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

Secretariat of the Convention on Biological Diversity
Outline

• Background
• Access and Benefit-sharing and traditional knowledge
• The Nagoya Protocol
• The Inter-sessional process
• Entry into force
Nagoya Protocol to operationalize one of the three objectives of the CBD:

- Conservation of biological diversity
- Sustainable use of its components
- Fair and equitable sharing of benefits from the use of genetic resources
Fundamental ABS principles (Article 15 CBD):

• Sovereign rights over natural resources
• Prior informed consent
• Mutually agreed terms, including the sharing of benefits arising from the commercial and other utilization of genetic resources

Article 8 (j) CBD

• Governments are to respect, preserve, maintain and promote the wider application of traditional knowledge with the approval and involvement of relevant indigenous and local communities
Why a Protocol on Access and Benefit-sharing?

- CBD provisions not fully implemented
- Cases of misappropriation of genetic resources and associated traditional knowledge

Need for legal certainty and transparency

- Concern to ensure benefit-sharing once genetic resources have left the provider country
- Need for clear procedures when accessing genetic resources
Mandate for negotiations:

- **WSSD, 2002**: Political mandate for international regime on ABS
- **COP VII, 2004**: WG-ABS mandated to negotiate an international regime on ABS
- **COP X, 2010**: Finalization of the negotiations and adoption of the Nagoya Protocol on ABS
Access and Benefit-sharing (ABS) and Traditional Knowledge

- **Traditional knowledge** related to biological resources can be an important source of information for identifying new uses of genetic resources

- **How does ABS work?**
  - Prior informed consent (PIC) is granted by a provider to a user
  - Negotiations between the provider and the user to develop mutually agreed terms (MAT) that ensure that the benefits from traditional knowledge are shared equitably
Access and Benefit-sharing (ABS) and Traditional Knowledge

Access to TK

PIC and MAT from ILCs

Compliance

Benefit-sharing

Five key themes that underpin access and benefit-sharing of genetic resources. These are addressed in a series of factsheets, which tackle each theme individually.

Living in harmony with nature
Access and Benefit-sharing (ABS) and Traditional Knowledge

Prior Informed Consent (PIC)

Provider of GR (& associated TK): e.g. National Competent Authority

User of GR (& associated TK): e.g. industry, research universities

Mutually Agreed Terms (MAT) between provider and user

- Non-commercial or commercial utilization of GR (& associated TK): e.g. basic research, research and development, development of new pharmaceuticals, biotechnological products
- Benefit-Sharing (monetary & non-monetary): e.g. royalties, technology transfer, training

Community Protocols
Overview

- Objective
- Scope
- Core Elements
- Tools and Mechanisms to assist with implementation
Objective

The fair and equitable sharing of the benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity
The Nagoya Protocol on ABS

Scope of the Protocol

• Genetic resources within the scope of Article 15 CBD and the benefits arising from the utilization of such resources

• Traditional knowledge associated with genetic resources within the scope of the CBD and the benefits arising from the utilization of such knowledge
Core elements of the Nagoya Protocol

- Access
- Benefit-sharing
- Compliance
- Traditional knowledge and indigenous and local communities
Core elements: Traditional Knowledge and ILCs

• During these negotiations, indigenous and local communities (ILCs) used the UN Declaration on the Rights of Indigenous Peoples, as a legal framework to interface with Party negotiators with a good deal of success.

• Fundamental to this effort was recognition of the community protocols.
Core elements: Traditional Knowledge and ILCs

References to TK and ILCs in the preamble:

• Relevance of Article 8(j)
• Interrelationship between genetic resources and TK and their inseparable nature for ILCs
• Importance of TK for the conservation and sustainable use of biodiversity, and for the sustainable livelihoods of ILCs
• Diversity of circumstances in which TK is owned or held
• UN declaration on the Rights of Indigenous Peoples
• Nothing in Protocol should be construed to diminish or extinguish existing rights
Access to Genetic Resources

Obligation to take measures in accordance with domestic law:

• For obtaining **PIC or prior approval** and involvement of indigenous and local communities (ILCs) for access to genetic resources where they have the established rights to grant access to those resources

• Setting out criteria and/or processes for obtaining PIC or approval and involvement of ILCs

Access to TK associated with Genetic Resources

Obligation to take measures in accordance with domestic law:

• With the aim of ensuring that TK held by indigenous and local communities is accessed with PIC or approval and involvement of ILCs and MAT established
Benefit-Sharing

Obligation to take measures for the sharing of benefits with indigenous and local communities:

- With respect to genetic resources held by ILCs in accordance with domestic legislation regarding established rights of these ILCs over these genetic resources
- With respect to TK associated with genetic resources held by ILCs
The Nagoya Protocol recognizes the value of community protocols of ILCs in the ABS process.

• Article 12 (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.”

• Article 12 (3): “Parties shall endeavour to support, as appropriate, the development by ILCs, including women within these communities, of:

   (a) Community protocols in relation to access to traditional knowledge associate with genetic resources and the fair and equitable sharing of benefits arising out of utilization of such knowledge…”
• Obligation of Parties to establish mechanisms to inform potential users of TK associated with genetic resources about their obligations, including measures as made available through the ABS Clearing-House.

• Obligation to not restrict the customary use and exchange of genetic resources and associated TK within and amongst ILCs
Parties to the CBD included Article 14, in the Nagoya Protocol, which establishes an Access and Benefit Sharing Clearing House (ABS-CH), to allow countries to:

- facilitate the implementation of the NP
- Main function: facilitate exchange of relevant information
- the goal of the ABS-CH:
  - legal certainty, clarity, transparency
  - fair and non-arbitrary rules and procedures
  - monitoring to ensure compliance
Benefits of the ABS-CH for ILCs

ILCs can contribute and benefit from the ABS-CH by:

- Sharing relevant information related to the Traditional Knowledge of how to use specific genetic resources;
- Sharing information, as determined by Parties through national legislation, on procedures to grant access to certain genetic resources, like community protocols and customary laws;
- Creating a community where knowledge and best practices from ILCs of other countries are shared;
- Sharing and accessing awareness-raising and capacity-building materials on Traditional Knowledge with other stakeholders;
- Publishing ABS related material in their own indigenous language.
The Access and Benefit-sharing Clearing-house (ABSCH) is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the Nagoya Protocol.
Core elements : Traditional Knowledge and ILCs

Compliance with national legislation on TK

- **Obligation to take measures:**
  - To provide that TK associated with genetic resources is accessed with PIC or approval and involvement of indigenous and local communities and MAT, as required by domestic ABS legislation
  - To address situations of non-compliance

- **Obligation to cooperate in cases of alleged violation of national law on TK**
Compliance

- The **internationally recognized certificate of compliance (IRCC)**:
  - 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 (Paragraph 3 of Article 17)

- The **minimum information** required for the IRCC when it is not confidential, which in turn provides the minimum information to be reported to the ABS Clearing-House in this regard. This information includes:
  - Issuing authority;
  - Date of issuance;
  - The provider;
  - Unique identifier of the certificate;
  - The person or entity to whom prior informed consent was granted;
  - Subject-matter or genetic resources covered by the certificate;
  - Confirmation that mutually agreed terms were established;
  - Confirmation that prior informed consent was obtained; and
  - Commercial and/or non-commercial use.
Constituting an internationally recognized certificate of compliance (IRCC)
Using the IRCC at checkpoints

User of GR → IRCC/ PIC/ MAT/source → Checkpoint
ABSCH-IRCC-IN-204353-1

Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 3, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (a) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

General Information

Issuing country
India

Verification link (view latest version)
http://absch.cbd.int/database/ABSCH-IRCC-IN-204353

ABS-CH Unique Identifier (UID)
ABSCH-IRCC-IN-204353-1

Issuing Authority

National Biodiversity Authority (NBA)
5th Floor, VCBI Building, CSIR Road, Taramani
Chennai, Tamil Nadu
600 113, India
Phone: +91 44 2264 2777
Fax: +91 44 2264 1000
Email: secretary@nba.gov.in, chairman@nba.gov.in, secretary@nba.gov.in
Website: http://www.nbasindia.org

Details of the permit or its equivalent

Reference number of the permit or its equivalent
India/NBA/Permit/004

Additional national references or identifiers
Application Ref No: 2019

Date of issuance of the permit or its equivalent
27 Mar 2015

Date of expiry of the permit or its equivalent
26 Mar 2018

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted
YES

Provider
The person or entity that holds the right to grant access to the genetic resources in accordance with domestic legislation.

Entity to whom PIC was granted
M/s Deepa Solanki

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established
YES

Additional information about the mutually agreed terms
1. The user shall not obtain any form of IPR based on the biological resources and/or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.
2. The applicant shall submit a report to NBA on the outcome of the research work.

Subject-matter

Subject-matter or genetic resources covered
Accessing ethno-medicinal knowledge of the Siddi community from Gagra for research

Information on the utilization of the genetic resource(s)

Type of use allowed by the permit or its equivalent
CONFIDENTIAL INFORMATION

Conditions for third party transfer:
The user shall not transfer or part with the biological resources and/or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.

Certificate History

Date Action Author Comment
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Further Information

Questions about the permit or its equivalent constituting an internationally recognized certificate of compliance should be addressed to the concerned national authority issuing the permit or its equivalent. Additional information about the permit or its equivalent may be available in the Access and Benefit-sharing Clearing-House (http://absch.cbd.int).

Questions about the Nagoya Protocol on Access and Benefit-sharing or the operation of the Access and Benefit-sharing Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

https://absch.cbd.int/search/national-records/IRCC
Tools and Mechanisms to assist with implementation

- Capacity-building/Awareness-raising
- Technology Transfer
- National Focal Points and Competent National Authorities
- ABS Clearing House
- Financial Mechanism
- Monitoring and Compliance with the Protocol
Tools and Mechanisms to assist with implementation

Capacity-building

- Obligation to cooperate in the capacity-building and development to effectively implement the Protocol in developing country Parties and Parties with economies in transitions, including by:
  - Special measures to increase the capacity of ILCs, particularly women within these communities.
Tools and Mechanisms to assist with implementation

Awareness-raising

- **Obligation to take measures to raise awareness**, including the importance of genetic resources and TK associated with genetic resources and related ABS issues. Such measures may include:
  - Involvement of ILCs in the implementation of the Protocol
  - Awareness-raising of community protocols and procedures
Tools and Mechanisms to assist with implementation

National focal point
Obligation to establish a national focal point that, among other things, will provide information to applicants seeking access to TK on:
- Information on procedures for obtaining PIC and MAT from ILCs, where possible.

Competent national authorities
- Obligation to designate one or more national competent authorities responsible for:
  - Granting access or issuing evidence that access requirements have been met.
  - Advising on applicable procedures for obtaining PIC and entering into MAT.
Thank you for your attention!

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