementation. Provider countries may have special treatments for material that falls under the ITPGRFA. However, if these plant genetic resources are utilised for purposes other than research and breeding for food and agriculture they fall within the scope of the Nagoya		If use is to be entirely under the Treaty ensure provisions are managed effectively. Put systems in place to manage any transfer to use under the Nagoya Protocol. Ensure partner country is Party to ITPGRFA and/or NP.

Resource type	*Does this fall under the Nagoya Protocol?*	*Does your organization use this resource? (Y/N)*	*Steps to take (to consider under Step 4)*
	Protocol. Utilisation of crops not included in the ITPGRFA (e.g. soya, coffee, etc) also fall under the Protocol.		
Material sourced for plant breeding (covered by The International Convention for the Protection of New Varieties of Plants, UPOV)	While this may be considered an international agreement that might fall under Article 4 of the Nagoya Protocol this does not automatically remove material sourced for breeding from requirements of the Nagoya Protocol.		Regulations in both Provider and user countries should be consulted to determine legal obligations for access and use.
Marine biological material from Areas Beyond National Jurisdiction (ABNJ)	Samples including genetic resources taken from marine areas beyond national jurisdiction do not fall within the scope of the Nagoya Protocol, nor national Access regulations. At the time of writing there is negotiation within the UN and UNCLOS about the development of a benefit-sharing regime to cover ABNJ, but it is not yet in place.		Be certain where marine specimens are sourced, and seek appropriate permission if required.
Marine biological material sourced from within the Exclusive Economic Zone of a country	This falls under the sovereign rights of the country, and may be covered by Access legislation. The EEZ extends 200 nautical miles from the coastline.		Be certain where marine specimens are sourced, and seek appropriate permission from the coastal state if required prior to collection.
Marine biological material sourced from the Continental shelf outside the EEZ of a country.	Sedentary (benthic) organisms sourced from the continental shelf when this extends from the coastline beyond 200 nautical miles up to 350 nautical miles. The restriction does not apply to pelagic organisms. This aspect falls under UNCLOS Article 246.6. Note that		Be certain where and how marine specimens are sourced, and seek appropriate permission from the coastal state if required prior to collection.

Resource type	*Does this fall under the Nagoya Protocol?*	*Does your organization use this resource? (Y/N)*	*Steps to take (to consider under Step 4)*
	countries may have regulations requiring permission to be sought for access to the continental shelf area for marine scientific research, irrespective of whether or not the benthos is to be sampled.		
Biological material from areas under the Antarctic Treaty System	The Antarctic Treaty System includes the 1959 Antarctic Treaty, the 1991 Protocol on Environmental Protection to the Antarctic Treaty, and the 1980 Convention on the Conservation of Antarctic Marine Living Resources. It relates to marine and terrestrial biota in "the area south of 60° South Latitude, including all ice shelves" (Antarctic Treaty Art. VI). Samples including genetic resources from this area fall outside of the scope of the Nagoya Protocol. There may be other requirements under the ATS for sharing Benefits.		Seek appropriate permission if required.
Material sourced from within the borders of a Party to the Nagoya Protocol	This potentially falls within the scope of the Nagoya Protocol. However, a country may choose not to have legislation on Access, and may not require PIC and MAT. If a country does not exercise its sovereign rights, then there may be no legally-enforceable legal responsibilities. Note that countries may have legislation regarding collecting biota that is not access legislation as such, but which may still impose restrictions and requirements, although not under the Nagoya Protocol.		Ensure compliance with providing country legislation and regulations.

Resource type	*Does this fall under the Nagoya Protocol?*	*Does your organization use this resource? (Y/N)*	*Steps to take (to consider under Step 4)*
Material sourced from within the borders of a Party to the Nagoya Protocol before it became a Party.	This will include all countries prior to 12th October 2014, when the Nagoya Protocol came into force. Such material may not fall under the regulatory legislation of the user country. However, some provider countries are seeking to apply their access legislation under the Nagoya Protocol retrospectively, at least after 29 December 1993, when the CBD came into force. There may also have been access or other relevant legislation in place in the providing country prior to 2014, which could have put contractual requirements under PIC and MAT in place.		Ensure compliance with providing country legislation and regulations. Even though there may be no compliance issues under the Nagoya Protocol, consider reputational and civil-law challenges from providing countries.
Material sourced from within the borders of a Country which is not Party to the Nagoya Protocol.	Such a country may or may not have legislation in place which managed collecting or other activities relevant to accessing and using genetic resources. This legislation may require PIC to be granted and MAT to be agreed, creating a contract which should be honoured. The agreements do not, however, fall under the Nagoya Protocol and thus are unlikely to fall under compliance measured under the Protocol put in place in user countries.		Ensure compliance with providing country legislation and regulations. Even though there may be no compliance issues under the Nagoya Protocol, consider reputational and civil-law challenges from providing countries.
Material sourced from within the borders of a Country prior to the coming into force of the CBD	Prior to the 29th December 1993 countries did not, under international law, hold sovereign rights to genetic resources occurring within their borders. However, they may have enacted legislation requiring permission to be		Ensure compliance with providing country legislation and regulations. Good Practice would be to seek PIC and MAT if this is not in place, if

Resource type	*Does this fall under the Nagoya Protocol?*	*Does your organization use this resource? (Y/N)*	*Steps to take (to consider under Step 4)*
	sought for collecting and using such resources. Some countries may also be seeking to apply the Nagoya protocol to resources collected prior to that date.		utilization is leading to material benefit, particularly monetary.
Material held in *ex situ* collections in the country of origin	Some countries are applying their access legislation to material collected within their borders and held within *ex situ* collections (botanic gardens, museums, culture collections etc) also within their borders.		GR should be treated legally in both provider and user country as if it had been accessed from *in situ* at the time acquisition is sought from the *ex situ* collection.
Preserved material held in *ex situ* collections in countries other than the country of origin	Access to and use of such material is likely to be governed by the agreements entered into (PIC and MAT) when it was originally accessed, and thus may or may not fall under the provisions of the Nagoya Protocol. User countries may have regulations concerning the steps to be taken by users acquiring material from such collections.		Establish conditions under which material can be used.
Living material held in *ex situ* collections in countries other than the country of origin of the ancestors of the living organisms	The legal requirements surrounding such material may not be clear. In some cases the collections will have acquired the material with clear contractual conditions from the providing country. The collection holder may also have policies requiring benefit sharing or other action.		Establish conditions under which material can be used.
Traditional knowledge not associated with genetic resources but accessed in	This does not fall under the Nagoya protocol but may be addressed by other legislation in the providing country. It may also be addressed by WIPO		Consult government and other relevant stakeholders in the country of origin.

Resource type	*Does this fall under the Nagoya Protocol?*	*Does your organization use this resource? (Y/N)*	*Steps to take (to consider under Step 4)*
the country of origin			
Traditional knowledge associated with genetic resources accessed in the country of origin	This falls under the Nagoya Protocol, and consequently under any relevant legislation the country might have. There may be other legislation in the providing country. It may also be addressed by WIPO		Consult government and other relevant stakeholders in the country of origin.
Traditional knowledge associated or not associated with genetic resources not accessed in the country of origin	This may fall under the Nagoya Protocol, depending on where it was originally accessed (Party or non-party) and when (see notes on temporal scope above).		There may be ethical as well as legal reasons to investigate appropriate terms with the country of origin and indigenous communities within that country.

Worksheet 2.2 – What activities may fall under other ABS-related regulations?

The previous worksheet focussed on whether your organizations activities fall under the Nagoya Protocol. The purpose of this checklist is to help you think about what other ABS-related regulations may apply, and which you will have to address. Use Table 1 to help you.

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
2.2.1. Acquisition of genetic resources and /or traditional knowledge associated with genetic resources	Directly from *in situ* sources in the countries where they originate		International: ITPGRFA	
			International: UPOV	
			International: UNCLOS	
			International: Antarctic Treaty	
			Regional legislation as it is implementing in the Providing country.	
			National ABS legislation in providing country	
	From collections or other *ex situ* sources in the countries where they originate		Other National legislation or regulations in providing country	
			Regional legislation as it is implementing in the user country.	
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
	From third parties as a permanent transfer (e.g. collections, collectors, commercial suppliers, internet sellers, donations)		Other (list)	
	From third parties as a			

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
	temporary transfer (e.g. identification requests, on loan)			
	Organization has an internal supply system operating between different countries		Depending on when the material was originally accessed there may be requirements from both providing and user countries.	
	Organization accesses traditional knowledge associated with Genetic Resources		If the Traditional Knowledge is accessed with Genetic Resources it potentially falls under the Nagoya Protocol and thus provider and user country legislation. (see list above)	
	Researchers not employed by your organization bring GR or aTK into your organization to undertake research		Legislative frameworks and regulatory requirements likely to apply as if your organization holds the material.	
2.2.2. Maintaining collections of genetic resources	Living collections (e.g. plants, seeds, animals, insect cultures, microbial or fungal cultures)		International: ITPGRFA	
			International: UPOV	
			International: UNCLOS	
			International: Antarctic Treaty	
	Herbarium materials, preserved animals and other organisms		Regional legislation as it is implementing in the Providing country.	
			National ABS legislation in	

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
	DNA and tissue cultures		providing country at the time of access	
			Other National legislation or regulations in providing country	
			Regional legislation as it is implementing in the user country.	
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	
	Biochemical extracts (derivatives)			
	Traditional knowledge or artefacts			
2.2.3. Supply of Genetic Resources, extracts or derivatives to third parties	For non-commercial research only		International: ITPGRFA	
			International: UPOV	
	For research that may lead to commercialization (e.g. Pharmaceutical, botanicals, cosmetics, agricultural and horticultural sectors)		National ABS legislation in providing country	
			Regional legislation as it is implementing in the user country.	
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
	For unspecified purposes			
2.2.4. Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)	Involves sequencing genetic material		International: ITPGRFA	
			International: UPOV	
	Involves research and development on the biochemical composition of genetic resources		National ABS legislation in providing country	
			Regional legislation as it is implementing in the user country.	
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	
	Research is supported by grants		This can be a trigger for reporting under the user country legislation, for example in the EU.	
2.2.5. Non-commercial or commercial research involving traditional knowledge associated with genetic resources			International: ITPGRFA	
			International: UPOV	
			National ABS legislation in providing country	
			Regional legislation as it is implementing in the user country.	

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	
2.2.6. Research involving utilisation of GR on behalf of others			International: ITPGRFA	
			International: UPOV	
			National ABS legislation in providing country	
			Regional legislation as it is implementing in the user country.	
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	
2.2.7. Researchers not employed by your organization carry out utilisation of GR on your premises			International: ITPGRFA	
			International: UPOV	
			National ABS legislation in providing country	
			Regional legislation as it is implementing in the user country.	

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	
2.2.8. Commercialization or sale to others the results of your research on genetic resources	Organization is involved in natural product development		International: ITPGRFA	
			International: UPOV	
			National ABS legislation in providing country	
			Regional legislation as it is implementing in the user country.	
			ABS regulations under the Nagoya Protocol in user country (if user is a party to the Protocol).	
			Other (list)	
2.2.9. Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced	Organization shares monetary or non-monetary benefits with provider countries		National ABS legislation in providing country	
2.2.10. Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge	The organization has policies that address ABS requirements		Best practices and Codes of Conduct may be called for under the user country legislation and have a role in compliance monitoring (e.g. within the EU).	
	The sector has agreed best practices, codes of conduct or			

Organization activity	*Detail*	*Y/N from Worksheet 1*	*Legal frameworks that may apply*	*Potentially applicable to the organization? (Y/N)*
	guidelines on ABS		They are also called for in the Nagoya Protocol Article 20.	

Worksheet 3 – What are the requirements for policies and processes to manage compliance with ABS matters?

The first column in the table lists the 'Organizational activities' and the detail addressed in 'Questions to Consider' from Worksheet one. The column 'Relevant or not' should be populated with the responses to 'Y/N' from Worksheet one. For the activities and requirements identified as relevant in Worksheet one please enter the detailed requirements that your policies and procedures will have to meet. This will enable you to develop the tools needed when you come to Step four. Tick column 'completed' when the requirement is finalised.

Organization activities and requirements	**Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)**	**Completed**
3.1. Acquisition of genetic resources and /or traditional knowledge associated with genetic resources		
Requirement outline: The policies and procedures should ensure - Appropriate staff are aware of legislation and regulations for each case		
Detailed requirements for your organization: For example: Means of targeting relevant staff established; Tools to help staff be aware of regulations in a timely fashion Training programme developed and implemented Training / reference materials prepared and distributed Regular review		
3.1.1. Directly from *in situ* sources in the countries where they originate		
Requirement outline: The policies and procedures should ensure - Staff and anyone else acting in the name of the organization take appropriate actions when collecting GR from in situ sources, including obtaining permits and other relevant agreements and documents.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Agreements for collecting and research (including collecting permits, Memoranda of Cooperation etc) are in accordance with organization policy and capacity to meet, and are authorised by the appropriate person. This may include legal requirements under		

Organization activities and requirements	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Completed
the Nagoya Protocol, contractual agreements on details of benefit-sharing.		
Detailed requirements for your organization:		
3.1.2. From collections or other ex situ sources in the countries where they originate **And/or** **3.1.3. From third parties as a permanent transfer (e.g. collections, collectors, commercial suppliers, internet sellers, donations)**		
Requirement outline: The policies and procedures should ensure - GR sourced from third parties has known legal provenance, and is accompanied by appropriate documentation.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Non-legal GR or GR of uncertain provenance are identified as such at point of acquisition by organization and appropriate action taken		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Storage and of data and documents of (i) all GR entering the organization and (ii) all GR passing under the ownership of the organization.		
Detailed requirements for your organization:		
3.1.4. From third parties as a temporary transfer (e.g. identification requests, on loan)		
Requirement outline: The policies and procedures should ensure - Provenance of the material is understood and its acceptance and incorporation into research projects involving utilization managed appropriately.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Reporting and benefit-sharing requirements understood and followed.		
Detailed requirements for your organization:		

Organization activities and requirements	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Completed
3.1.5. Organization has an internal supply system operating between different countries		
Requirement outline: The policies and procedures should ensure - Appropriate data and documentation are associated with GR transferred within the organization, and compliance with the different regulatory requirements operating in the countries where supply and receipt are based.		
Detailed requirements for your organization:		
3.1.6. Organization accesses traditional knowledge associated with Genetic Resources		
Requirement outline: The policies and procedures should ensure - Traditional Knowledge accessed with Genetic Resources is acquired with appropriate legal and ethical management, including to the owners of the TK.		
Detailed requirements for your organization:		
3.1.7. Researchers not employed by your organization bring GR or aTK into your organization to undertake research		
Requirement outline: The policies and procedures should ensure - Data collection is managed so that there is clarity between material belonging to the institution and that which is brought in and being utilized by someone not belonging to the organization. Because the organization may be responsible for reporting on utilization to a national regulator, to manage any visitor's utilization, even of material the visitor has brought with them, meets legal requirements. Data required for reporting should be collected.		
Detailed requirements for your organization:		
3.2. Maintaining collections of genetic resources		
3.2.1. Living collections (e.g. plants, seeds, animals, insect cultures, microbial or fungal cultures) **And/or** **3.2.2. Herbarium materials, preserved animals and other organisms** **And/or**		

Organization activities and requirements	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Completed
3.2.3. DNA and tissue cultures **And/or** **3.2.4. Biochemical extracts (derivatives)** **And/or** **3.2.5. Traditional knowledge or artefacts**		
Requirement outline: The policies and procedures should ensure - The organization and its staff understand what collections are held by the organization and who had responsibility for ABS compliance actions.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - To ensure that any collections on the organization's property that are not the responsibility of the organization are recognised and the person responsible for ABS issues regarding that collection is aware of the fact and is managing the issues appropriately.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Policies and processes emplaced to manage compliance with ABS legislation and conditions are applied to all collections that are the responsibility of the organization.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Restrictions and requirements associated with the specimens or samples are known and are followed, so that benefits are shared as agreed and prohibited actions are not carried out.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Information relevant to ABS agreements and regulations are stored so that the institution can manage compliance, including delivery of benefits, preventing unauthorised utilization and facilitating reporting under national legislation.		

Organization activities and requirements	**Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)**	**Completed**
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Traditional knowledge or artefacts are stored appropriately and conditions under which is documented, digitized, archived, released or made public are managed in accordance with conditions under which it was acquired.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Material is disposed of only in a manner consistent with the conditions under which it was acquired.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - The collection is audited for ABS compliance on a regular basis.		
Detailed requirements for your organization:		
3.3. Supply of Genetic Resources, extracts or derivatives to third parties		
3.3.1. For non-commercial research only **And/or** **3.3.2. For research that may lead to commercialization (e.g. Pharmaceutical, botanicals, cosmetics, agricultural and horticultural sectors)** **And/0r** **3.3.3. For unspecified purposes**		
Requirement outline: The policies and procedures should ensure - Genetic resources are supplied to third parties only under the conditions with which it was acquired.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - If the third party wishes to utilize the GR in a		

Organization activities and requirements	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Completed
manner not agreed under the original conditions of acquisition there is a mechanism to seek approval form the providing country for change of use.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Appropriate documentation is transferred to the third party with the material.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Appropriate action can be taken regarding third parties borrowing material who do not abide by the terms and conditions regarding its utilization.		
Detailed requirements for your organization:		
3.4. Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)		
3.4.1. Involves sequencing genetic resources **And/or** **3.4.2. Involves research and development on the biochemical composition of genetic resources, including derivatives**		
Requirement outline: The policies and procedures should ensure - Utilization is only carried out if this is allowed by the original or renegotiated agreement with the country of origin. Staff need to discover this rapidly and efficiently. Consider also associated organisms (e.g. parasites) not mentioned in the original permit.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Process for seeking revised PIC and renegotiate MAT if proposed utilization different from what has been agreed		
Detailed requirements for your organization:		

Organization activities and requirements	**Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)**	**Completed**
Requirement outline: The policies and procedures should ensure - Reporting to national Regulator can be made and clarity as to who has responsibility for making it.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Records of the utilization and when it ceased are made and retained		
Detailed requirements for your organization:		
3.5.3. Research is supported by grants		
Requirement outline: The policies and procedures should ensure - In the EU this may be a trigger for reporting		
Detailed requirements for your organization:		
3.5. Non-commercial or commercial research involving traditional knowledge associated with genetic resources		
Requirement outline: The policies and procedures should ensure - TK is acquired with legal compliance and operate ethically		
Detailed requirements for your organization:		
3.6. Research involving utilization of GR on behalf of others		
Requirement outline: The policies and procedures should ensure - Clarity on who should be making any reports to national Regulator.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Clarity on provenance of GR and whether utilization is permitted, and means of response to information.		

Organization activities and requirements	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Completed
Detailed requirements for your organization:		
3.7. Researchers not employed by your organization carry out utilization of GR on your premises		
Requirement outline: The policies and procedures should ensure - Clarity on who should be making any reports to national Regulator.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Clarity on provenance of GR and whether utilization is permitted, and means of response to information.		
Detailed requirements for your organization:		
3.8. Commercialization or sale to others the results of your research on genetic resources		
Requirement outline: The policies and procedures should ensure - Reports are made to the national Regulator when required under legislation, and information is made available efficiently to enable this to happen.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Appropriate information on ABS requirements is transferred to others in the value chain.		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - Commercialization is permitted in the agreement with the providing country and others in the value chain, and that benefit sharing arrangements are in place and activated.		
Detailed requirements for your organization:		
3.9. Sharing benefits (monetary or non-monetary) with the countries from which genetic resources		

Organization activities and requirements	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Completed
or traditional knowledge associated with genetic resources were sourced		
Requirement outline: The policies and procedures should ensure - Mechanism is in place to ensure benefits are shared as agreed, and this is recorded.		
Detailed requirements for your organization:		
3.10. Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge		
3.10.1. The organization has policies that address ABS requirements **And/or** **3.10.2. The sector has agreed best practices, codes of conduct or guidelines on ABS**		
Requirement outline: The policies and procedures should ensure - Policies are developed and periodically reviewed		
Detailed requirements for your organization:		
Requirement outline: The policies and procedures should ensure - If there are agreed sectoral best practices, the organization's policies and processes implement these effectively.		
Detailed requirements for your organization:		

Worksheet 4 – What tools (policies and procedures) are required to manage compliance with ABS matters?

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
4.1. Acquisition of genetic resources and /or traditional knowledge associated with genetic resources			The following apply to acquisition of GR from other countries, irrespective of the route:	
			Organizational policy on ABS aspects of acquisition, including field collecting by staff, object entry to the organization, passing into ownership of the organization.	
			Identification of individual within organization responsible for authorising acquisition and implementing acquisition policies.	
			Identification of Legal vs non-legal GR at point of acquisition by organization; surety of obtaining necessary information and documentation.	
			Means of discovering whether the providing country is a Party to the Nagoya Protocol at time of in situ access of the GR.	
			Document and information entry process to ensure both can be retrieved optimally and specimens or samples can be associated with them at subsequent stages of use or storage.	

WORKSHEET FOR STEP 4: PREPARATION FOR IMPLEMENTATION

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
			Will need to include (i) all GR entering the organization and (ii) all GR passing under the ownership of the organization.	
	Directly from *in situ* sources in the countries where they originate		Procedures to ensure staff and anyone else acting in the name of the organization take appropriate actions when collecting GR from in situ sources	
	From collections or other *ex situ* sources in the countries where they originate		Procedures to ensure material from ex situ collections are accessed and accepted in accordance with the providing country ABS legislation, and any additional institutional requirements are met with.	
	From third parties as a permanent transfer (e.g. collections, collectors, commercial suppliers, internet sellers, donations)		Procedures to ensure GR sourced from third parties has known legal provenance, and is accompanied by appropriate documentation.	
	From third parties as a temporary transfer (e.g. identification requests, on		Procedures to record legal provenance.	
			Procedures to ensure staff ensure and comply with requirements and restrictions	

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
	loan)		Guidelines on what may be done with such material and how to dispose of it once the permitted activity has been carried out.	
	Organization has an internal supply system operating between different countries		Procedures and MTAs to transfer appropriate data and documentation associated with GR within organization.	
			Compliance measures for different regulatory requirements operating in the countries where supply and receipt are based are in place and incorporated into transfer systems.	
	Organization accesses traditional knowledge associated with Genetic Resources		Processes to acquire Traditional Knowledge accessed with Genetic Resources with appropriate legal and ethical management, including to the owners of the TK.	
	Researchers not employed by your organization bring GR or TKaGR into your organization to undertake research		Specific entry protocols for GR brought in by external researchers, including clear labelling.	
			Data collection and storage process system in place if the organization has legal responsibility for reporting on utilization under national legislation	

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
4.2. Maintaining collections of genetic resources	Living collections (e.g. plants, seeds, animals, insect cultures, microbial or fungal cultures)		Identity of person or persons responsible for ABS compliance actions, and the scope of their responsibilities clear to all staff. Responsibilities of all staff clearly understood	
			Policies and processes emplaced to manage compliance with ABS legislation and conditions are applied to all collections that are the responsibility of the organization.	
			Policies and procedures to ensure uniformity of ABS management and information management across organization	
			Procedures to address collections on the organization's property that are not the responsibility of the organization are recognised and that issues are managed appropriately.	
			Procedures to make restrictions and requirements associated with the specimens or samples easily and rapidly known to personnel.	
	Herbarium materials,		Data management system that stores information relevant to ABS agreements and regulations so that the institution can manage	

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
	preserved animals and other organisms		compliance, including delivery of benefits, preventing unauthorised utilization and report under national legislation.	
	DNA and tissue cultures		System to store Traditional knowledge or artefacts and the information gathered from them securely, as well as other sensitive information; safeguards against inadvertent release of digitised or undigitized information.	
	Biochemical extracts (derivatives)		Disposal policy and procedures include means of ensuring material is disposed of only in a manner consistent with the conditions under which it was acquired.	
	Traditional knowledge or artefacts		Regular ABS audit scheduled	
4.3. Supply of Genetic Resources, extracts or derivatives to third parties	For non-commercial research only		Genetic resources are supplied to third parties only under the conditions with which it was acquired.	
	For research that may lead to commercialization (e.g. Pharmaceutical, botanicals, cosmetics, agricultural and horticultural sectors		If the third party wishes to utilize the GR in a manner not agreed under the original conditions of acquisition there is a mechanism to seek approval form the providing country for change of use.	
			Appropriate documentation is transferred to	

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
			the third party with the material.	
	For unspecified purposes)		Policies and processes to dictate action should third parties borrowing material not abide by the terms and conditions regarding its utilization.	
4.4. Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)	Involves sequencing genetic material		Procedures that enable staff discover restrictions on utilization rapidly and efficiently.	
			Procedure in place for seeking revised PIC and renegotiate MAT if proposed utilization different from what has been agreed	
	Involves research and development on the biochemical composition of genetic resources		Procedure in place to ensure and facilitate reporting to national Regulator.	
			Procedure and database available to retain records of the utilization and when it ceased.	
	Research is supported by grants		If required, means of associating grant information with utilization records	

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
4.5. Non-commercial or commercial research involving traditional knowledge associated with genetic resources			Policies and procedures must ensure that staff are particularly careful to ensure that they follow national, local and international procedures to obtain prior informed consent from all relevant stakeholders for the work they wish to do. This may involve working with local and indigenous communities to an extent greater than national regulations may require, to ensure that the organization is completely legally and ethically correct.	
			Special care may neeed to be taken over aTK when stored in a database, to prevent inadvertent publication or sharing in contravention to PIC and MAT.	
4.6. Research involving utilization of GR on behalf of others			Policy in place determining responsibility for reporting and information made available automatically to partners or others supplying GR for utilization	
			Procedures to establish and record provenance of GR and whether utilization is permitted.	
			Procedures in place to address situations where utilization is not permitted.	

WORKSHEET FOR STEP 4: PREPARATION FOR IMPLEMENTATION

Organization activity	Detail	Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)	Implementation tools and procedures	Tool in place to meet requirements identified in Step 3 (Y/N)
4.7. Researchers not employed by your organization carry out utilization of GR on your premises			Policy in place determining responsibility for reporting and information made available automatically to visiting researchers	
			Procedures to establish and record provenance of GR and whether utilization is permitted.	
			Procedures in place to address situations where utilization is not permitted.	
4.8. Commercialization or sale to others the results of your research on genetic resources	Organization is involved in natural product development		Procedures to prepare and deliver reports to the national Regulator when required under legislation	
			Procedures in place to transfer appropriate information on ABS requirements is to others in the value chain.	
			Procedures to check that commercialization is permitted in the agreement with the providing country and others in the value chain	

WORKSHEET FOR STEP 4: PREPARATION FOR IMPLEMENTATION

Organization activity	**Detail**	**Is this Relevant to your organization or not? (from Worksheet 1 – delete any rows that are not relevant)**	**Implementation tools and procedures**	**Tool in place to meet requirements identified in Step 3 (Y/N)**
4.9. Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced	Organization shares monetary or non-monetary benefits with provider countries		Mechanism is in place to ensure benefits are shared as agreed, and this is recorded.	
4.10. Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge	The organization has policies that address ABS requirements		Policies in place Policy review scheduled	
	The sector has agreed best practices, codes of conduct or guidelines on ABS		Sectoral best practices used to inform policies and procedures of organization	

Worksheet 5 – Checklist for training elements covering tools and procedures developed in Step 4

Organization activity	Detail	Y/N from Worksheet 1	Implementation tools and procedures	Training materials developed (Y/N)
5.1. Acquisition of genetic resources and /or traditional knowledge associated with genetic resources			The following apply to acquisition of GR from other countries, irrespective of the route:	
			Organizational policy on ABS aspects of acquisition, including field collecting by staff, object entry to the organization, passing into ownership of the organization.	
			Identification of individual within organization responsible for authorising acquisition and implementing acquisition policies.	
			Identification of Legal vs non-legal GR at point of acquisition by organization; surety of obtaining necessary information and documentation.	
			Means of discovering whether the providing country is a Party to the Nagoya Protocol at time of in situ access of the GR.	
			Document and information entry process to ensure both can be retrieved optimally and specimens or samples can be associated with them at subsequent stages of use or storage. Will need to include (i) all GR entering the organization and (ii) all GR passing under the ownership of the organization.	
	Directly from *in situ* sources in the countries where they originate		Procedures to ensure staff and anyone else acting in the name of the organization take appropriate actions when collecting GR from in situ sources	
	From collections or other *ex*			

Organization activity	Detail	Y/N from Worksheet 1	Implementation tools and procedures	Training materials developed (Y/N)
	situ sources in the countries where they originate		Procedures to ensure material from ex situ collections are accessed and accepted in accordance with the providing country ABS legislation, and any additional institutional requirements are met with.	
	From third parties as a permanent transfer (e.g. collections, collectors, commercial suppliers, internet sellers, donations)		Procedures to ensure GR sourced from third parties has known legal provenance, and is accompanied by appropriate documentation.	
	From third parties as a temporary transfer (e.g. identification requests, on loan)		Procedures to record legal provenance.	
			Procedures to ensure staff ensure and comply with requirements and restrictions	
			Guidelines on what may be done with such material and how to dispose of it once the permitted activity has been carried out.	
	Organization has an internal supply system operating between different countries		Procedures and MTAs to transfer appropriate data and documentation associated with GR within organization.	
			Compliance measures for different regulatory requirements operating in the countries where supply and receipt are based are in place and incorporated into transfer systems.	
	Organization accesses traditional knowledge associated with Genetic Resources		Processes to acquire Traditional Knowledge accessed with Genetic Resources with appropriate legal and ethical management, including to the owners of the TK.	

Organization activity	Detail	Y/N from Worksheet 1	Implementation tools and procedures	Training materials developed (Y/N)
	Researchers not employed by your organization bring GR or TKaGR into your organization to undertake research		Specific entry protocols for GR brought in by external researchers, including clear labelling.	
			Data collection and storage process system in place if the organization has legal responsibility for reporting on utilisation under national legislation	
5.2. Maintaining collections of genetic resources	Living collections (e.g. plants, seeds, animals, insect cultures, microbial or fungal cultures)		Identity of person or persons responsible for ABS compliance actions, and the scope of their responsibilities clear to all staff. Responsibilities of all staff clearly understood	
			Policies and processes emplaced to manage compliance with ABS legislation and conditions are applied to all collections that are the responsibility of the organization.	
			Policies and procedures to ensure uniformity of ABS management and information management across organization	
			Procedures to address collections on the organization's property that are not the responsibility of the organization are recognised and that issues are managed appropriately.	
			Procedures to make restrictions and requirements associated with the specimens or samples easily and rapidly known to personnel.	
	Herbarium materials, preserved animals and other		Data management system that stores information relevant to ABS agreements and regulations so that the institution can manage compliance, including delivery of benefits,	

Organization activity	Detail	Y/N from Worksheet 1	Implementation tools and procedures	Training materials developed (Y/N)
	organisms		preventing unauthorised utilisation and report under national legislation.	
	DNA and tissue cultures		System to store Traditional knowledge or artefacts and the information gathered from them securely, as well as other sensitive information; safeguards against inadvertent release of digitised or undigitized information.	
	Biochemical extracts (derivatives)		Disposal policy and procedures include means of ensuring material is disposed of only in a manner consistent with the conditions under which it was acquired.	
	Traditional knowledge or artefacts		Regular ABS audit scheduled	
5.3. Supply of Genetic Resources, extracts or derivatives to third parties	For non-commercial research only		Genetic resources are supplied to third parties only under the conditions with which it was acquired.	
	For research that may lead to commercialisation (e.g. Pharmaceutical, botanicals, cosmetics, agricultural and horticultural sectors		If the third party wishes to utilise the GR in a manner not agreed under the original conditions of acquisition there is a mechanism to seek approval form the providing country for change of use.	
	For unspecified purposes)		Appropriate documentation is transferred to the third party with the material.	
			Policies and processes to dictate action should third parties borrowing material not abide by the terms and conditions regarding its utilisation.	
5.4. Non-commercial or commercial	Involves sequencing genetic		Procedures that enable staff discover	

Organization activity	Detail	Y/N from Worksheet 1	Implementation tools and procedures	Training materials developed (Y/N)
research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)	material		restrictions on utilisation rapidly and efficiently.	
			Procedure in place for seeking revised PIC and renegotiate MAT if proposed utilisation different from what has been agreed	
	Involves research and development on the biochemical composition of genetic resources		Procedure in place to ensure and facilitate reporting to national Regulator.	
			Procedure and database available to retain records of the utilisation and when it ceased.	
	Research is supported by grants		If required, means of associating grant information with utilisation records	
5.5. Non-commercial or commercial research involving traditional knowledge associated with genetic resources			Policy and procedure in place to train staff.	
			Specific database and document handling procedures in place.	
5.6. Research involving utilisation of GR on behalf of others			Policy in place determining responsibility for reporting and information made available automatically to partners or others supplying GR for utilisation	
			Procedures to establish and record provenance of GR and whether utilisation is permitted.	
			Procedures in place to address situations where utilisation is not permitted.	
5.7. Researchers not employed by your organization carry out utilisation of GR on your premises			Policy in place determining responsibility for reporting and information made available automatically to visiting researchers	

Organization activity	Detail	Y/N from Worksheet 1	Implementation tools and procedures	Training materials developed (Y/N)
			Procedures to establish and record provenance of GR and whether utilisation is permitted.	
			Procedures in place to address situations where utilisation is not permitted.	
5.8. Commercialization or sale to others the results of your research on genetic resources	Organization is involved in natural product development		Procedures to prepare and deliver reports to the national Regulator when required under legislation	
			Procedures in place to transfer appropriate information on ABS requirements is to others in the value chain.	
			Procedures to check that commercialisation is permitted in the agreement with the providing country and others in the value chain	
5.9. Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced	Organization shares monetary or non-monetary benefits with provider countries		Mechanism is in place to ensure benefits are shared as agreed, and this is recorded.	
5.10. Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge	The organization has policies that address ABS requirements		Policies in place Policy review scheduled	
	The sector has agreed best practices, codes of conduct or guidelines on ABS		Sectoral best practices used to inform policies and procedures of organization	

Worksheet 6 – Detailed ABS Audit

Organization activity	Detail	Y/N from Worksheet 1	Organizational Requirement to be met	Is this in place? (Y/N)
6.1. Acquisition of genetic resources and /or traditional knowledge associated with genetic resources	From other countries		Appropriate staff are sufficiently aware of legislation and regulations for each case	
			Staff and anyone else acting in the name of the organization take appropriate actions when collecting GR from in situ sources, including obtaining permits and other relevant agreements and documents.	
	Directly from *in situ* sources in the countries where they originate		Agreements for collecting and research (including collecting permits, Memoranda of Cooperation etc) are in accordance with organization policy and capacity to meet, and are authorised by the appropriate person. This may include legal requirements under the Nagoya Protocol, contractual agreements on details of benefit-sharing.	
			GR sourced from third parties has known legal provenance, and is accompanied by appropriate documentation.	
			Legal vs non-legal GR are filtered at point of acquisition by organization.	
	From collections or other *ex situ* sources in the countries where they originate		Storage and timely location of data and documents of (i) all GR entering the organization and (ii) all GR passing under the ownership of the organization.	

Organization activity	Detail	Y/N from Worksheet 1	Organizational Requirement to be met	Is this in place? (Y/N)
	From third parties as a permanent transfer (e.g. collections, collectors, commercial suppliers, internet sellers, donations)			
	From third parties as a temporary transfer (e.g. identification requests, on loan)		Inappropriate actions (e.g. incorporation into research projects involving utilization) are not undertaken, and that provenance of the material is understood and managed appropriately [***NB – I think this will need attention and further explanation***]	
	Organization has an internal supply system operating between different countries		Appropriate data and documentation are associated with GR transferred within the organization, and compliance with the different regulatory requirements operating in the countries where supply and receipt are based.	
	Organization accesses traditional knowledge associated with Genetic Resources		Traditional Knowledge accessed with Genetic Resources is acquired with appropriate legal and ethical management, including to the owners of the TK.	
	Researchers not employed by your organization bring GR or TKaGR into your organization to undertake research		Data collection is managed so that there is clarity between material belonging to the institution and that which is brought in and being utilized by someone not belonging to the organization. Because the organization may be responsible for reporting on utilization to a national regulator, to manage any visitor's utilization, even of material the visitor has brought with them, meets legal requirements. Data	

Organization activity	Detail	Y/N from Worksheet 1	Organizational Requirement to be met	Is this in place? (Y/N)
			required for reporting should be collected.	
6.2. Maintaining collections of genetic resources	Living collections (e.g. plants, seeds, animals, insect cultures, microbial or fungal cultures)		The organization and its staff understand what collections are held by the organization and who had responsibility for ABS compliance actions.	
			To ensure that any collections on the organization's property that are not the responsibility of the organization are recognised and the person responsible for ABS issues regarding that collection is aware of the fact and is managing the issues appropriately.	
			Policies and processes emplaced to manage compliance with ABS legislation and conditions are applied to all collections that are the responsibility of the organization.	
			Restrictions and requirements associated with the specimens or samples are known and are followed, so that benefits are shared as agreed and prohibited actions are not carried out.	
	Herbarium materials, preserved animals and other organizms		Information relevant to ABS agreements and regulations are stored so that the institution can manage compliance, including delivery of benefits, preventing unauthorised utilization and facilitating reporting under national legislation.	
	DNA and tissue cultures		Traditional knowledge or artefacts are stored appropriately and conditions under which is documented, digitized, archived, released or made	

Organization activity	Detail	Y/N from Worksheet 1	Organizational Requirement to be met	Is this in place? (Y/N)
	Biochemical extracts (derivatives)		public are managed in accordance with conditions under which it was acquired.	
			Material is disposed of only in a manner consistent with the conditions under which it was acquired.	
	Traditional knowledge or artefacts		The collection is audited for ABS compliance on a regular basis.	
6.3. Supply of Genetic Resources, extracts or derivatives to third parties	For non-commercial research only		Genetic resources are supplied to third parties only under the conditions with which it was acquired.	
	For research that may lead to commercialization (e.g. Pharmaceutical, botanicals, cosmetics, agricultural and horticultural sectors		If the third party wishes to utilize the GR in a manner not agreed under the original conditions of acquisition there is a mechanism to seek approval form the providing country for change of use.	
			Appropriate documentation is transferred to the third party with the material.	
	For unspecified purposes)		Appropriate action can be taken regarding third parties borrowing material who do not abide by the terms and conditions regarding its utilization.	
6.4. Non-commercial or commercial research on genetic resources (e.g. systematics, ethnobotany, phytochemistry, biochemical properties)	Involves sequencing genetic material		Utilization is only carried out if this is allowed by the original or renegotiated agreement with the country of origin. Staff need to discover this rapidly and efficiently.	
			Process for seeking revised PIC and renegotiate MAT if proposed utilization different from what has been agreed	
	Involves research and development on the		Reporting to national Regulator can be made and clarity as to who has responsibility for making it.	

WORKSHEET FOR STEP 6: DETAILED ABS AUDIT

Organization activity	Detail	Y/N from Worksheet 1	Organizational Requirement to be met	Is this in place? (Y/N)
	biochemical composition of genetic resources		Records of the utilization and when it ceased are made and retained.	
	Research is supported by grants		In the EU this may be a trigger for reporting	
6.5. Non-commercial or commercial research involving traditional knowledge associated with genetic resources			Staff understand special requirements for dealing with aTK	
			Data and document management systems treat aTK appropriately	
6.6. Research involving utilization of GR on behalf of others			Clarity on who should be making any reports to national Regulator.	
			Clarity on provenance of GR and whether utilization is permitted, and means of response to information.	
6.7. Researchers not employed by your organization carry out utilization of GR on your premises			Clarity on who should be making any reports to national Regulator.	
			Clarity on provenance of GR and whether utilization is permitted, and means of response to information.	
6.8. Commercialization or sale to others the results of your research on genetic resources	Organization is involved in natural product development		Reports are made to the national Regulator when required under legislation, and information is made available efficiently to enable this to happen.	
			Appropriate information on ABS requirements is transferred to others in the value chain.	

Organization activity	Detail	Y/N from Worksheet 1	Organizational Requirement to be met	Is this in place? (Y/N)
			Commercialization is permitted in the agreement with the providing country and others in the value chain, and that benefit sharing arrangements are in place and activated.	
6.9. Sharing benefits (monetary or non-monetary) with the countries from which genetic resources or traditional knowledge associated with genetic resources were sourced	Organization shares monetary or non-monetary benefits with provider countries		Mechanism is in place to ensure benefits are shared as agreed, and this is recorded.	
6.10. Organizational or sectoral best practices or guidelines dealing with genetic resources or traditional knowledge	The organization has policies that address ABS requirements		Policies are developed and periodically reviewed	
	The sector has agreed best practices, codes of conduct or guidelines on ABS		If there are agreed sectoral best practices, the organization's policies and processes implement these effectively.	