4.2 Practical and Implementable Mechanisms for Compliance with the Nagoya Protocol: Access and Benefit Sharing

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Live cultures for use in the development of basic and applied science must be collected and utilised in compliance with the regulatory environment. In October 2014 the Nagoya Protocol on Access and Benefit Sharing (ABS) came into force and its implementation is the responsibility of all countries that are signatory to the Protocol. By June 2017 there were 96 Parties to the Nagoya Protocol and 3 had ratified and still to become a party; of these 31 countries had published legislative, administrative or policy measures. 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 controlling access, see the ABS Clearing House (2017).

In its work, CABI accesses biological and genetic resources and undertakes sampling and collection of biological materials including, among other uses, for discovery of biological control agents to manage invasive species. CABI is working with its partners to establish best practices to comply with ABS requirements. CABI is an international not-for-profit organization that improves people's lives worldwide by providing information and applying scientific expertise to solve problems in agriculture and the environment. CABI's 48 member countries guide and influence its work which is delivered by scientific staff based in a global network of centres (CABI, 2017). Thirty of the 48 CABI member countries (Fig. 4.2.1) have already taken steps to implement ABS measures, 9 have ratified, 8 signed with 13 Party to the Protocol. Several member countries have provided useful feedback resulting in the first agreement with a provider country, Ghana, being signed.

Fig. 4.2.1. CABI member countries.

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European Union Regulation no. 511/2014 implements the Nagoya Protocol elements that govern compliance measures for users. It offers the opportunity for users of genetic resources to demonstrate due diligence in sourcing their organisms by selecting from holdings of 'registered collections'. The UK has introduced a Statutory Instrument, the Nagoya Protocol (Compliance) Regulations 2015 (UK, 2017) which puts in place enforcement measures within the UK to implement this Regulation. 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. The goal is to prevent 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. Therefore users of genetic resources need to be aware of the requirements of both the country in which they work and those of the provider country. These differ from country to country. Importantly the Protocol has been developed to support the effective implementation of benefit sharing commitments set out in mutually agreed terms (MAT) and to improve legal certainty in utilization of genetic resources and traditional knowledge.

To facilitate the process of compliance, scientific communities have begun to design policy and best practices; a number of are available via the ABS Clearing House (2017). The Microbial Resource Research Infrastructure (MIRRI), a pan-European distributed research infrastructure that provides access to high-quality micro-organisms for research, development and application has published the MIRRI Best Practice Manual on ABS (Verkley *et al.*, 2016). This provides guidance for microbial domain Biological Resource Centres (mBRCs) in implementing their ABS policies and covers the acquisition of material, supply to third parties and the delivery of other services. It increases transparency on how mBRCs conduct research on their holdings. The European Commission has published general guidance on the scope of the EU Regulation (2017) and is currently drafting sector specific guidance; of specific relevance is the *Guidance Document for the Biocontrol and Biostimulants sector*. The main purpose of this document is to arrive at a shared interpretation of the terms "utilisation" and "research and development" as contained in Regulation (EU) No 511/2014. It enables the user to determine what activities are in and out of scope of the EU regulation. It explores the range of activities that may be carried out in the context of product development, and presents the obligations of users that follow.

The EU regulation requires a user of genetic resources or the associated traditional knowledge to declare that benefit sharing mechanisms are in place when securing funding for the research and secondly when a product goes to market. It is applicable when conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. The EU Regulation applies:

- to genetic resources from countries that exercise sovereign rights
- to genetic resources when countries have established applicable access measures and ratified the Nagoya Protocol
- if genetic resources were accessed after 12 October 2014
- to genetic resources that are not already governed by specialised international instruments

In the EC guidance document several case scenarios are described. The isolation, growth and storage do not constitute utilisation in the context of the EU Regulation. However, activity that selects and optimises the biochemical properties of a genetic

resource is considered 'utilisation'. If the taxonomic characterization of a genetic resource is combined with the discovery of specific genetic and/or biochemical properties, this would again qualify as 'utilisation'. Testing of a new product based on genetic resources for regulatory requirements does not constitute research and development. However, if based on the outcome of the tests, further research and development is carried out on the genetic and/or biochemical composition of genetic resources on which the product is based, in order to fulfil additional requirements, then this is within the scope of the EU ABS Regulation.

The International Organisation for Biological Control (IOBC) has produced specific best practice for the use and exchange of biological control genetic resources (IOBC, 2009; Cock *et al.*, 2010). More recently, Mason *et al.* (2017) proposed best practice which includes collaborations to facilitate information exchange, knowledge sharing, cooperative research to develop capacity in source countries and transfer of production technology to provide opportunities for small-scale economic activity. There are a number of publications that raise awareness and offer specific guidance for example its implication for microbiology (Smith *et al.*, 2017) and more generally (Beckett, 2017). However, the key source of information is the ABS Clearing House (https://absch.cbd.int/), a platform for exchanging information on access and benefit-sharing where each Party to the Nagoya Protocol is required to make available legislation, contacts for the national focal point and competent national authority and permits issued including PIC – Prior Informed Consent, MAT – Mutually Agreed Terms and the IRCC – Internationally Recognised Certificate of Compliance.

The CABI Development Fund supported a project to introduce ABS best practice producing an information resource to keep CABI staff aware of developments and assist their compliance and a strategy to reduce administrative burden for both provider and user. CABI is currently seeking approval of policy and procedure from National Authorities; negotiating open access for its scientists to collect materials through a single agreement using the genetic materials solely to deliver its mission. A description of all uses CABI staff make of genetic resources and a list of benefits that CABI provides in return for access, alongside its best practice, define the terms and conditions for negotiation. If commercial use is envisaged or is serendipitously discovered, this will constitute a new use and CABI will negotiate appropriate benefit sharing specifically for this. This process is beginning to bear fruit with Ghana a signatory to a memorandum of understanding (MoU). CABI envisages at least four levels of country response:

1. A country may see no reason to agree anything if they not claiming sovereign rights and controlling access to their genetic resources
2. In Europe the majority of countries are not claiming access but want users to employ "due diligence"; CABI is seeking country endorsement or agreement its best practice in such cases
3. Countries who wish to claim sovereign rights and control access may want something more formal and this could be a two levels the MoU or:
4. A more formal contractual agreement (a rough first draft is available)

It is hoped that when most countries have become Party to the Nagoya Protocol access and use of genetic resources will become easier as providers will know that users will be obliged to implement benefit sharing commitments.

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