

Explanation of the Nagoya Protocol on Access and Benefit Sharing and its implication for microbiology

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Abstract

Working with genetic resources and associated data requires greater attention since the Nagoya Protocol on Access and Benefit Sharing (ABS) came into force in October 2014. Biologists must ensure that they have legal clarity in how they can and cannot use the genetic resources on which they carry out research. Not only must they work within the spirit in the Convention on Biological Diversity (<https://www.cbd.int/convention/articles/default.shtml?a=cbd-02>) but also they may have regulatory requirements to meet. Although the Nagoya Protocol was negotiated and agreed globally, it is the responsibility of each country that ratifies it to introduce their individual implementing procedures and practices. Many countries in Europe, such as the UK, have chosen not to put access controls in place at this time, but others already have laws enacted providing ABS measures under the Convention on Biological Diversity or specifically to implement the Nagoya Protocol. Access legislation is in place in many countries and information on this can be found at the ABS Clearing House (<https://absch.cbd.int/>). For example, Brazil, although not a Party to the Nagoya Protocol at the time of writing, has Law 13.123 which entered into force on 17 November 2015, regulated by Decree 8.772 which was published on 11 May 2016. In this case, export of Brazilian genetic resources is not allowed unless the collector is registered in the National System for Genetic Heritage and Associated Traditional Knowledge Management (SisGen). The process entails that a foreign scientist must first of all be registered working with someone in Brazil and have authorization to collect. The enactment of European Union Regulation no. 511/2014 implements Nagoya Protocol elements that govern compliance measures for users and offers the opportunity to demonstrate due diligence in sourcing their organisms by selecting from holdings of 'registered collections'. The UK has introduced a Statutory Instrument that puts in place enforcement measures within the UK to implement this European Union Regulation; this is regulated by Regulatory Delivery, Department for Business, Energy and Industrial Strategies. Scientific communities, including the private sector, individual institutions and organizations, have begun to design policy and best practices for compliance. Microbiologists and culture collections alike need to be aware of the legislation of the source country of the materials they use and put in place best practices for compliance; such best practice has been drafted by the Microbial Resource Research Infrastructure, and other research communities such as the Consortium of European Taxonomic Facilities, the Global Genome Biodiversity Network and the International Organisation for Biological Control have published best practice and/or codes of conduct to ensure legitimate exchange and use of genetic resources.

INTRODUCTION

Microbiology research has increasingly been operating against a background of laws and regulations that impact on the collection of new material from the wild, the research that is carried out on it and the ways in which the results of

that research are shared with the originating country. These laws and regulations come under the heading of 'Access and Benefit Sharing' (ABS), and they have recently been brought into sharp relief by the coming into force of a new international regime, the Nagoya Protocol. This paper is intended

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Abbreviations: ABS, Access and Benefit Sharing; CABI, Centre for Agriculture and Biosciences International; CBD, Convention on Biological Diversity; CNA, Competent National Authority; CETAF, Consortium of European Taxonomic Facilities; Defra, Department for Environment, Food and Rural Affairs; EU, European Union; ICMBio, Instituto Chico Mendes de Conservação da Biodiversidade; IRCC, Internationally Recognized Certificate of Compliance; MAT, mutually agreed terms; mBRC, microbial domain Biological Resource Centre; MIRRI, Microbial Resource Research Infrastructure; MTA, material transfer agreement; NFP, National Focal Point; PIC, prior informed consent.

to provide clarity on how microbiology is affected and on how research and collections should react.

The Convention on Biological Diversity (CBD) recognizes in its Article 3 that ‘States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources’. Thus, countries may control who can collect (‘access’) biological specimens and samples within their borders. Under the Convention’s Objectives and specifically Article 15, which recognizes the sovereign rights of states over their natural resources, countries expect a fair and equitable share of any benefits arising from the commercial and other utilization of the ‘genetic resources’ of this material. To facilitate this, countries are required to enact legislation or other regulatory requirements to manage access and, as part of the process of granting permission to users to acquire specimens and samples from within their borders, require the user to seek and receive ‘prior informed consent’ (PIC) for what they wish to do. Furthermore, users and providers of genetic resources and associated traditional knowledge are expected to agree ‘mutually agreed terms’ (MAT) of use, including the benefits they might share. Such benefits might be monetary or non-monetary, such as capacity building or information.

An issue for many countries has been that they had no clear way of managing compliance by users once they had left their borders. This is addressed by the Nagoya Protocol. Parties to the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, which came into force on 12 October 2014, are required to ensure that users of genetic resources within their jurisdiction operate in compliance with regulations and laws in providing countries. Countries become Party to the Protocol through a process of ratification and, as part of that process, are likely to put relevant legislation in place; at the time of writing, 74 countries have ratified the Nagoya Protocol.

The objective of the Protocol is to ensure benefit sharing from the utilization of genetic resources and associated traditional knowledge in order to contribute to the conservation and sustainable use of biodiversity; this is done through the following:

- Preventing the utilization of genetic resources, or associated traditional knowledge, which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol
- Supporting the effective implementation of benefit-sharing commitments set out in MAT between providers and users
- Improving the conditions for legal certainty in connection with the utilization of genetic resources and traditional knowledge.

In order to achieve this, Parties will provide on the ABS Clearing House (<https://absch.cbd.int/>) records of the

relevant legislation or other regulatory requirements, including where access provisions apply, and they will designate an ABS National Focal Point (NFP) to provide information and a Competent National Authority (CNA) to provide PIC and the necessary permits. When a permit or equivalent is issued, the CNA will publish this (without confidential content) as an Internationally Recognized Certificate of Compliance (IRCC) on the ABS Clearing House. Parties will also monitor utilization within their jurisdiction by designating checkpoints to determine whether genetic resources being utilized have been accessed in accordance with PIC and whether MAT have been established, and they will place reports of utilization on the ABS Clearing House as Checkpoint Communiqués.

The European Union (EU) ratified the Nagoya Protocol in October 2014 and, as a Party, enacted EU Regulation (no. 511/2014) on ABS compliance (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511>) simultaneously with the coming into force of the Nagoya Protocol. It was followed in November 2015 by a Commission Implementing Regulation (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_275_R_0003&from=FR).

All Member States (and users of genetic resources and associated traditional knowledge in the EU) are bound by these regulations, whether or not they are individually Party to the Protocol, but are free to decide whether or not they control access, which is not covered by the EU Regulations. Most EU Member States will grant free access to their genetic resources (although some are considering controls, such as Croatia, Hungary, France and Spain).

The UK has chosen not to control access at this time but has enacted a Statutory Instrument which puts in place the required enforcement measures to implement the EU Regulations. UK researchers need to be aware of the Nagoya Protocol (Compliance) Regulations 2015 (www.legislation.gov.uk/ukxi/2015/821/pdfs/ukxi_20150821_en.pdf). The Regulations require users to make Declarations of Due Diligence at set points in the process of utilization and commercialization. As required by the EU Regulation, the UK Statutory Instrument provides the framework by which the UK can enforce the Regulation. This legal framework will continue to apply until any legal changes resulting from the UK withdrawal from the EU are put in place.

Many countries have existing ABS measures, such as South Africa and India, but Parties are only just putting in place specific measures to implement the Nagoya Protocol and it is therefore difficult to get accurate information on national requirements. The NFP could be swamped if advice was sought for clarity on each sample that is taken. In microbiology, the genetic resources are normally hidden in an environmental sample or infected host and a scientist may have access to many thousands of micro-organisms within a single sample. Therefore, negotiating access can become quite complicated, given the unknown number and types of organisms being accessed or their possible potential. PIC

will be given by a country for particular uses of the genetic resources accessed as detailed in the MAT; if the proposed use changes, then a researcher will need to go back and renegotiate terms and conditions regarding benefit sharing.

For legal and contractual compliance, users of biological and genetic resources in academic research institutions and industry need to understand their responsibilities and risks and need to ensure that their practices enable compliance with national laws and regulations of countries where they acquire material, managing delivery against MAT and responsibilities under implementing legislation of the Nagoya Protocol of countries within which they carry out their research work. Overall, and particularly where legislation is weak or absent, users should work within the spirit of the CBD. Users have to take responsibility to ensure that genetic resources are acquired legally and that any benefits arising from their utilization are shared fairly and equitably with the country that provided them or particular individuals within that country.

A European microbiologist needs to understand when their work is in scope of the EU Regulation and the requirements for how this is implemented in their country and the responsibilities they have as a result. Guidance is being prepared by the EU and nationally; information can be sought on the global level from the ABS Clearing House and nationally from the NFP; for the UK, this is the Department for Environment, Food and Rural Affairs (Defra) and the enforcement authority in the UK is Regulatory Delivery, a Directorate within the Department for Business, Energy and Industrial Strategy.

REQUIREMENTS FOR THOSE SEEKING TO UTILIZE GENETIC RESOURCES (WHERE LEGISLATION IS IN PLACE)

A researcher in the EU must first know if the micro-organism on which he/she is carrying out research and development (utilization) falls into scope of the EU Regulation.

- (1) It is only in scope if it was accessed from a provider country after the Nagoya Protocol came into force (12 October 2014). Moreover, the provider country must have been a Party to the Nagoya Protocol at the time of access. Clarity will be needed on the meaning of access used by the provider country. For example, acquisition of material held in an *ex situ* collection in a provider country may (or may not) be considered as access. Brazil, for example, has issued a new law which specifies that an isolate from an *ex situ* collection in Brazil that was isolated pre-CBD would be in scope of their national legislation and the Nagoya Protocol. Thus, material collected pre-Nagoya is in the scope of the Brazilian national legislation and the Nagoya Protocol if accessed for use from a Brazilian Collection after Brazil becomes Party to the Nagoya Protocol.

- (2) Where was it collected? The European Regulation applies only to genetic resources accessed from countries which are Party to the Nagoya Protocol and which have access requirements in place. Not all countries are Party to the Nagoya Protocol and not all that have access legislation. The provider country or the country of origin of the micro-organism will indicate whether controls might be in place.
- (3) What is it going to be used for? There is still further guidance to be produced on the nature of ‘utilization’ or ‘research and development’ in the EU that puts use into scope. However, if researchers are carrying out research and development and not simply observing or describing the micro-organism, the use could be in scope.

Importantly, whether or not a particular research project or utilization of a sample falls within scope of the EU Regulation or not, researchers are still obliged by national laws within their jurisdiction to follow the laws of the countries where they access the material and abide by any terms applied to their access and utilization, which is enforceable through private law.

If not accessed directly from the country of origin, material, within the scope of the Protocol, should arrive in the researcher’s hands with a Material Transfer Agreement (MTA) describing what can and cannot be done with the material under the original PIC and MAT which the recipient must adhere to or go back to renegotiate new terms, plus information about its legal provenance, including the country of access and the date when this was carried out. There is a list of the information required in the EU in Article 4 of the EU Regulation. Researcher must make themselves aware of these issues and comply with terms and conditions of the PIC and MAT. In theory, newly isolated materials should have an IRCC that links back through the ABS Clearing House to the original PIC and MAT, and the IRCC number, if it exists, is one of the items required for a Declaration of Due Diligence under the EU Regulation.

For material in scope of the European Regulation, the Regulation requires the user to conduct ‘due diligence’ in sourcing genetic resources to ensure that they have been accessed legally.

- All materials received should have PIC and MAT where there is a National Authority to issue them.
- The MAT ideally will include:
 - Benefit-sharing agreements
 - Permission to export the subject out of the country of origin
 - What can be done with the material once utilized (e.g. permission to deposit the subject in collections, destruction, mandatory return to the country of origin)
 - Agreement on third-party distribution
 - The specific research and/or end use envisaged by the recipient.

- The provider country will lodge this information, normally as an Internationally Recognized Certificate of Origin (IRCC) with a unique identifier, on the ABS Clearing House.

In the UK, there are two points where Due Diligence Declarations to the Regulator are required; the first is when genetic resources that fall within scope of the Regulation (broadly this is utilization of genetic resources accessed from a Party to the Nagoya Protocol which has access requirements) are utilized (in the meaning of the Nagoya Protocol) in a grant-funded project and the second is when a product arising from utilization is placed on the market. The Declaration of Due Diligence must indicate that the materials were acquired legitimately, that PIC was obtained and whether MAT are in place. Work carried out on the material must be in accordance with the MAT and, in addition to the declarations foreseen in the EU Regulation, MAT may include additional reporting requirements to the provider country.

FINDING INFORMATION

The CBD website provides information on all signatory/ratified countries; see specific country page where information includes contact points and the ABS Measures – Regulations, where in place (links through to the entries on the ABS Clearing House).

- ABS Clearing House (<https://absch.cbd.int/>)
 - The ABS Clearing House is a platform for exchanging information on ABS, managed by the CBD Secretariat.
 - Each Party to the Nagoya Protocol is required to make available the following:
 - (1) Legislative, administrative and policy measures on ABS
 - (2) Information on the NFP and CNA or authorities
 - (3) Permits or their equivalent issued at the time of access as evidence of the decision to grant PIC and of the establishment of MAT. This creates the IRCC on the ABS Clearing House. Although the wording of the Protocol states that Parties shall do this, in practice, some countries are excluding permits for taxonomic and similar work from the workflow generating an IRCC.

Unfortunately, many of the country pages on the ABS Clearing House are currently incomplete; they can only be updated by the countries concerned, some countries have not implemented relevant obligations, have appointed focal points or have not yet updated their entry on the clearing house mechanism. Moreover, even where information on the legislation is present, it is not always translated from the original language, and it lacks a clear description of the steps necessary to gain access and remain compliant for each country (i.e. the process for negotiating access and MAT). A coordinated effort is needed to bring together this information; the Secretariat of the CBD are working with countries

to support the development and upload of legislation and measures. Over time, the ABS Clearing House will be populated fully with regulation information and contact points for information (NFP) and contacts for negotiations (CNA).

GENERIC GUIDANCE: WHAT BIOLOGISTS MUST DO (SEE FIG. 1.)

Collecting genetic resources for use

- At project/study visit proposal stage, check the ABS measures of the country being visited to understand the relevant rules and regulations that apply to the anticipated activity; see www.cbd.int and <https://absch.cbd.int/>.
- Ascertain whether the provider country has ratified the Nagoya Protocol and if ABS measures are in place.
- When submitting project proposals, factor in the need to acquire PIC and MAT for any genetic resources; a statement should be made in the project application that these will be secured before accessing genetic resources.
- Acquire PIC and MAT before collecting or exporting.
- Where there is no national legislation in place.
 - Work with the NFP to establish what procedure should be followed
 - If there is no NFP or CNA, work with an appropriate ministry and/or government agency to establish what procedures should be followed
 - Institutions (employers) should provide their staff with draft MAT agreements based on good practice and encourage their use where practical.
- Where national legislation does not regulate access to the genetic resources, then access and use should still be documented for future accountability.
- Staff should be aware that other legislation and international agreements are relevant for access to and export of genetic resources, e.g. CITES, collecting in protected areas, phytosanitary requirements, airline regulations, etc., but these are not addressed here.
- Check whether the intended use of genetic resources falls within the scope of the Nagoya Protocol. This in itself will vary from country to country due to the differences between the various interpretations of utilization and research and development and to what extent the countries include these different genetic resources or uses of genetic resources within their national ABS laws.
- If it is the intention to take a product to market from the beginning, typically access for this purpose must be negotiated before the project starts, although this depends on the country's approach to access.
- Introduce reporting mechanisms back to National Authorities of provider countries at the request of the providers (as well as considering reporting requirements in the country where utilization takes place). For example, the obligation to make a Declaration of Due Diligence if operating within the EU and reaching one

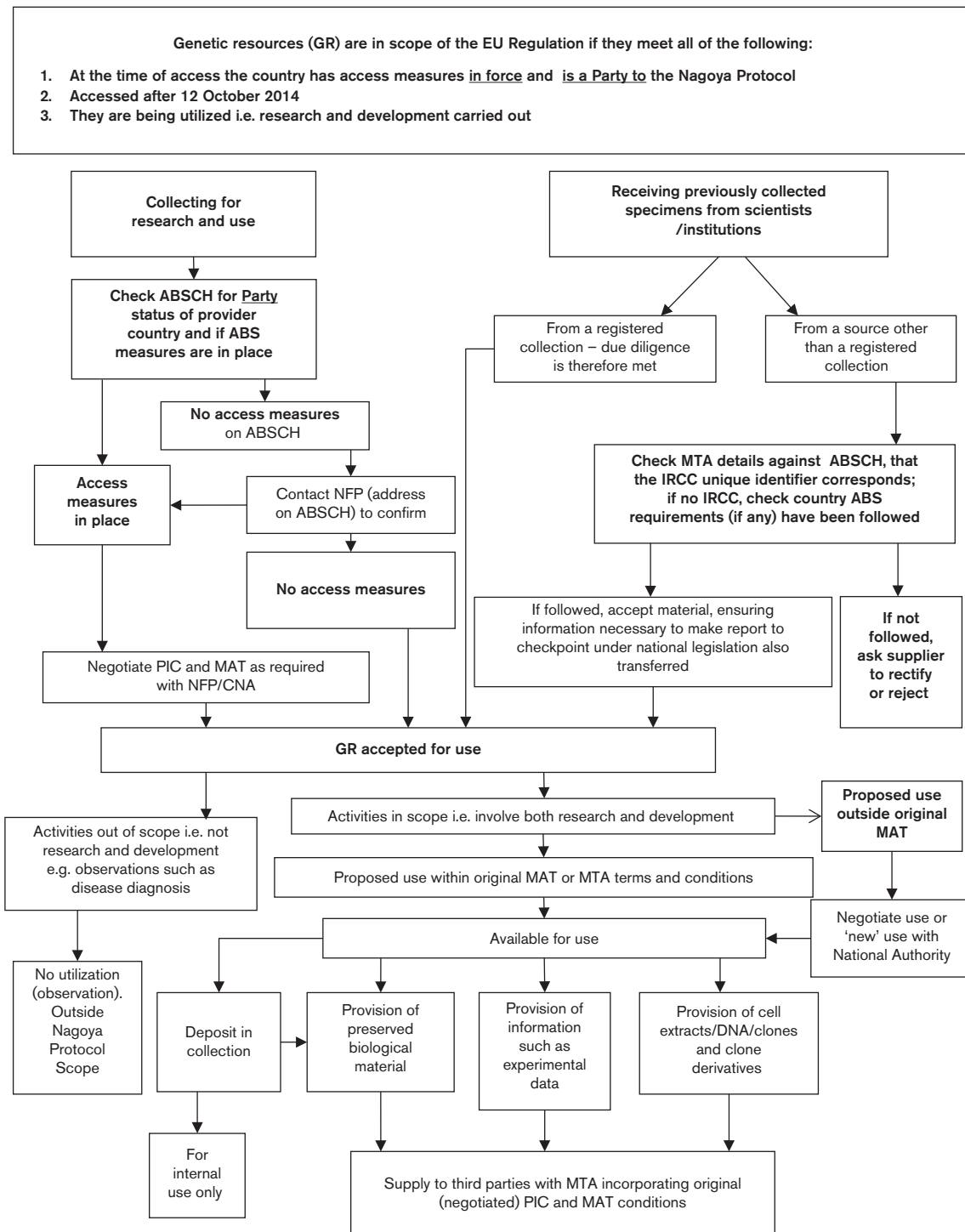


Fig. 1. Example decision tree for implementing ABS best practice for both the CBD and the Nagoya Protocol.

- of the two points where such a declaration is required (Articles 7.1 and 7.2 of EU ABS Regulation).
- If there is a change in use outside MAT, negotiate change of use with the National Authority of country of origin.

- Transfers to third parties are not permitted unless specifically stated in the MAT.
- It is good practice to:
 - Work through a local partner in the provider country

- Deposit samples of materials to be utilized in provider country collections
- Record generated data.
- Information on genetic resource use and benefits shared should be reported to the country of origin; this may be required in the MAT.

Receiving genetic resources from collaborators, collections or other providers

Ensure that the materials have been collected in compliance by asking for evidence, e.g. a copy of the IRCC, the equivalent ABS Clearing House unique identifier and copy of PIC and MAT; all this information should be provided in an accompanying MTA. It might also be possible for providers to be in possession of material that is not within scope of the Nagoya Protocol (or other ABS legislation) and so, therefore, it will not be possible to have this information; however, users should be able to satisfy themselves with the response of the suppliers that this is reasonably the case.

Under the EU Regulation Article 4, users shall seek, keep and transfer to subsequent users:

- The IRCC, as well as information on the content of the MAT relevant for subsequent users; or
- Where no IRCC is available, information and relevant documents on:
 - (1) The date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
 - (2) The description of the genetic resources or of traditional knowledge associated with genetic resources utilized;
 - (3) The source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;
 - (4) The presence or absence of rights and obligations relating to ABS including rights and obligations regarding subsequent applications and commercialization;
 - (5) access permits, where applicable;
 - (6) MAT, including benefit-sharing arrangements, where applicable.

The enactment of the EU Regulation (no. 511/2014), which implements the parts of the Nagoya Protocol that govern compliance measures for users, offers the opportunity for companies to exercise due diligence in sourcing their organisms by selecting from holdings of ‘registered collections’. This is one of the tools to facilitate compliance; standards have been set in the Regulation that need to be met by registered collections. The supporting Implementing Acts (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866>) lay down the information to be provided by applicants; verification is by Member State authorities along with the rights for granting/withdrawing

recognition and performing risk-based checks. The European Commission is responsible for establishing and maintaining the register. Registered collections must apply measures that result in supplying genetic resources and related information only with documentation providing evidence of legal access and ensuring the establishment of MAT, where required.

To request inclusion of a collection in the register information including the details of the holder of the collection, a description of the collection and evidence of the collection’s capacity to comply with Article 5 (3) is required. This Article requires the collection to demonstrate capacity to apply standardized procedures, supply genetic resources with the correct documentation, keep records, establish unique identifiers and use tracking and monitoring tools. The Regulator will use a risk-based approach to verify collections, this may include:

- On-the-spot checks;
- Examination of documentation
- Examination of whether selected samples of the collection concerned are in accordance with Article 5 (3)
- Interviews.

NEW BRAZILIAN ABS REGULATIONS: BIODIVERSITY LAW (LAW 13.123)

The situation in Brazil offers an example of what a biologist needs to be aware of when collecting samples from other countries. Each individual country will have different requirements, procedures or contacts for negotiation. At present, export of Brazilian genetic resources is not allowed unless the collector is registered in the National System for Genetic Heritage and Associated Traditional Knowledge Management (SisGen). The key steps for compliance in Brazil are the following:

- To collect, a foreign scientist must first of all be registered working with a partner in Brazil and have an Authorization Request for Collecting and Research (Scientific Expeditions) from the National Council for Scientific and Technological Development
- When this is in place, the Brazilian collaborator can seek a permit for collecting from Instituto Chico Mendes de Conservação da Biodiversidade (ICMBio; www.icmbio.gov.br), through the electronic system SisBio.

Along with the Brazilian Institute of Environment and Renewable Natural Resources, ICMBio oversees the National Environmental Systems. ICMBio is in charge of protecting Brazil’s natural heritage, promoting biodiversity conservation through research and education and promoting ecologically sound management practices. It operates primarily in the management of federally protected areas, and is responsible for proposing, implementing, managing and monitoring conservation units as part of the National System of Conservation Units. This is through SisBio (www.icmbio.gov.br/)

sisbio/). SisBio is a system of care at a distance that allows researchers to request permits for collection of biological material and conducting research in federal conservation units and caves. Researchers must meet Instruction ICMBio no. 03/2014 which established and regulates SisBio. The types of requests available in SisBio are:

- Permits for activities with scientific purpose
- Permits for activities with didactic purpose (in higher education)
- Permanent licen
- Voluntary registration for collection and the transportation of botanical, fungal and microbiological material.

When collected samples are to be sent out of the country to be accessed (in accordance to the Law 13.123/2015 and Decree 8.772/2016), this constitutes a ‘shipment’ and must be registered with the Genetic Heritage Management Council by the electronic system SisGen, which at present is not yet available. ‘Accessed’ in the context of Brazilian law is when the genetic resource is utilized, not when it is collected. The different uses of terms and definitions (e.g. access=acquisition in Europe versus access=utilization in Brazil; genetic resources versus genetic heritage in Brazil) should be recognized when interpreting national ABS measures. Once a specimen/sample has a shipment registration unique identifier, the material can leave the country. The user, through the Brazilian collaborator, must then notify Brazil if research and technical development results in a product for the market. This will trigger benefit sharing.

According to its new law, materials constituting genetic heritage in Brazil can be ‘sent’ out of the country to carry out a service such as sequencing or identification. This, in Brazilian terms, is not ‘access’, i.e. research and development (utilization); normally, under such circumstances, the entity carrying out the service will be required to return or destroy the samples.

BEST PRACTICES

Consistent with Article 20 in the Nagoya Protocol, scientific communities, individual institutions and organizations are developing and adopting best practices for ABS. These procedures may be for internal use within companies or sectors (and may also be published by the CBD Secretariat on the ABS Clearing House Mechanism) or they may be officially recognized by the European Commission as best practice for complying with the EU ABS Regulation. There have been three applications for recognition of best practices including two from the cosmetics industry and that of the Consortium of European Taxonomic Facilities (CETAF) at the time of writing. CETAF has delivered a package of documents in order to fully support the operations of taxonomic collection holding and non-commercial biological research institutions in complying with the Nagoya Protocol of the CBD and the EU ABS Regulation [1, 2]. Other research communities such as CETAF, the Global

Genome Biodiversity Network [3] and the International Organisation for Biological Control [4] have published best practice and/or codes of conduct to ensure legitimate exchange and use of genetic resources. The Commission on Genetic Resources for Food and Agriculture has produced a useful document, Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Sub-sectors of Genetic Resources for Food and Agriculture [5].

The Microbial Resource Research Infrastructure (MIRRI) has developed a policy statement on how MIRRI partner microbial domain Biological Resource Centres (mBRCs) commit themselves to contributing and reaching the main objectives of the CBD while operating in compliance with all applicable national and international laws on ABS and regulatory requirements. MIRRI is a pan-European distributed research infrastructure that provides facilitated access to high-quality micro-organisms for research, development and application and connects public mBRCs with researchers, policy makers and other stakeholders to deliver biological material and services more effectively and efficiently to meet the needs of innovation in biotechnology. The MIRRI Best Practice Manual [6] provides guidance for the mBRCs in implementing their ABS institutional policies with regard to genetic resources and associated traditional knowledge, as well as working procedures for the acquisition of material, including accession, i.e. formal acceptance of new material in the public collections of the mBRCs, for transfer of material including supply to third parties and the delivery of other services. It also aims to increase transparency on how the mBRCs themselves conduct research on their holdings.

The UK Biological Resource Centre Network (www.sfam.org.uk/en/news-features/news/index.cfm/the-uk-biological-resource-centre-network-ukbrcn-meeting-the-needs-of-the-scientific-community) member microbial resource collections are exploring what they can do together to support compliance in the UK. Each member collection is considering whether it should apply to Defra to become a ‘registered collection’ with all that this requires and in light of the UK’s intention to withdraw from the EU. Likewise, the partners of MIRRI, the European Culture Collections’ Organisation (www.eccosite.org/) and individual collections are also considering their actions. The European Culture Collections’ Organisation has a long history in addressing issues around exchange and use of micro-organisms and has published core text for MTA (www.eccosite.org/ecco-core-mta/).

Centre for Agriculture and Biosciences International (CABI) is an international organization owned by 48 countries (www.cabi.org/about-cabi/) and houses one of the UK National Culture Collections; it is both a user and a provider of genetic resources. CABI has said ‘In the use of genetic resources, CABI will put in place best practices to comply with national legislation on ABS including those to implement the Nagoya Protocol and will perform due diligence regarding ABS in all its activities involving those resources’. CABI’s aims are to engender trust, to facilitate science and

to ensure that benefits are shared. Given that each of the 48 countries could introduce quite different mechanisms to implement the Nagoya Protocol, CABI staff need to be kept informed of practices and procedures to ensure compliance. The CABI Development Fund supported a project with the objective to introduce best practice in compliance with national regulatory requirements when sourcing and utilizing genetic resources. This was done by:

- Preparing a policy statement
- Outlining policy and best practice for staff and the source countries of genetic resources
- Seeking approval of policy and procedure from National Authorities
- Raising awareness of responsibilities and best practice with CABI staff
- Creating a resource cataloguing all country approaches to implementing the Nagoya Protocol and key contacts to provide CABI staff with current information on how to comply.

At CABI Regional Consultations, meetings held from October 2015 to February 2016, representatives of CABI's member countries unanimously endorsed the need for CABI to comply with the requirements of the CBD and specifically with the Nagoya Protocol. CABI received broad support for its proposals to develop an operational policy to define how it will adopt and apply the provisions of the Nagoya Protocol. The CABI goal is to negotiate open access for its scientists to collect materials through a single agreement using the accessed genetic materials solely to deliver its mission to its member countries. A description of all uses CABI staff normally could make of genetic resources for has been defined and a list of benefits that CABI will provide in return for access in delivery of its mission has been elucidated. These, alongside its best practice, define the terms and conditions for CABI access. If commercial use is envisaged or is serendipitously discovered, this will constitute a new use and CABI will negotiate appropriate benefit sharing for this. CABI is requesting that member country representatives come to the 19th Review Conference to approve CABI's ABS policy and best practice and support any further contact with their National Authority or Authorities that may be necessary.

SUMMARY

- Before considering work with genetic resources, ask the questions: When was the material isolated and where was it isolated?
- Use the CBD and ABS Clearing House websites to get initial advice; if not available, contact the country's NFP or CNA.
- When materials are subject to legislation, ensure that you have:
 - PIC
 - MAT which include the specific use you intend
 - MTA (when receiving materials collected by others)

- IRCC (where possible).
- When materials are not (yet) subject to legislation, follow best practice (as above or presented in recognized community best practice).
- Documentation is to be lodged on the ABS Clearing House by Provider Countries and MTA should refer to associated unique identifiers.
- If you are working in the EU or another country that is Party to the Nagoya Protocol, ensure that you are also aware of your own country requirements for monitoring (checkpoints) and reporting the utilization of genetic resources from other Parties to the Protocol and comply with these requirements.

We must work together to ensure that regulation is complied with and that the simplest systems are put in place to facilitate science and discovery but that they meet the needs of benefit sharing. The UK Stakeholder Group run by Defra enables input to best practice and is a conduit for information. The Regulator and Defra together are available to help raise awareness and ensure that due diligence is performed in sourcing and use of genetic resources and that practitioners are aware of the requirements. The MIRRI ABS Manual (www.mirri.org/downloads.html) provides best practice from a microbial domain resource collection perspective but is relevant to all microbiologists and other communities also provide such guidance. Examples of community best practices are given above and cited in the references below.

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Conflicts of interest

The authors declare that there are no conflicts of interest.

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