Access and benefit sharing - ABS: Understanding international and national laws

With the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilisation soon coming into force, there is growing momentum for putting in practice ABS.

Many countries already have in place ABS policies, laws or regulations. These rules implement the ABS principles set out in the Convention on Biological Diversity (CBD) and establish the requirements and procedures for companies seeking access to genetic or biological resources for research and development.

This note provides an overview of selected ABS laws and regulations in Brazil, India and South Africa, biodiversity-rich countries that have pioneered ABS requirements and are actively engaging with companies on ABS implementation. The focus is on explaining what activities are covered by ABS in these countries, who is responsible for compliance and how ABS actually works in specific cases.

Several countries are also developing or revising their ABS requirements in line with the Nagoya Protocol. In March 2014, the European Parliament approved a regulation implementing the Nagoya Protocol. As a result, companies engaged in research and development on genetic material or biochemical compounds in the European Union must now ascertain that genetic resources and associated traditional knowledge used comply with any ABS rules in the provider country. An overview of the regulation is also included in this note.

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 through practical tools and workshops. By addressing ABS in its outreach activities, UEBT is also helping to raise awareness of ABS within the industry.

UEBT resources on ABS

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

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

BRAZIL

What ABS rules are in place?	The basic set of rules on ABS in Brazil is a provisory measure issued in 2001 (Medida Provisória 2.186-16), which has the force of a law. This provisory measure has been complemented by decrees, including defining the role of the National Genetic Heritage Council (CGEN). In turn, CGEN has issued numerous resolutions, orientation notes and procedural decisions.
What activities do ABS rules cover?	Regulation focuses on access to components of genetic heritage and to associated traditional knowledge, for the purposes of scientific research, technological development or bioprospecting. "Access" of genetic origin or molecules and substances deriving from the metabolism of living beings and extracts obtained from such organisms. The scope of “access” activities has been further defined by various decisions and resolutions. For example, the production of fixed oils, essential oils or extracts is exempt from ABS requirements, as long as their characteristics in the final product are substantially equivalent as in the raw material.
Who is responsible for complying with ABS requirements?	Authorisation to access components of genetic heritage or associated traditional knowledge is required for Brazilian, public or private, institutions collecting samples or information for research and development. Foreign institutions are required to enter an association with a Brazilian institution, who will be responsible for submitting the application and will assume full legal responsibility.
How do ABS requirements work?	To authorise access or transfer of samples, CGEN or other accredited authorising body requires information on the institutions and the research project; and proof of the prior informed consent of the owner of the area where genetic resources are to be collected. Prior informed consent requirements differ if there is potential for commercial use and/or an indigenous or local community involved. When access activities include bioprospecting or technological activities, the CGEN must also approve a contract for the use of genetic patrimony (CURB). Depending on the area of collection, the CURB may be signed between private parties, with an indigenous or local community or with the State. The terms of benefit sharing are negotiated among parties, except for parameters provided for cases in which the State is a party or in which benefits cannot be shared with the provider.
What are practical experiences on ABS?	In 2002-2013, CGEN and other accredited institutions issued 527 authorisations for access. These authorisations cover primarily scientific research, with only slightly more than 20% covering bioprospecting activities. Up to March 2013, 103 CURB were presented for CGEN approval. Of these contracts, 89 focus exclusively on components of genetic patrimony (rather than traditional knowledge). In terms of the economic sectors involved, 79 of the contracts fall in the cosmetics sector and 14 in the pharmaceutical sector. Starting in 2010, there have been compliance measures linked to ABS requirements. These measures included fines issued to 80 institutions in 2010 and, in 2012, additional fines issues to 70 companies and 30 research institutes.
What are latest developments or trends?	There is broad agreement on the need for a new legal framework in Brazil that avoids bureaucratic requirements and includes clear procedures for regularisation of prior access. A draft ABS law has been sent to the Casa Civil, an entity responsible for introducing bills to Congress. Changes to existing procedures are currently expected to include: • An online registry system would replace access authorisations and proof of prior consent would be required only in cases of access to associated traditional knowledge; • Foreign institutions will be able to apply directly for access authorisation without the need for association with a Brazilian partner institution; and • Calculation of benefits would be based on a fixed percentage to be paid into a benefit sharing fund.

ABS Rules

INDIA

What ABS rules are in place?	In 2002, India enacted the Biological Diversity Act (BDA), which became operational once the Biological Diversity Rules (BDR) were adopted in 2004. These instruments establish a three-tiered structure on ABS at the national, state and local levels. These bodies are required to coordinate in ABS decision-making processes.
What activities do ABS rules cover?	ABS rules cover access to biological resources or associated knowledge for research or commercial utilisation or for bio-survey and bio-utilisation. "Commercial utilisation" means using biological resources for products including drugs, industrial enzymes, food flavors, fragrance, cosmetics, colors and extracts. The definition of “biological resources” excludes "value added products," which means that access to products that may contain portions or extracts of plants and animals in unrecognisable and physically inseparable form is not subject to ABS requirements. Similarly, ABS requirements do not apply to biological resources normally traded as commodities.
Who is responsible for complying with ABS requirements?	The BDA regulates activities of foreign and Indian persons and institutions. Foreign institutions require prior approval for access from the National Biodiversity Authority (NBA). Indians and Indian institutions do not require the approval of the NBA for engagement in research activities. However, they need to inform biodiversity boards established at the state level, prior to undertaking such activities. Any commercial application related to use of biological resources and the transfer of samples to foreign institutions must be approved by the NBA.
How do ABS requirements work?	Access authorisations are granted upon completing an application form and paying a fee. The NBA may also impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and associated knowledge. Benefit sharing agreements are mostly negotiated and signed directly with the NBA, but it may consult entities at other levels. Benefit sharing is determined on a case by case basis. In cases in which biological resources or associated knowledge is accessed from a specific group of individuals, the NBA may take steps to ensure that the agreed amount is paid directly to them through the district administration.
What are practical experiences on ABS?	According to the NBA, a total of 844 applications have been received to date. Of these applications, 477 have been processed with 117 ABS agreements concluded. Of the 117 ABS agreements, 63 involve permission to apply for intellectual property rights related to biological resources, all granted to Indian institutions, primarily the Council of Scientific and Industrial Research (CSIR), a government body. In most cases, ABS Agreements are for non-commercial utilisation of biological resources. In terms of compliance measures, one case has been brought to court under the BDA. The case refers to alleged violations of the BDA by Monsanto, through its Indian subsidiary Mahyco, in obtaining native eggplant varieties. There are ongoing discussions with other companies that may also lead to further formal compliance measures.
What are latest developments or trends?	The BDA is seen as a well-crafted legislation, but lack of awareness has created significant difficulties in implementing ABS. For example, at the state level, biodiversity boards often define the scope of ABS requirements in an extremely broad manner. On the other hand, users have insufficient guidance on obligations and good practices. These challenges are being addressed through capacity-building, projects and guidelines. Though no changes to legislation are foreseen, steps may be taken to enhance ABS procedures, including: • Establishing mechanisms for multi-stage negotiations on ABS; • Establishing a help-desk on ABS; and • Develop market-based tools, including certification schemes, to ensure compliance.

SOUTH AFRICA

What ABS rules are in place?	The National Biodiversity management: Biodiversity Act (NEMBA), adopted in 2004, establishes rules for ABS in South Africa. The Bioprospecting, Access and Benefit Sharing Regulations (BABS regulations), which came into force in 2008, regulate the bioprospecting permit system.
What activities do ABS rules cover?	ABS rules in South Africa focus on bioprospecting. Bioprospecting is widely defined to include "any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation." In turn, the NEMBA defines indigenous biological resources as including any organisms of an indigenous species or related genetic material, chemical compounds and products obtained through technological applications. Additionally, ABS rules are understood to cover the entire value chain – that is, from the collection or harvest of raw material to the point where the resulting product is ready to be sold to consumers – as long as there are bioprospecting intentions or activities somewhere along the line.
Who is responsible for complying with ABS requirements?	In terms of research, no bioprospecting permit is necessary in the discovery phase, but a notification procedure must be followed. Nevertheless, the export of indigenous biological resources for research requires a permit. Research for commercial or industrial exploitation also requires a bioprospecting permit. In terms of other activities, bioprospecting permits are required for the collection or cultivation of indigenous biological resources, basic processing, extraction and manufacturing, and exporting material.
How do ABS requirements work?	A bioprospecting permit is only issued if prior informed consent has been obtained from stakeholders giving access to the indigenous biological resources (e.g. a land owner) and/or the indigenous communities whose knowledge or traditional use of indigenous biological resources may contribute to bioprospecting activities. Benefit-sharing agreements must be entered into with both categories of stakeholders and, in addition, a material transfer agreement must be entered into with stakeholders who give access to the indigenous biological resources. Templates for these agreements are included in the BABS Regulations. The NEMBA also establishes a Bioprospecting Trust Fund, into which all money arising from benefit-sharing agreements must be paid.
What are practical experiences on ABS?	Until 2013, 78 notifications of discovery activities have been received by the Department of Environmental Affairs (DEA), as well as 73 bioprospecting permit applications. Fifteen permit applications have been granted, seven of which are for trade and processing activities. Of the 58 permit applications currently under review - 30 are linked to pharmaceuticals, 14 to trade and processing activities, and 12 to cosmetics. In total, 69 material transfer agreements and 19 benefit sharing agreements have been approved.
What are latest developments or trends?	Putting in practice of ABS requirements in South Africa has been slow, due to constraints linked to the identification of stakeholders, insufficient information provided in permit applications and the complexity of regulating a wide range of very different types of activities related to biological resources. In February 2014, proposed amendments to the BABS regulations were published. The proposed regulations would explicitly include "biotrade," defined as buying and selling of indigenous biological resources for the purpose of bioprospecting, product development, or product manufacturing. Biotrade permits would be required for such activities, with the possibility of seeking and obtaining integrated biotrade and bioprospecting permits.

EUROPEAN UNION

What ABS rules are in place?	In March 2014, the European Parliament approved the Regulation 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 Utilisation.
What activities do ABS rules cover?	The EU regulation applies to genetic resources and to associated traditional knowledge over which countries exercise sovereign rights and that are accessed after the entry into force of the Nagoya Protocol for the European Union. The “utilisation” of these genetic resources, defined as conducting research and development on the genetic and/or biochemical composition of genetic resources, in the European Union is now subject to the obligations set out in this regulation. Traditional knowledge is only considered as described in any mutually agreed terms applying to the utilisation of genetic resources.
Who is responsible for complying with ABS requirements?	The EU regulation applies to “users of genetic resources," defined as the persons or entities conducting research and development on the genetic and/or biochemical composition of genetic resources. In the proposal for the regulation, the European Commission noted that a broad range of entities in the European Union, including companies from sectors such as plant and animal breeding, biocontrol, cosmetics, food and beverage, horticulture, industrial biotechnology and pharmaceutical, use genetic resources for research and development purposes.
How do ABS requirements work?	The EU regulation establishes due diligence requirements for the users of genetic resources. They must ascertain that genetic resources and associated traditional knowledge with genetic resources they utilise comply with applicable ABS rules in the provider country. For this purpose, users must seek, keep and transfer information such as the date and place of access of genetic resources, their source and any subsequent users and the relevance and compliance with any ABS requirements. When there are uncertainties around ABS compliance, users must obtain relevant permits or discontinue utilisation. EU Member States will establish different checkpoints, including during final stages of product development, to request users to declare compliance with their due diligence requirements. They will also carry out checks to verify whether users comply with these obligations.
What are practical experiences on ABS?	In the impact assessment for the proposed regulation, the due diligence obligation was expected to establish an EU-level playing field for the utilisation of genetic resources. The due diligence approach was also deemed to be flexible enough to accommodate differences between sectors utilising genetic resources and associated traditional knowledge. Users would be able to identify for themselves a suitable and cost-effective way of meeting their obligation and rely on codes of conducts or best practices in their sector.
What are latest developments or trends?	The regulation will enter into force with the entry of the Nagoya Protocol, expected in October 2014. With the approval of the regulation, the European Commission and the Member States of the European Union are enabled and obliged to take appropriate measures for its implementation. For example, the European Commission will need to issue implementing legislation on registered collections, best practices and monitoring user compliance. At the national level, EU member states will need to establish competent authorities and establish checks and penalties for non-compliance.

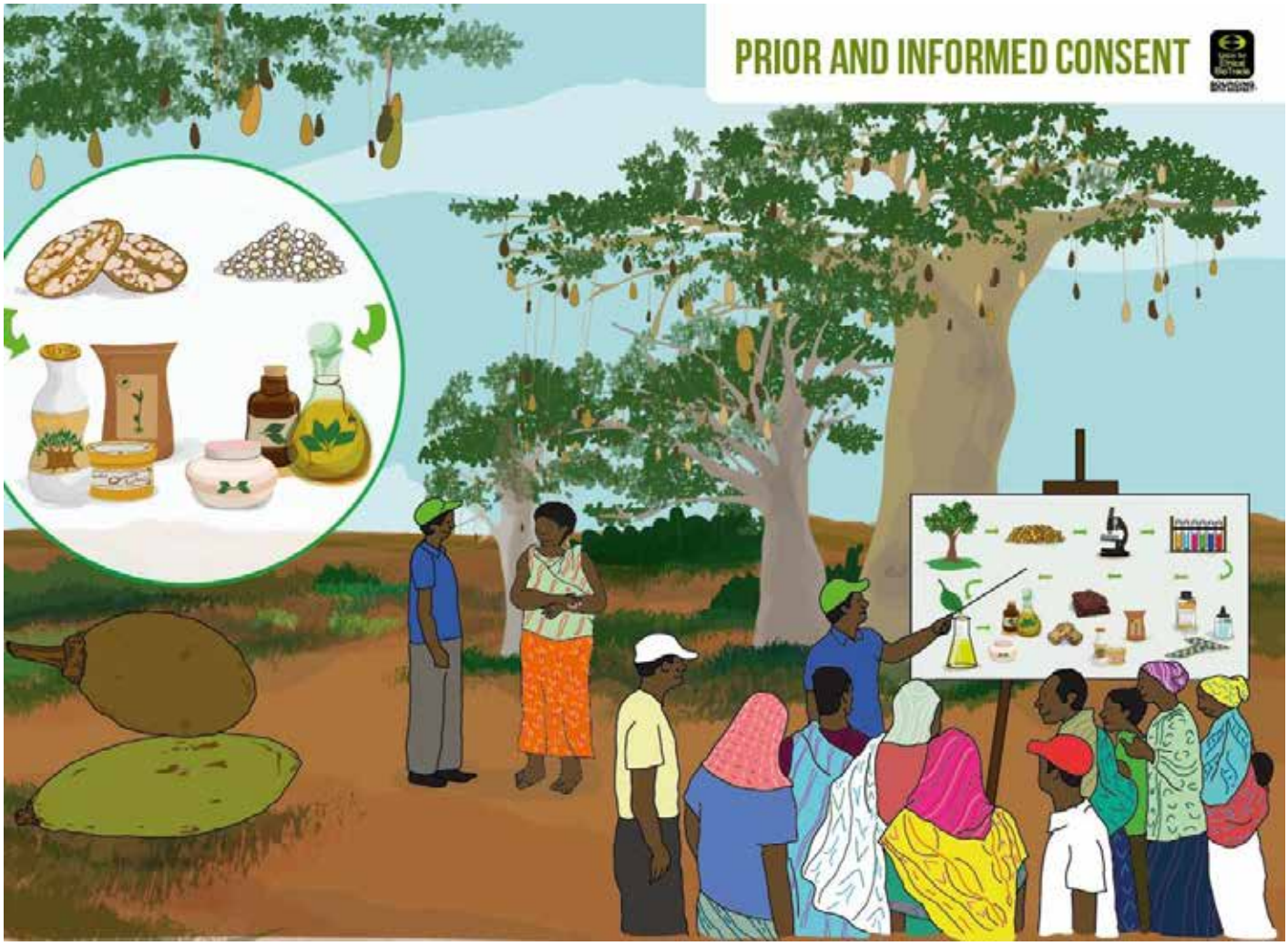

Illustration of 'prior informed consent' in the Ethical BioTrade Learning Set, a UEBT capacity development kit for local communities.

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