

Access and benefit sharing: Evolving laws and regulations around the world



What is ABS?

In the CBD, ABS refers to the system for access to genetic resources and associated traditional knowledge and the fair and equitable sharing of benefits arising out of their utilization, on the basis of prior informed consent and mutually agreed terms. In many of the laws and regulations implementing the CBD, as well as in the Ethical BioTrade Standard, access and benefit sharing requirements extend more broadly to biodiversity-based research and development, as well as subsequent applications and commercialization activities.

Implementation of the ABS principles set out by the CBD takes place through domestic legislation. For example, how and when companies must obtain prior informed consent depends on the country in which they are seeking access. Similarly, the content of the mutually agreed terms will depend on local requirements and specific circumstances.

Putting the Nagoya Protocol in Practice

With new international rules soon coming into force, there is growing momentum for the national implementation of access and benefit sharing (ABS). The Nagoya Protocol on ABS, adopted in 2010 under the Convention on Biological Diversity, established rules to provide more clarity for the use of biodiversity for research and development, as well as to ensure the equitable sharing of resulting benefits. With an increasing number of countries signing up to its provisions, the Nagoya Protocol is expected to enter into force in 2014.

Countries are already developing, revising and putting into practice measures in line with the Nagoya Protocol. Although ABS principles are set out at the international level, governments can decide how to implement according to their particular circumstances. Measures for implementing ABS may include national or regional strategies, policies, laws and regulations. These measures provide information and procedures on issues such as the competent authority to grant access to genetic resources or how to obtain prior informed consent. This note highlights some recent development on measures for implementing ABS in selected countries and regions.



Status of the Nagoya Protocol

As of 7 March 2013, ninety-two countries have signed the Nagoya Protocol. Fifteen countries, including Botswana, India, Mexico, Panama and South Africa, have formally ratified it. The Nagoya Protocol will enter into force 90 days after the 50th ratification.

Timeline for selected ABS rules and measures

- 1992 Adoption of Convention on Biological Diversity (CBD)
- 1993 CBD enters into force
- 2002 Adoption of Bonn Guidelines on ABS
- 2007 Interim Bioprospecting Committee (IBPC) established in Namibia
- 2010 Adoption of Nagoya Protocol on ABS
- 2012 Formal adoption of revised Ethical BioTrade Standard
- 2014 XII Conference of the Parties to the CBD in South Korea



Brazil



Provisional measure 2.186-16 is the basis of the Brazilian legal framework for ABS. It regulates access to components of the Brazilian genetic

heritage and associated traditional knowledge, as well as the sharing of benefits from the commercial use of resulting products or processes. Though operational, the provisional measure is currently under revision to improve its role as an incentive for innovation, research and development, as well as to establish a more efficient system for decision-making. A draft measure is expected to reach the Executive Office of the President of Brazil, charged with starting the legislative procedure, in April 2013.

Discussions on the revision of the provisional measure include a range of stakeholders. For example, the Ministry of Environment has requested the International Finance Corporation (IFC), with the support of the Union for Ethical BioTrade (UEBT) to provide private sector perspectives on effective ABS mechanisms. The Business Movement for Biodiversity – Brazil (MEBB), which promotes sustainable use of biodiversity in the private sector, has submitted suggestions on concepts such as genetic heritage and benefit sharing, as well as on permitting systems. The National Commission of Traditional Peoples and Communities (CNPCT) also put forth its views – in some cases endorsing MEBB suggestions. CNPCT, however, called for further consultation with indigenous and local communities.

Colombia



In Colombia, measures on ABS include the Andean regional regime on genetic resources and several national decrees that put it into practice. These

rules have largely not been implemented. In 2011, for example, Colombian universities estimated that over five hundred biodiversity research projects required access permits, yet only 46 permits had ever been granted. As a result, there is ongoing discussion on a draft decree that would replace existing rules on access to genetic resources, derived products and associated traditional knowledge. The adoption of this decree is expected by the end of 2013. At the same time, specific rules for basic research and biological collections are also being discussed.

Costa Rica



The 1998 Biodiversity Law regulates the use of biodiversity and associated knowledge of Costa Rica, as well as the sharing of the costs and benefits

derived from this use. It requires access permits for all research or bioprospecting activities on biodiversity. Regulations outline procedures for access to genetic and biochemical elements of biodiversity. The National Biodiversity Institute (INBio), created to promote bioprospecting as a strategy for the sustainable use of biodiversity, conducts most biodiversity-based research, in collaboration and benefit sharing with academic and private sector organizations. ABS regulations are currently being reviewed in light of the Nagoya Protocol, as well as to address some concerns regarding the scope of application and the need for simplified procedures for basic research.



European Union



In October 2012, the European Commission presented a draft regulation on ABS, which aims to set the basis for the implementation

of the Nagoya Protocol within the European Union (EU). The main focus of the draft regulation is on 'user measures', recognizing that genetic resources and associated traditional knowledge are widely utilized in the EU for research and development in various sectors, including plant breeding, cosmetics, food and beverage, and pharmaceuticals. The draft regulation also proposes an EU platform for streamlining any access requirements established by EU member states. In March 2013, discussion on the draft regulation began at the European Parliament, which may introduce amendments to the text. A final text will be negotiated between the EU Council of Ministers, the European Commission and the European Parliament. The regulation is expected to be adopted by the end of 2013.

India



India enacted its Biological Diversity Act in 2002 and notified its regulations in 2004. The Biodiversity Act is implemented through a

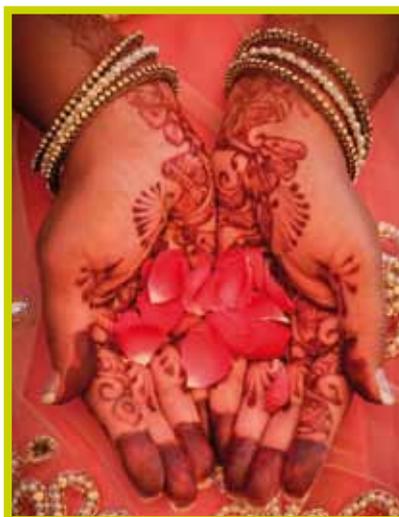
decentralized system. At the national level, the National Biodiversity Authority (NBA) has an enabling, regulatory and advisory role on biodiversity issues, including access and benefit sharing. In specific cases, the NBA is also charged with providing authorization for access to biological resources or associated traditional knowledge. At the state level, there are State Biodiversity Boards, while Biodiversity Management Committees are constituted at the local level. In terms of ABS, State Biodiversity Boards are charged with reviewing and authorizing requests made by Indian nationals or organizations for research, development or commercial use of biological resources. At the local level, there are over thirty thousand Biodiversity Management Committees, which maintain a register on access permits granted and on the sharing of resulting benefits.

Malaysia



In late 2012, Malaysia published a draft 'Access to Biological Resources and Benefit Sharing Act' for public review and comment. This draft draws

upon several elements of the Nagoya Protocol, while also considering policies already enacted at the state level. For example, the Malaysian states of Sarawak and Sabah have both developed measures on ABS, including centers to manage their biodiversity. The draft national law covers access to biological resources, which is defined as the taking of biological resources for research and development. In terms of benefit sharing, the draft foresees agreements with the resource provider, as well as the possible payment of a percentage of monetary benefits derived from the agreement to a fund dedicated to conservation and sustainable use of biodiversity.



South Africa



The 2004 Biodiversity Act and its 2008 regulations on bioprospecting, access and benefit sharing regulate the research, development and

application of native South African biological resources, as well as their genes or biochemical compounds, for commercial or industrial purposes. Permits for such activities are only issued if individuals or groups giving access to biological resources and indigenous communities providing traditional knowledge grant prior informed consent and the Minister of Water and Environmental Affairs is satisfied that certain conditions set out in the legislation are met. For example, one of the first permits to be granted referred to research and development on *Aloe ferox* sap, extracts and crystals for national and international markets. South Africa is currently in the process of revising its national measures on ABS to meeting its obligations under the Nagoya Protocol.

Namibia



Having delayed ABS legislation until the adoption of the Nagoya Protocol, legislation on 'Access and Benefit Sharing for Sustainable Utilization of

Cultural and Natural Assets' is now under review and close to finalization. To date, Namibia has regulated ABS through contracts, existing laws and the engagement of a range of stakeholders through an Interim Bioprospecting Committee (IBPC), established in 2007 to regulate and facilitate all bioprospecting activities. The draft bill on ABS, which has undergone regional consultations as part of the review process, would create a new dedicated unit on genetic resources and traditional knowledge within the Ministry of Trade and Environment to replace the IBPC.

Main rules and guidelines on ABS

Convention on Biological Diversity (CBD).

Adopted in 1992, it is the most comprehensive international agreement on biodiversity. Over 190 countries have ratified the CBD. Its objectives are the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits derived from the use of genetic resources.

Nagoya Protocol on ABS. Adopted in 2010, this international agreement confirms and builds on the CBD principles on fair and equitable sharing of benefits. Its rules aim to facilitate, promote and ensure the effective implementation of ABS.

National legislation. CBD and Nagoya Protocol provisions on ABS are put in practice through national legislation. National laws determine, for instance, stakeholders, procedural and substantive requirements, types of activities and resources covered, and relevant compliance mechanisms. A growing number of countries have ABS legislation in place, including Australia, Brazil, India, and South Africa.



UEBT and ABS

The fair and equitable sharing of benefits derived from the use of biodiversity is at the core of Ethical BioTrade, and constitutes one of the key elements of the work of UEBT. ABS principles are included in the Ethical BioTrade Standard, both expressly and in the context of broader benefit sharing requirements. The UEBT third-party verification system assesses company policies and their implementation, and determines any necessary changes that need to be gradually implemented to comply with Ethical BioTrade practices, including on ABS. In addition, UEBT provides technical advice and support on ABS issues, including through practical tools and workshops. By addressing ABS in its outreach activities, UEBT is also helping to raise awareness of ABS within industry.

UEBT resources on ABS

These resources, available on the UEBT website: www.ethicalbiotrade.org, provide additional information on ABS:

- The Ethical BioTrade Standard
- The Introductory Video on ABS
- The ABS Basic Information Sheet
- The Technical Brief on the Nagoya Protocol on ABS
- The Introductory Video on Patents and Biodiversity
- The Principles on Patents and Biodiversity
- The Notes on Trends in Patents, Cosmetics and Biodiversity.



Contact UEBT

UEBT is a membership-based, nonprofit organisation - www.ethicalbiotrade.org.

Union for Ethical BioTrade

Secretariat

Keizersgracht 158
1015 CX, Amsterdam, Netherlands

Phone: + 31 20 22 34 567
info@ethicalbiotrade.org

Financial Administration
p/a CR Gestion et Fiduciaire SA
Rte des Jeunes 9

1227 Carouge, Switzerland
Phone : + 41 22 5661585
info@ethicalbiotrade.org

Brazilian Representation

Sao Paulo, Brazil
Phone: + 55 11 99431 1880
brazil@ethicalbiotrade.org