

Day Two

Review Session

Session 6
ABS Regime and Key Components of ABS

Session 7
International Treaties on ABS

Session 8
Customary Arrangements on ABS

Session 9
Evolving ABS Policies and National Legislation in the HKH

Session 10
Actors in the ABS Process, Legal Procedures for ABS and ABS Tools



Review Session

Time: 30 minutes

Objectives

To review the participants' perceptions of the previous day's session.

- ▶ To find out what participants learned from the previous day
- ▶ To give participants an opportunity to ask questions and the trainer an opportunity to provide clarification
- ▶ To get feedback on the training and session theme
- ▶ To identify any pressing issues

Materials

Flipchart, markers, tape, and board

Method

Participatory discussion marked on a flipchart

Suggested Questions

- What did you learn from yesterday's session?
- Is any clarification needed?
- Did the methodology used help you to engage in the sessions?
- Do you have any other suggestions?

It is not necessary that only these questions be asked. If other questions arise, the trainer should record the question and politely promise that the feedback will be considered. The trainer should not spend too much time on each question during the review session, keeping the time and purpose of the session in mind.

Immediately after the review, the trainer should move to the first session of the day.

Suggestions for the trainer

Start the day with an energiser exercise, either one you have chosen or one suggested by the participants. Always have an energiser ready in case it is needed. Start the review session after the energiser. Hang a flipchart on the board and record the feedback from the participants.

Session 6

ABS Regime and Key Components of ABS

Time: 90 minutes

Objectives

To discuss the ABS regime in depth and review the important components of ABS.

- ▶ To learn about the CBD ABS regime
- ▶ To know about ABS provisions in the CBD
- ▶ To be aware of important components of ABS

Methodology

The trainer should choose the methodology for this session. The objectives can be presented verbally or using a media tool like PowerPoint.

Suggestions for the trainer

Start by reviewing the CBD framework for ABS and the relevant CBD articles, and then discuss the important components of ABS. Discuss prior informed consent (PIC), mutually agreed terms (MAT), and access and benefit sharing in detail using the bioprospecting case studies prepared for Session 5 or other examples. It is important to mention the negotiation elements in each component. Tell the participants that a detailed process discussion will be held for each theme separately in a later session. Remind participants that the resource materials for the session are provided in the manual.

Attention!

This session is purely technical and the trainer should have an in depth knowledge of the content. If the trainer is not fully equipped to deal with the content, a resource person(s) can be invited to conduct the session.

Activities

Activity 1: Presentation on ABS and key components

Do participants need an energiser?

Session 6 Resource Materials

Access and Benefit Sharing (ABS)

The Convention on Biological Diversity (CBD) guarantees individual states sovereign rights over biodiversity and the patterns of utilisation. Under the CBD access and benefit sharing regime (ABS), states are entitled to regulate access to their genetic resources for environmentally sound purposes, but cannot impose restrictions that are counter to the objectives of the CBD. The CBD has proposed an international regime on access and benefit sharing (ABS) of genetic resources and associated traditional knowledge. The overall aim is to ensure that the country of origin receives a fair share of the benefits in return for sharing its resources with the accessing parties (Article 15).

Article 15 (1,2,3) states that, subject to the individual states' sovereign rights over their biological resources, national governments under their own legal provisions have the authority to determine access to genetic resources. Article 15 (4,5) states that the party responsible for providing access should base its agreement on mutually agreed terms (MAT) and prior informed consent (PIC). Article 15 (6) emphasises that the full participation of the provider in scientific research on genetic resources should be sought. Article 15 (7) states that accessing and providing parties are required to take legislative, administrative and policy measures as appropriate, and in accordance with articles 16 and 19, and where necessary through the financial mechanism established by Articles 20 and 21 for sharing in a fair and equitable way, and such sharing shall be upon mutually agreed terms. The CBD provisions relevant to access and benefit sharing are given in Table 3.

In 2002, COP 6 adopted the Bonn Guidelines to facilitate the implementation of the ABS regime. The Bonn Guidelines assist parties, governments, and other stakeholders in developing overall access and benefit sharing strategies and in identifying the steps involved in the process of obtaining access to genetic resources and benefit sharing. They also facilitate the establishment of legislative, administrative, and policy measures on access and benefit sharing.

Key components of ABS

The CBD contains provisions dealing with various components of ABS regimes in relation to access, bioprospecting, and benefit sharing. These components are a crucial part of any ABS regime and should be included by parties in their respective regional and national ABS legislation. These components, if properly implemented within ABS legal frameworks, can promote cooperation and trust between the parties involved in the bioprospecting process. The components are followed by many research institutions, commercial bioprospecting companies, and national governments, but they are not consolidated into one ABS legal framework. In the absence in many countries of an appropriate legal framework addressing the ABS mechanism, some provisions are present in the form of codes of conduct, while others are absent or vested as a discretionary power in the government and/or leading members of

Table 3: Provisions in the CBD relevant to access and benefit sharing

Article	Details
Preamble	The desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations, and practices relevant to the conservation of biological diversity and the sustainable use of its components.
Article 1	One of the three objectives of the CBD is the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, by access to genetic resources and technology transfer.
Article 8 (j)	Requires parties to the CBD to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities, promote their wider application with their holders' approval and involvement, and encourage the equitable sharing of the benefits arising from their utilisation.
Article 10(c)	Requires parties to the CBD to protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation and sustainable use requirements.
Article 15 (1)	States have the sovereign right to regulate access.
Article 15 (2)	Requires parties to the CBD to facilitate access for environmentally sound purposes and not impose restrictions that are counter to the CBD.
Article 15 (3)	Provides that only the country of origin or a country that has acquired genetic resources in compliance with the CBD may grant access to genetic resources.
Article 15 (4)	Provides for access only on mutually agreed terms.
Article 15 (5)	Provides for access subject to prior informed consent.
Article 15 (6)	Provides for full participation of the provider in scientific research based on the genetic resources provided.
Article 15 (7)	Requires parties to the CBD to take legislative, administrative, or policy measures to share benefits from research and development and commercialisation equitably and on mutually agreed terms.
Article 16 (3)	Requires parties to the CBD to take legislative, administrative, or policy measures to provide access to and transfer of technology that makes use of genetic resources accessed on mutually agreed terms and in accordance with international law.
Article 18 (4)	Requires parties to the CBD to encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies.
Article 19 (1)	Requires parties to the CBD to take legislative, administrative, or policy measures to ensure the effective participation by providers in biotechnological research on the genetic resources.
Art 19 (2)	Provides for priority access to the results and benefits from biotechnologies based on genetic resources provided.

Source: CBD 1993

indigenous and local communities. The CBD has tried to make it mandatory to enact these provisions into national ABS legislation after the ratification of the convention.

Components that are central to the development and implementation of an ABS regime include

- **prior informed consent (PIC)** for access to biological resources,
- **benefit sharing from access** to and use of genetic resources and associated traditional knowledge, and
- **mutually agreed terms (MAT)** for access and use of biological resources and traditional knowledge.

These are based on concepts of **intellectual property rights** and **traditional knowledge**.

Each component is defined and described briefly in the following. More detailed discussion of each will take place in later sessions, when discussing the legal steps in the ABS process.

Prior informed consent

Article 15 (5) of the CBD states that the access agreement is subject to the prior informed consent (PIC) of the providing parties, that PIC must also be taken from the communities who own the genetic resources and associated traditional knowledge, and that such provisions should be contained in the individual country's legislation. Prior informed consent is not defined in the CBD, but its key elements are: **prior** – before access to knowledge or genetic resources takes place; **informed** – based on truthful information about the use that will be made of the knowledge or genetic resources that is adequate for the authority to understand the implications; and **consent** – the explicit consent of the government, and stakeholders or rights holders according to national law (ICCBD Canada 2000). Thus, prior informed consent is approval in advance for the use of genetic resources and any associated traditional knowledge (Hansen and Fleet 2003).

PIC is an established norm in some international legal instruments. For example, in the Basel Convention on Control of Transboundary Movement of Hazardous Wastes and their Disposal, PIC is required from the receiving and dumping country before the movement of hazardous waste from the source to the destination country. Similarly, in the medical field, before undertaking an operation on a patient, PIC is required to be taken from the patient or from his/her guardian as to the potential consequences of the operation. Similarly, in bioprospecting under the CBD, PIC has to be obtained from the concerned institutions in the country from where the genetic resources and associated traditional knowledge will be taken. This includes obtaining PIC from the responsible government agency, from indigenous and local communities, and from the holders of the traditional knowledge and genetic resources. This is an important requirement as stipulated in Article 15 of the CBD. However, the requirements will be based on the national ABS legislation. Some laws may only require PIC from the government authority while others may seek it from different levels including from local, indigenous, and marginalised communities.

Benefit sharing

Benefit sharing is the sharing of whatever accrues from the utilisation of biological resources, community knowledge, technologies, innovations, or practices. It also means the sharing of all forms of compensation for the use of genetic resources, whether monetary or non-monetary (CBD 2002a,b). Monetary benefits may be upfront payments, access fees, milestone payments, licence fees, research funding for salaries and infrastructure, joint ventures, and joint ownership of intellectual property rights. Non-monetary benefits may include the sharing of research results, collaboration in scientific research, participation in product development, collaboration in education and training, and technology transfer (CBD 2002a,b). The CBD stresses the 'fair and equitable sharing of benefits'. Section 21(1) of the Indian Biodiversity Act defines benefit sharing as the 'sharing of benefits arising out of the use of accessed biological resources, their byproducts, innovations, and practices associated with their use and application and knowledge thereto, in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned, and the benefit claimers' (NBA 2005).

Access

Access generally means the acquisition of biological resources or their derivatives, community knowledge, innovations, technologies, or practices, and refers to the granting of permission to enter an area for the purpose of sampling, collecting, surveying, or acquiring genetic resources for general study, examination, or research for scientific or commercial purposes. Access to genetic resources involves obtaining samples of biological or other material that contain genetic material for the purpose of research, conservation, or commercial/industrial application.

After the CBD came into force, access facilitation was vested in national governments holding genetic material and associated traditional knowledge. Therefore, the ABS system applies to research and industrial applications, and other forms of bioprospecting for which genetic resources and associated traditional knowledge are obtained from the providing country/party to the user country/party.

Mutually agreed terms

Article 15 (4) of the CBD stipulates that the access should be based on mutually agreed terms (MAT) between the parties providing the genetic resources and the parties using them. MAT are the terms and conditions agreed by the contracting parties at the time of entering into a contract, in this case for bioprospecting. It refers to the various types of authorisations defining the conditions for access and benefit sharing by means of which users obtain access to genetic resources, or permission to collect, study, or utilise genetic resources commercially. The same basic principles of PIC apply to MAT, but in this case, the focus is on the terms and conditions set while reaching an agreement and signing a contract for bioprospecting, which both parties have to mutually agree upon.

Intellectual property rights

Establishing rights over the creations and innovations of individuals, groups, and communities, in relation to both processes and products, is an important incentive for the promotion of inventions. The establishment of rightful gains for such inventions is called intellectual property rights (IPR). The key international IPR instruments relevant to plants, biodiversity, and trade are the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreements; and the International Convention for the Protection of New Varieties of Plants (UPOV).

Patents are available for any invention, whether for products or processes, in all fields of technology, provided that they are new, involve inventive steps, and are capable of industrial application.

The CBD also contains provisions in relation to IPR. For example, Article 16 (2.1 and 2.3) on access to, and transfer of, technology; Article 8 (j), which states that parties must "...respect, preserve, and maintain knowledge..."; Article 18(4) to develop methods of cooperation for the development of technologies including indigenous and traditional technologies, and Article 17 on the exchange of information, including the results of research, as well as specialised knowledge and indigenous and traditional knowledge.

The UPOV and TRIPS are more concerned with the protection of the IPR of individuals, while the CBD is more concerned with the protection of community rights in relation to the developers and custodians of traditional knowledge and technologies, the source of many innovations.

Traditional knowledge

There is no agreed definition of traditional knowledge. The World Intellectual Property Organization (WIPO) refers to it as tradition-based literary, artistic, or scientific works: performances, inventions, scientific discoveries, designs, marks, names, and symbols, undisclosed information, and all other tradition-based innovations and creations resulting from intellectual activities in the industrial, scientific, literary, or artistic fields. WIPO also suggests that the terms traditional knowledge and indigenous knowledge could be interchangeable (WIPO 2001). The CBD defines traditional knowledge as the knowledge, innovations, and practices of indigenous and local communities around the world, developed from experience gained over the centuries and adapted to the local culture and environment. Traditional knowledge is transmitted orally from generation to generation, it tends to be collectively owned, and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Traditional knowledge is mainly of a practical nature, particularly in such fields such as agriculture, fisheries, health, horticulture, and forestry. The CBD refers to indigenous people's knowledge, innovations, and practices in order to highlight the intellectual efforts of indigenous and local communities as they relate to biodiversity conservation and sustainable use (see CBD Article 8 (j)), CBD no date b).

It appears that the term traditional knowledge is only one of the various words used to describe similar subject matter, namely the intellectual efforts of, and the results generated by, indigenous people and local communities that have enabled them to adapt and live in relative harmony with their natural environment throughout the centuries and contribute innumerable products to modern society.

Traditional knowledge is also considered to be a 'prior art'. A prior art or state of art usually refers to the complete body of knowledge on the subject which is available to the public before a patent application is filed. This is required in order to understand whether the innovation subject to patent application is 'novel' or just taken from the existing knowledge. If it is just taken from the existing knowledge with slight alteration, the innovation may not meet the criteria of patentability. Therefore the novelty is measured against the state of art at the time of administering patent. The inventive steps of an invention are established when it is not obvious to a person skilled in the art, taking into account any matter which forms part of the state of the art.

Session 7

International Treaties Related to ABS

Time: 45 minutes

Objective

To review and discuss relevant international treaties related to the ABS regime and their ratification.

- ▶ To highlight relevant international treaties related to ABS
- ▶ To examine their ratification by countries in the Hindu Kush-Himalayan region

Methodology

The person who presents the session can choose to do a verbal presentation or use a media tool such as PowerPoint.

Suggestions for the trainer

Start the session by reviewing other relevant treaties related to ABS, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). WTO and TRIPS should be mentioned briefly in relation to how they conflict with the CBD. Do not focus on detailed discussion and debate as it tends to create confusion. Mention that any other issues can be discussed further during the breaks. Explain to the participants about the strengthening effect of ITPGRFA on ABS. Participants should be able to understand the implications of ratifying these treaties and the CBD. This is enough information. It is critical to mention to the participants that these treaties emerged at, or after, the time that the the debate on ownership of biodiversity and genetic resources gained momentum. Remind participants that the resource materials for the session are provided in the manual.

Attention!

This session is purely technical and the trainer should have an in depth knowledge of the content. If the trainer is not fully equipped to deal with the content, a resource person(s) can be invited to conduct the session.

Activity

Activity 1: Presentation on various international treaties related to ABS.

Session 7 Resource Materials

ABS Related International Treaties

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

After the CBD came into force in 1992, the debate over access and benefit sharing of plant genetic resources for food and agriculture (PGRFA) was continued in the Food and Agriculture Organization of the United Nations (FAO). The debate centred on the ownership of genetic resources for food and agriculture and the mechanisms for facilitating access under national jurisdictions. Seven years of negotiation followed the coming into force of the CBD, and in November 2001 the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was approved by FAO and adopted to address the issue of PGRFA in harmony with the CBD. The ITPGRFA came into force on 29 June 2004. This treaty aims “at conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use, in harmony with the CBD” (FAO 2004). Recognising the sovereign rights of countries over their genetic resources, this treaty recognises the role of farmers in conserving and developing genetic resources and places the responsibility on national governments to establish farmers’ rights. The ‘Multilateral Systems of Access and Benefit Sharing’ and provision for ‘Farmers’ Rights’ are important features of the treaty, which aims for the fair and equitable sharing of benefits from the use of PGRFA for food security and sustainable agriculture.

Both the CBD and ITPGRFA address the fundamental issues of ABS of genetic resources and associated traditional knowledge. Both recognise the sovereign rights of countries over genetic resources and the role of indigenous local communities and farmers in conserving and developing genetic resources. Both introduce a system for regulating the collection of genetic resources and different types of mechanisms for access to genetic resources, referred to as the access and benefit sharing system. This is a process of joint regulation of access and benefit sharing arising out of the use of genetic resources and associated traditional knowledge by researchers, industries, companies, indigenous/local communities, concerned governments, and holders of traditional knowledge.

World Intellectual Property Organization (WIPO)

“WIPO is an international organisation dedicated to promoting the use and protection of intellectual property. It is one of the 16 specialised agencies of the United Nations system of organisations that administers 21 international treaties dealing with different aspects of intellectual property protection” (UNTERM 2006). In relation to the ABS process, WIPO’s role has been to support the CBD COP by developing operational definitions of traditional knowledge and related terms, reviewing existing intellectual property protection of traditional knowledge, and identifying elements of a sui generis system [will be explained during the session] of protecting traditional knowledge. The WIPO provides a forum for

international policy debate and the development of legal mechanisms and practical tools for the protection of traditional knowledge and traditional cultural expressions (folklore) against misappropriation and misuse, and in relation to the intellectual property (IP) aspects of access to and benefit-sharing of genetic resources (WIPO no date a,b).

International Union for the Protection of New Varieties of Plants (UPOV)

The International Union for the Protection of New Varieties of Plants (UPOV) was established by the International Convention of the same name. The Convention was adopted in Paris in 1961 and revised in 1972, 1978, and 1991. The objective of the Convention is the protection of new varieties of plants as intellectual property. Its mission is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants for the benefit of society (UPOV 2008a,b,c).

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is an international agreement between governments that resulted from a resolution adopted in 1963 at a meeting of the members of The World Conservation Union (IUCN). It entered into force on 1 July 1975. The major aim of this agreement is to ensure that the international trade in specimens of wild animals and plants does not threaten their survival. It is voluntary for states to adhere to the CITES. Parties who have joined CITES have to implement the Convention. It provides a framework that parties should respect and adopt in their own national legislation to ensure that CITES is implemented at the national level (CITES no date).

CITES provides a critical legal mechanism for the control of the illegal transboundary movement of genetic resources and illicit and unsustainable harvesting of resources, thus helping to achieve the first and second objectives of the CBD: conservation and the sustainable use of biodiversity.

World Trade Organization (WTO) and Trade Related Aspects of Intellectual Property Rights (TRIPS)

The enforcement of the CBD led the World Trade Organization (WTO) to attempt to control the economic aspects of biodiversity through patents in the agreement on TRIPS. Article 27(3)(b) of TRIPS calls for the enactment of protection and the regulation of plant varieties through patents, an effective sui generis system, or a combination of both. The provisions of TRIPS, however, conflict with the sovereign rights of states over biodiversity, as recognised in the CBD. Existing IPR systems are oriented around the concept of private ownership and individual innovation. There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use, and, in addition, without the fair sharing of benefits with the holders of this knowledge. The provisions of TRIPS in relation to ABS are still under debate, in particular, Article 27(3)(b). Some of WTO's developing country members have called for this Article to be amended to include the requirement to produce proof of origin of the biological/genetic resources, while other WTO country members are seeking more progressive ways that do not restrict intellectual property rights. The debates on WTO/TRIPS are ongoing. (see WTO no date a,b)

Ratifications in the HKH

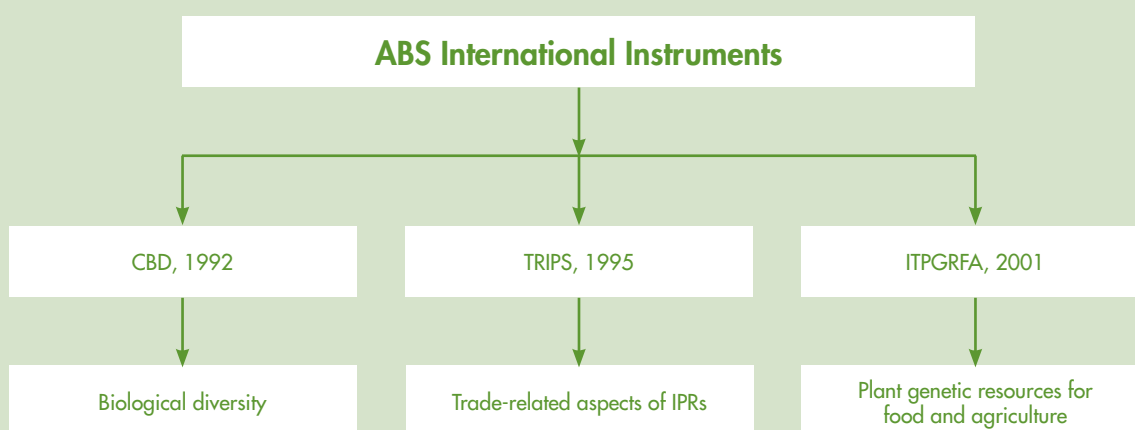
International conventions and other instruments (Figure 5), once signed and ratified, are binding on contracting parties. As of 2009, 194 countries are party to the CBD, including the EU and the eight countries of the Hindu Kush-Himalayan region (Table 4), and over 78 countries have signed the ITPGRFA. All eight countries in the HKH are party to the CITES; and, with the exception of Afghanistan, all are WTO members. Ratification of these treaties by these countries obliges them to enact national legislation implementing the treaties.

Table 4: Parties to the CBD in the HKH region

Country	Signed	Party	Focal Institution
Afghanistan	12 June 1992	19 September (ratification)	National Environment Protection Agency
Bangladesh	5 June 1992	3 May 1994	Ministry of Environment and Forests
Bhutan	11 June 1992	25 August 1995 (ratification)	National Environment Commission
China	11 June 1992	5 January 1993	State Environmental Protection Organization
India	5 June 1992	18 February 1994 (ratification)	Ministry of Environment and Forests
Myanmar	11 June 1992	25 November 1994	National Commission for Environmental Affairs & Ministry of Foreign Affairs
Nepal	12 June 1992	23 November 1993 (ratification)	Ministry of Forests and Soil Conservation
Pakistan	5 June 1992	26 July 1994	Ministry of Environment

Source: CBD no date a

Figure 5: Chart illustrating ABS international instruments



Session 8

Customary Arrangements on ABS

Time: 60 minutes

Objectives

To review customary arrangements on ABS and their relevance to the ABS regime.

- ▶ To understand customary laws regarding the use of biological resources
- ▶ To become acquainted with the customary system(s) in the region and their relevance to the ABS regime

Methodology

Group exercise and presentation.

Materials

Two case studies (preferably one from the trainer and one from the participants)

Suggestions for the trainer

Decide on the specific methodology for this session and prepare it in advance. The session can be made interesting by sharing real stories or cases of customary arrangements on ABS in the HKH region or in other parts of the world for managing and utilising genetic resources and traditional knowledge according to customary laws in a group discussion at the beginning of the session. Cases can be your own or from the participants. You can also use the case study given in the resource materials for this section. The case studies should illuminate the theme of the session. Follow the discussion with a detailed presentation on the theme of the session. Any clarifications can be made during the presentation and discussion. Relate the customary arrangements to the articles of the CBD, which countries are obliged to incorporate into national legislation. Wherever possible (in this and the next session), talk about the customary laws (customs, beliefs, and traditions) incorporated into the statutory ABS legislation of Eastern Himalayan countries, while discussing the ABS legislation of different countries.

Activities

Activity 1: Exercise – Case studies, discussion, and learning outcome

Time: 45 minutes

Aim

To help participants become aware of customary arrangements on ABS in their community and country and the HKH region as a whole.

- Participants are able to understand the customary arrangements on the use of biological resources in the HKH.
- Participants are aware of the CBD provisions that safeguard customary arrangements that exist among communities.

Method

Group exercise

Materials

Handouts of case studies

Steps

- Step 1** Split the participants into groups by allocating a random number based on the number of groups (e.g., for three groups, allocate each person a number from one to three).
- Step 2** Introduce the aim of the exercise.
- Step 3** Distribute the case studies among the groups (the cases in the resource materials for this section can be used).
- Step 4** Ask each group to discuss the case studies within their group.
- Step 5** When all groups are finished with the group discussion, ask them about any similar or other arrangements in their community.
- Step 6** Allow one or two participants to volunteer to share a case from their community.
- Step 7** After sharing, open the floor for discussion.
- Step 8** The outcome of the exercise should lead to further discussion and clarification of the session theme.

Activity 2: Presentation on customary arrangements on ABS

Session 8 Resource Materials

Customary Legal Arrangements

The CBD establishes that nations should respect, preserve, and maintain the knowledge, innovations, and practices of local communities relevant to the conservation and sustainable use of biodiversity.

Customary law is a branch of jurisprudence dealing with rules, laws, or arrangements developed by communities to deal with specific socio-environmental conditions. They may be written or oral, but are adopted by the community. Black's Law Dictionary defines 'customary' as "customs or usages: founded on, or growing out of, or dependent on customs" (Black and Nolan 1990). For the larger part, customary rules or laws are established and have become part of the customs of a community. Even when the customary rule or law cannot be found in any text, it is binding if it has been customary for a long time. Article 10(c) of the CBD provides that parties to the CBD should protect and encourage the customary use of biological resources in accordance with traditional cultural practices compatible with conservation and sustainable use requirements. There are different definitions of customary law or systems, but the key elements are the same as defined in Black's Law Dictionary. For example, the International Institute for Environment and Development (IIED) has a working definition of customary laws as "locally recognised principles, and more specific norms or rules, which are orally held and transmitted, and applied by community institutions to internally govern or guide all aspects of life" (IIED 2008). The important aspect of customary law in relation to the ABS regime is that it generally promotes conservation and promotes and protects traditional knowledge through the sharing of resources and traditional knowledge and collective management for the benefit of the community. Customary law ensures access to resources for subsistence and survival, and promotes social cohesion, solidarity, and equity.

The majority of national constitutions in the Himalayan region respect customary arrangements. The Bonn Guidelines on ABS calls upon parties to the CBD to respect the customs, traditions, values, and customary practices of indigenous and local communities, as well as to secure the customary use of genetic resources and related knowledge. The CBD calls for the integration of such customary arrangements and laws in national ABS regimes. Customary governance still prevails in many parts of the Eastern Himalayas, including in Bangladesh, Bhutan, India, and Nepal, in relation to the management of genetic resources and associated traditional knowledge. In India, "the Indian Constitution under Article 13 treats customary law along with other branches of civil law. A custom or usage if proved would be law in force under this article. These customary rights having the force of law can be taken as judicial notice by courts under Section 57 of the Indian Evidence Act 1872." The Panchayats (Extension to Schedule Areas) Act of 1996 mandates that "states shall not make any law under (Part IX of the Constitution), which is inconsistent with customary law, social and religious practices, and traditional management practices of community resources" (Krishnan 2000).

Customary legal arrangements evolved in response to different situations faced by different societies. They were vital to preserve social order and to enforce the norms and values of the members of the society. Customary legal systems are essentially a combination of local norms, customs, morals, values, and traditions, which are enforced through a process of sanctions developed by the wider community. In the context of natural resource management, customary systems of managing resources are important for their sustainable usage, as customary institutions have much more legitimacy among communities who manage natural resources than statutory arrangements.

There is an urgent need to synergise statutory and customary systems and the overlap between the two to strengthen customary legal systems and make them more responsive to the needs of modern communities. In the ABS process, customary legal frameworks are an ideal mechanism for generating prior informed consent for ABS related activities. Systems for obtaining consent already exist in traditional/indigenous societies. Obtaining 'real' consent is more likely through this socially relevant legal framework. This would be an important contribution of the customary system to the implementation of ABS. As mentioned earlier, customs differ from place to place because they have been developed to address specific problems in specific contexts. Some examples of customary arrangements in natural resources management are given in the following case studies.

Case Study 1: Dzomsa – A Customary System in North Sikkim

Lachen and Lachung are two unique villages in North Sikkim where an age-old community participatory system called Dzomsa is practised. The practice of Dzomsa, which is based on the general consent of the entire community, is more than 200 years old and is still followed with little modification. This system has customary rules, norms, and values for the use of biological resources and aims to conserve the resources as well as promote sustainable

utilisation. In addition, Dzomsa promotes fair access and the equitable sharing of resources among the community.

Sap ko makai (*Arisaema* spp.) is a seasonal staple food enjoyed by the local community. The *Arisaema* tuber/bulbs are found at an elevation ranging between 2100 and 4000 masl (6800 and 13000 feet) under rhododendron and conifer forest. The collection of *Arisaema* is guided by the Dzomsa norms and values, as follows:

- When the appropriate time comes to harvest *Arisaema*, the Dzomsa announces the actual day of collection in each block of forest area. The harvest is limited to a maximum of 2-3 days.
- No member of the community is allowed to access any area except as identified by the Dzomsa.
- No family can collect before or after the fixed date.
- The Dzomsa prescribes the type of implement to be used for digging the bulbs. The prescribed tools are wooden shovels made of *Mallus* and *Biburrum* species.
- No iron or metal tools are allowed for the harvest. Anyone found using steel and iron is punished.
- After the annual collection, sometime in July/August, the harvested area is closed for at least three years to allow the resources to rejuvenate.



Source: Lachungpa 2008, see also ICIMOD 2002

Case Study 2: Uvouli and Undhouli – Customary Arrangements

In Upper Marsyangdi, in Lamjung District, Nepal, the year is divided into two parts: uvouli and undhouli. These terms refer to the season and are related to the migratory system of animal rearing.

Uvouli means proceeding uphill, signifying the period from when migratory animals start grazing upward after wintering in the lowlands, usually from mid-February, until they reach their highest grazing site at the start of the dry season. It is also the period when certain farm activities take place (sowing maize, potato, and other summer crops). Undhouli means the commencement of winter and starts with the downward movement of grazing animals, from the highest pasture towards their lowest point at the start of the harvest season for rice and other crops in the lowland areas. Both these terms are also related to the season and signify long and short days during the season.

The private and common property resources in upper Marsyangdi used to be regulated by an assembly attended by all settlements and their representatives called sathi sabha. The assembly used to sit twice a year just before uvouli and undhouli to decide on that year's 'thitis' (customary rules) for resource use and management, and to delineate the grazing sites and conservation areas. The customary rules adopted by the mountain communities included the following:

- a. Animals reared under the transhumant system should start their transhumance route for grazing from the lowland settlements from mid-February, and start coming down from highland grazing sites in the second week of October.
- b. Conserved areas should not be grazed or put to fire. Culprits breaking this rule are to be fined by the community.
- c. Grazing and other human activities are strictly prohibited in environmentally sensitive areas, such as heavily denuded areas, landslides, landslide-prone areas, and flooded areas. Persons and households disobeying this rule are fined.
- d. The harvesting of young bamboo shoots from the forest should commence on a fixed date and only mature shoots should be thinned. The young shoots shouldn't be damaged. Annually, each household is allowed to use 500 small bamboos (300 nigala and 200 malinga (*Arundinaria* spp.)) to make 10 to 20 bamboo mats.
- e. Encroachment in the delineated area should be reported to the assembly and, based on the nature of damage, the intruder will be fined. The funds raised from fines are to be used for social activities by the committee.
- f. Herdsmen should monitor the harvesting of medicinal plants, mushrooms, valuable timber species, wild oilseeds, small bamboo, lokta, herbal plants, and endangered wild animals, as well as any destruction of protected areas.
- g. For animals brought for wintering or grazing from other VDCs or districts lower down outside the jurisdiction of the community area, an animal head tax is to be levied by the settlement in which the animals are wintered/grazed and 'sherma' is to be paid to the primary users.
- h. A resource is allocated by the assembly in collaboration with the representatives of the users

These rules were strictly implemented by all the members. Any decisions perceived as unfair and not practised during the year were changed in the following year's assembly meeting and new rules set, allowing for the regular periodic review of customary rules.

Source: Oli 1998

Session 9

Evolving ABS Policies and National Legislation in the HKH

Time: 90 minutes

Objective

To review the evolving ABS policy framework in the HKH region and the ABS policy provisions in specific countries in the region.

- ▶ To learn about the development of ABS policy and legislation in the HKH countries (Afghanistan, Bangladesh, Bhutan, China, India, Myanmar, Nepal, and Pakistan)
- ▶ To understand ABS legislation and its provisions in the Eastern Himalayan countries

Methodology

The trainer should choose the methodology for this session. The objectives can be presented verbally or using a media tool like PowerPoint.

Suggestions for the trainer

Link the session to the previous one on customary law. Dedicate this session to the review of ABS policies in the HKH region and ABS legislation in the country where the training is taking place. Start the session by discussing the different stages that each country in the region is at in the process of developing and implementing ABS policies and laws. Discuss the various provisions in these legal instruments and refer to the components of ABS in the legislation. Discuss institutional and benefit sharing mechanisms referring to Figure 7 on ABS implementation arrangements. Briefly highlight the need for a regional framework while discussing the laws. Remind participants that the resource materials for this session are provided in the manual.

Attention!

This session is purely technical and the trainer should have an in depth knowledge of the content. If the trainer is not fully equipped to deal with the content, a resource person(s) can be invited to conduct the session.

Activity

Activity 1: Presentation on ABS policies and national legislation in the Hindu Kush-Himalayan region.

Step 1 Presentation

Step 2 Discussion

Do participants need an energiser?

Session 9 Resource Materials

Evolving National ABS Legislation in the HKH

ABS related legislation in the HKH countries

The HKH countries are all at different stages in the development and implementation of ABS laws (see Figure 6). Before the CBD came into force, other legal instruments existed for the regulation of biological resources in these countries.

Afghanistan

Afghanistan is in the early stage of the process of developing ABS related legal instruments.

Bangladesh

Bangladesh has a draft bill on a Biodiversity and Community Knowledge Protection Act 1998.

Bhutan

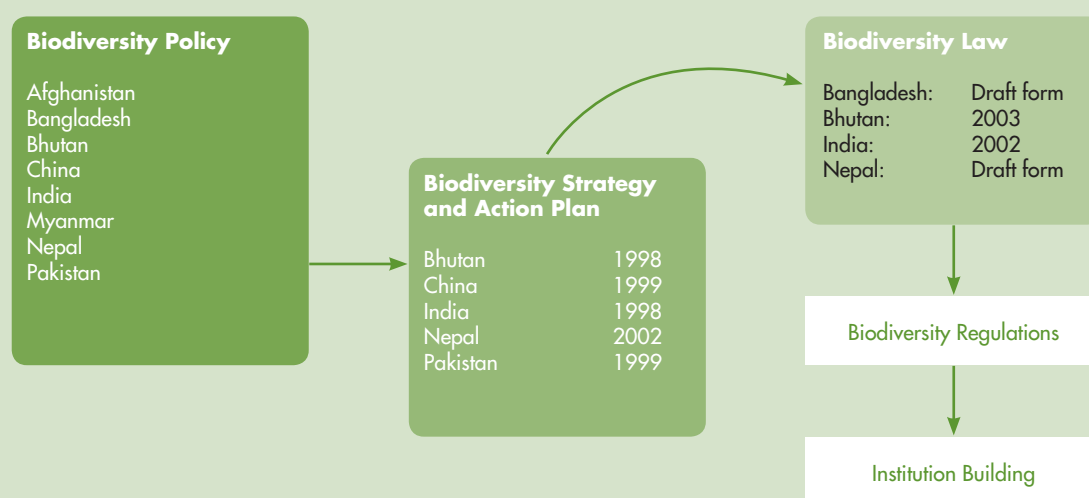
Bhutan has a Biodiversity Action Plan 1998, a Biodiversity Act 2003, and is in the process of developing regulations to enforce the Act.

China

China established a National Biodiversity Unit (NBU) in 1993 headed by the national Environment Protection Agency. It adopted a 10 point strategy in 1992 and a Biodiversity Conservation Action Plan in 1997. Access and benefit sharing arrangements are in force through the Wildlife Protection Law 1989, Wild Plant Protection Regulations 1997, Seed Management Regulations (Crop Seeds 1991, Tree Seeds 1995), and Regulation of Breeds of Stock and Poultry Management 1994. The process of making umbrella ABS legislation is evolving as stipulated in the Biodiversity Country Report 1997 (Xue Dayuan 1998).

India

India has a Biodiversity Act 2002, which is enforced through the Biodiversity Rules 2004. State biodiversity boards are in the process of being established and state biodiversity rules are being promulgated. The Protection of Plant Varieties and Farmers Rights Act is also in force. Other supportive legislation includes the Wildlife Protection Act passed in 1973, as amended in 1991 and 2003, the Indian Forest Act 1927, and the Forest Conservation Act 1980. The major policies outlined in this period were the Forest Policy of 1988 and the National Wild Life Action Plan 2002.

Figure 6: Status of ABS policy and legislation in the Hindu Kush-Himalayas

Myanmar

Myanmar has a National Environment Policy from 1994. A Forest Act 1992 and Wildlife Act 1994 were developed in response to the implementation of the CBD and to manage biodiversity resources in the country.

Nepal

Nepal has a Biodiversity Strategy 2002 and has prepared a Strategy Implementation Action Plan 2006-2010. ABS laws have been drafted and a draft Farmers' and Breeders' Rights Act has been prepared. Since the CBD, protected area legislation and forest laws have been amended and policies developed to protect biodiversity and implement the provisions of the CBD.

Pakistan

Pakistan adopted a Biodiversity Action Plan in 1999 with a view to promoting conservation and the sustainable use of biodiversity and the equitable sharing of benefits arising therefrom. Pakistan has a draft law on Access to Biological Resources and Community Rights 2004. Previously, the Plant Variety Protection Act was in force from 1994, which also dealt with ABS in relation to food crops, while the Environment Protection Act 1997, and various provincial acts and ordinances deal with the environment.

Legal provisions on ABS in the Eastern Himalayan countries

The national biodiversity legislation of the four Eastern Himalayan countries – Bangladesh, Bhutan, India, and Nepal – contains ABS provisions related to access, prior informed consent, benefit sharing, the ABS legislative framework, the bioprospecting process, and institutional mechanisms. These provisions are shown in detail in Table 5.

ABS implementation arrangements in India

Institutional mechanisms for the implementation of the access and benefit sharing regime have been constituted in India. A four-tier organisation has been developed to operate in an interrelated manner (Figure 7).

The competent authority is at the apex and oversees the work of ABS. The National Biodiversity Authority (NBA) regulates access to biological resources. The NBA is responsible for determining equitable benefit sharing and carries out negotiations for access and benefit sharing and the overall implementation of ABS laws in the country. The next authority is the state/provincial/district Biodiversity Board. Each Board is responsible for developing and implementing biodiversity rules in its own jurisdiction. The Biodiversity Boards regulate bioprospecting activities within the state and give advice on matters to the state government. At the base of the pyramid is the Biodiversity Management Committee (BMC), which is constituted at the local level by representatives of communities. They give prior informed consent, engage in benefit sharing agreements, prepare biodiversity registers, and perform functions as stipulated in the Biodiversity Rules 2004.

At each tier, a corresponding trust fund has been established in a decentralised manner so that benefits received from bioprospecting reach the appropriate level. The monetary benefits, fees, and royalties received as a result of approvals by the NBA are deposited in the 'National Biodiversity Fund'. The Fund is proposed to be used for the conservation and development of areas from where resources have been accessed, including the management and conservation of heritage sites wherever applicable. The State Biodiversity Funds will come through the NBA and other sources, as decided by the state governments. Such funds are proposed to be used for the management and conservation of heritage sites, compensation or rehabilitation of any group of people economically affected by the notification of biodiversity heritage sites, the conservation and promotion of biological resources, and the socioeconomic development of areas from where such biological resources have been accessed.

Figure 7: ABS implementation arrangements in India

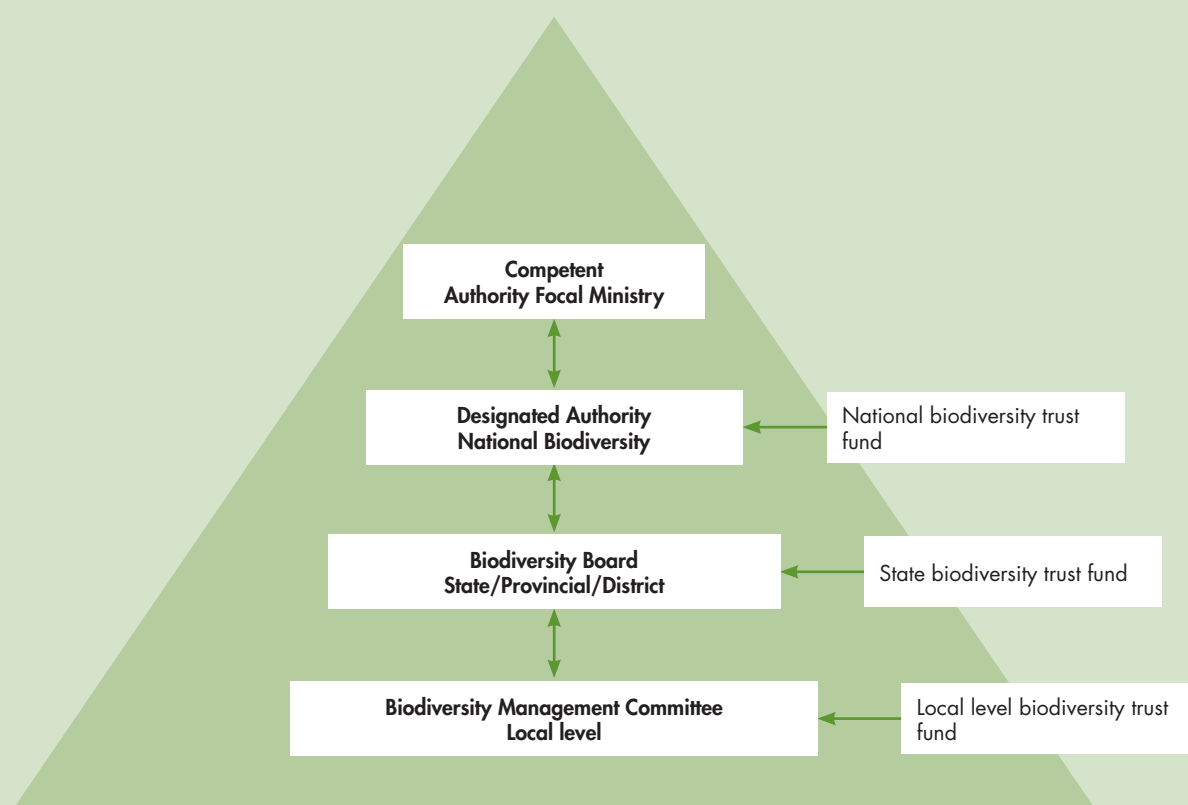


Table 5: Legislative provisions on ABS in the Eastern Himalayan countries

Country	Bangladesh	Bhutan	India	Nepal
Legislation	Biodiversity and Community Knowledge Protection Act, 1998 – Draft	Biodiversity Action Plan 1998 and Biodiversity Act 2003	Biodiversity Act 2002 and Biodiversity Rules 2004	Biodiversity Strategy 2002 and draft legislation
Principle	Recognises states sovereign rights over their biological resources, addresses the responsibility to establish a legal, administrative, and policy environment concerning access to genetic resources and associated traditional knowledge. Provides for the inventorying and documentation of traditional knowledge.			
Access	Prior written approval of the NBA and concerned communities is required for access to genetic resources and traditional knowledge. Communities' role in the ABS process is given extra emphasis.	The competent authority will determine the terms and conditions of access and is obliged to provide advice to the owners of traditional knowledge when they are negotiating a user's agreement. The competent authority has the final right to approve agreements in the national interest of the country.	Prior written approval is required from the National Biodiversity Authority (NBA). Access requests by foreign individuals, institutions, or companies, and all matters relating to access and benefit sharing, terms and conditions are to be dealt with by the NBA.	Permission to access is to be taken from the competent authority, which will determine the terms and conditions of access and benefit sharing.
Benefit sharing	<ul style="list-style-type: none"> Provides for the transfer of technology Provides for the association of scientists, benefit claimers, and communities with research and development in biological resources and bio-survey and bio-utilisation. State to ensure that not less than 50% of the net monetary gains go to the communities concerned. 	<ul style="list-style-type: none"> Provides for flat fees, upfront payments, royalties, the sharing of research results, and milestone payments. Recognises providers of genetic resources and traditional knowledge as partners in intellectual property ownership of products derived from the supplied material. Provides for joint research activities and technologies transfer. 	<ul style="list-style-type: none"> Provides for royalties Provides for fees to be prescribed Establishes a venture capital fund Provides for monetary compensation Locates research and production units to facilitate better living standards for benefit claimers 	<ul style="list-style-type: none"> Provides for technology transfer Provides for fees, royalties, and monetary compensation
Prior informed consent	Recognises the vital role played by communities in biodiversity conservation and recognises the communities as owners, custodians, and stewards of genetic resources and traditional knowledge and the state as a co-owner. The communities are the ones who will negotiate access and benefit sharing in the case of bioprospecting.	The Act states that for any non-customary use of traditional knowledge, PIC should be obtained from the host community. The Act provides a space for rejecting the application to the host community and states that if they accept any such application for access to their traditional knowledge they can enter into a written agreement.	PIC should be sought from the NBA, and the concerned communities as specified in the legislation. State biodiversity boards are to facilitate PIC requirements by engaging the BMC.	The draft legislation requires PIC to be sought from the competent authority and concerned communities. The district committee is required to facilitate the PIC process during the ABS process.
Legislation framework	The National Biodiversity Authority (NBA) in each country will be responsible for implementing a national biodiversity act and will be an autonomous body. The National Biodiversity Authority shall consult communities on matters related to the use of biological resources and associated traditional knowledge within their jurisdiction. Community institutions will be responsible for the conservation, sustainable use, and documentation of biodiversity, and for chronicling knowledge relating to biodiversity.			

(continued on next page)

Table 5. (continued)

ABS process	<p>The prior written approval of the NBA and concerned communities is required as part of the ABS process. The sharing of financial benefits must be based on the mutually agreed terms between the accessing party and the concerned communities, and then the NBA will sign an agreement on behalf of its communities and the state. Agreement is based on the terms and conditions of benefit sharing from commercial utilisation of resources and is initially for a period of three years.</p>	<p>Prior approval is required from the competent authority before commencing the ABS process. Terms and conditions of access will be decided by the authority and the owners of the genetic resources or associated traditional knowledge, who will be provided advice while negotiating a user's agreement. The competent authority has the final right to approve this agreement. The violation of terms and conditions regarding access and benefit sharing entails both criminal and civil liability.</p>	<p>Prior approval of the NBA is required for bioprospecting. The NBA, while granting approval, will impose benefit sharing requirements (fees or royalties or both) or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights. The Biodiversity Act also contains rigorous penalties, making offences under this Act both cognisable and non-bailable with a maximum imprisonment of five years.</p>	<p>Prior approval from the competent authority and subsequent consent from the community must be sought in the process.</p>
Institutional Mechanisms for ABS	<p>The legislation provides for a three-tiered structure at national, state, and local levels.</p> <ul style="list-style-type: none"> • The National Biodiversity Authority (NBA) will be responsible for implementing the Act and will be an autonomous body. • State Biodiversity Boards will deal with matters relating to access, only if desired by the communities and does not have the power to negotiate access to biological and genetic resources for commercial purposes. • Community institutions will be responsible for the conservation, sustainable use, and documentation of biodiversity and the chronicling of knowledge relating to biodiversity. The National Biodiversity Authority shall consult communities on matters related to the use of biological resources and associated traditional knowledge within their jurisdiction. 	<p>The tiered structure has not been decided on in Bhutan and is not contained in current legislation. However provision for a three-tiered structure is being discussed as part of the drafting of the Biodiversity Rules.</p>	<p>The legislation provides for the setting up of a three-tiered structure at national, state and local levels.</p> <ul style="list-style-type: none"> • The National Biodiversity Authority (NBA) will be responsible for implementing the Act and will be an autonomous body. • State Biodiversity Boards will deal with matters relating to access by Indians for commercial purposes and restrict any activity that violates the objectives of conservation, sustainable use, and equitable sharing of benefits. • The Biodiversity Management Committee (BMA) is the lowest tier consisting of institutions of self-government in their respective areas for conservation, sustainable use, and documentation and chronicling of knowledge relating to biodiversity. The NBA will consult the BMC on matters related to the use of biological resources and associated traditional knowledge. 	<p>The draft law calls for the setting up of an authority called the National Genetic Resources Council, which will also have representation at the district level. The mandate of this council will be to regulate access and benefit sharing primarily in the case of foreigners seeking to access biological resources and associated traditional knowledge.</p>

Session 10

Actors in the ABS Process, Legal Procedures for ABS and ABS Tools

Time: 2 hours

Objectives

To map ABS actors, to review the legal procedures in the bioprospecting process, and to practise the use of ABS tools.

- ▶ To understand the various actors in the ABS process
- ▶ To be aware of the general procedure for ABS from genetic resources and associated traditional knowledge
- ▶ To practise the use of ABS tools

Methodology

Individual and group exercises

Suggestions for the trainer

In this session, individual and group exercises are carried out based on a theme with each followed by a presentation. Clarify anything that is unclear during the presentation and discussion.

Exercise 1 (Mapping of ABS actors) is best presented at the start of the session. The mapping exercise will help you to review participants' understanding of the actors in the ABS process. Follow it with a presentation on the various actors, and their obligations and rights in the ABS process, complemented by the diagrammatic representation provided in the resource materials.

Exercise 2 (Role play on the ABS process) follows immediately after the first presentation. The ABS Poster (Figure 9) is the main focus of the role play and discussion. Give the poster to the participants and explain briefly. The role-play exercise will engage participants and help them to understand the ABS process. The use of various ABS tools can be practised during the role play, such as completing sample PIC and MAT forms (contained in the resource materials), but this depends on the extent to which participants have been able to grasp the ABS process. Follow the

(continued on next page)

Suggestions for the trainer (continued)

exercise with an in depth presentation, discussion, and clarification of the legal process, again using the ABS Poster. Highlight the important components of the ABS regime, such as PIC, MAT, and ABS. It is critical to mention the need for negotiation in the ABS process and highlight the points at which it is necessary. Remind participants that a detailed discussion of the process, tools, and negotiation will be done during a later session.

Mention that the sample ABS tools and other resource materials for this session are provided in the resource section. Hold an energiser if needed.

Activities

Activity 1: Exercise – Mapping of ABS actors

Time: 45 minutes

Aim

To review participants' perceptions and knowledge of the various actors involved in the ABS bioprospecting process.

- Participants reflect on their understanding of the actors involved in the ABS process.
- Participants know the various actors involved in the ABS process
- Participants understand the obligations, rights, roles, and responsibilities of the various actors in the process.

Method

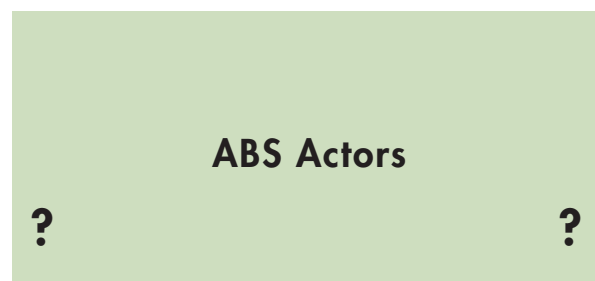
Individual exercise and review of diagram mapping the actors.

Materials

Flipchart, markers, tape, board, diagram of actors

Steps

- Step 1** Attach a flipchart to the board.
- Step 2** Write 'ABS Actors' in the middle of the chart.
- Step 3** Ask a volunteer to come forward as a scribe.
- Step 4** Ask the participants to identify the actors in the ABS process while the volunteer writes them on the chart.
- Step 5** When most of the actors have been mapped, or at least 10 participants have suggested an actor, initiate the presentation and open the floor for discussion.
- Step 6** Pin up the diagram mapping the actors
- Step 7** Hold a brief discussion, making clarifications as needed, before the presentation



Activity 2: Presentation on the actors in ABS and their obligations and rights

Activity 3: Exercise – ‘Learning by doing’, ABS process role play

Time: 45 minutes

Aim

To help participants to understand the ABS process through role play.

- Participants learn about the ABS process through role play.
- Participants understand the components of the ABS process and the actors involved in the process.
- Participants understand the obligations, rights, roles, and responsibilities of the various actors in the process.
- Participants are able to identify where negotiation is necessary in the ABS process and why.

Method

Group exercise and review of ABS poster

Materials

ABS Poster, flipchart, markers, tape, board

Steps

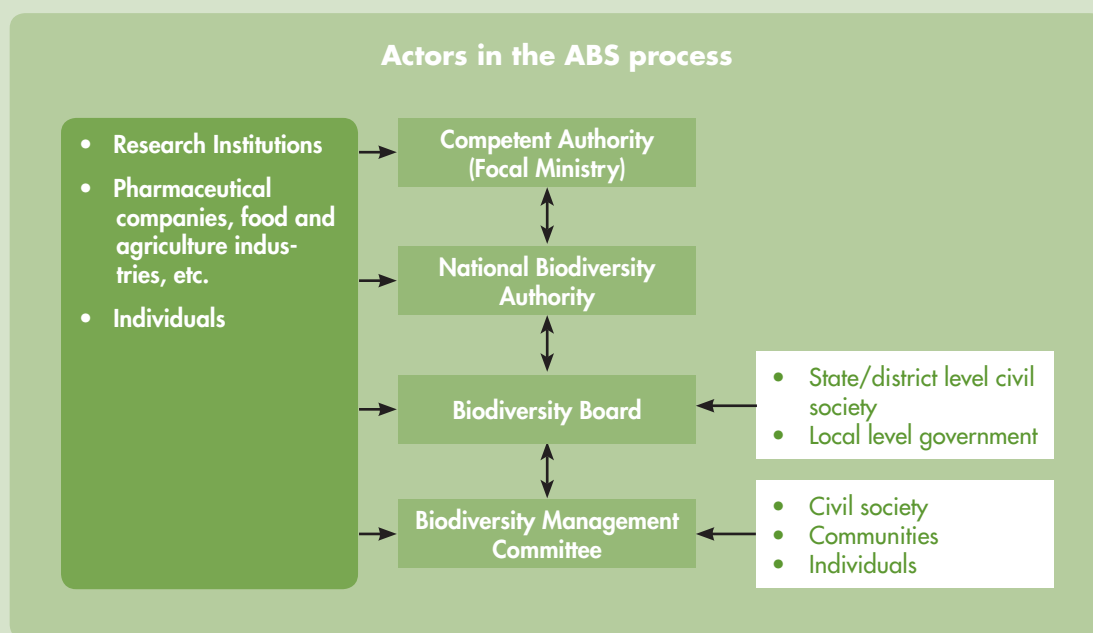
- Step 1** Split the participants into four groups.
- Step 2** Introduce the aim of the exercise.
- Step 3** Distribute the roles among the groups
First group: Company representatives
Second group: Responsible competent authority/government representative
Third group: Community representatives/biodiversity management committee
Fourth group: Audience
- Step 4** Each group should be briefed on the role that they will be playing during the exercise.
- Step 5** Ask the groups to refer to the ABS Poster for the script and chronology and to learn about their role.
- Step 6** Mentor each group on their role and functions.
- Step 7** Distribute the appropriate tools such as PIC and MAT forms to the relevant groups (provided in the resource materials).
- Step 8** Allow groups at least 10 minutes to prepare for the role play.
- Step 9** When the groups are ready, initiate the role playing exercise.
- Step 10** The trainer and the audience group should carefully observe the role play.
- Step 11** After the role play, open the floor for discussion.
- Step 12** Use a flipchart to record the outcome of the role play.

Activity 4: Presentation on the ABS legal process

Use the outcome of the role play to explain the ABS process in detail. This can be done through a media presentation or by referring to the role play together with the ABS Poster and tools. Discussion and clarifications should be made until it is time to move to the next session.

Session 10 Resource Materials

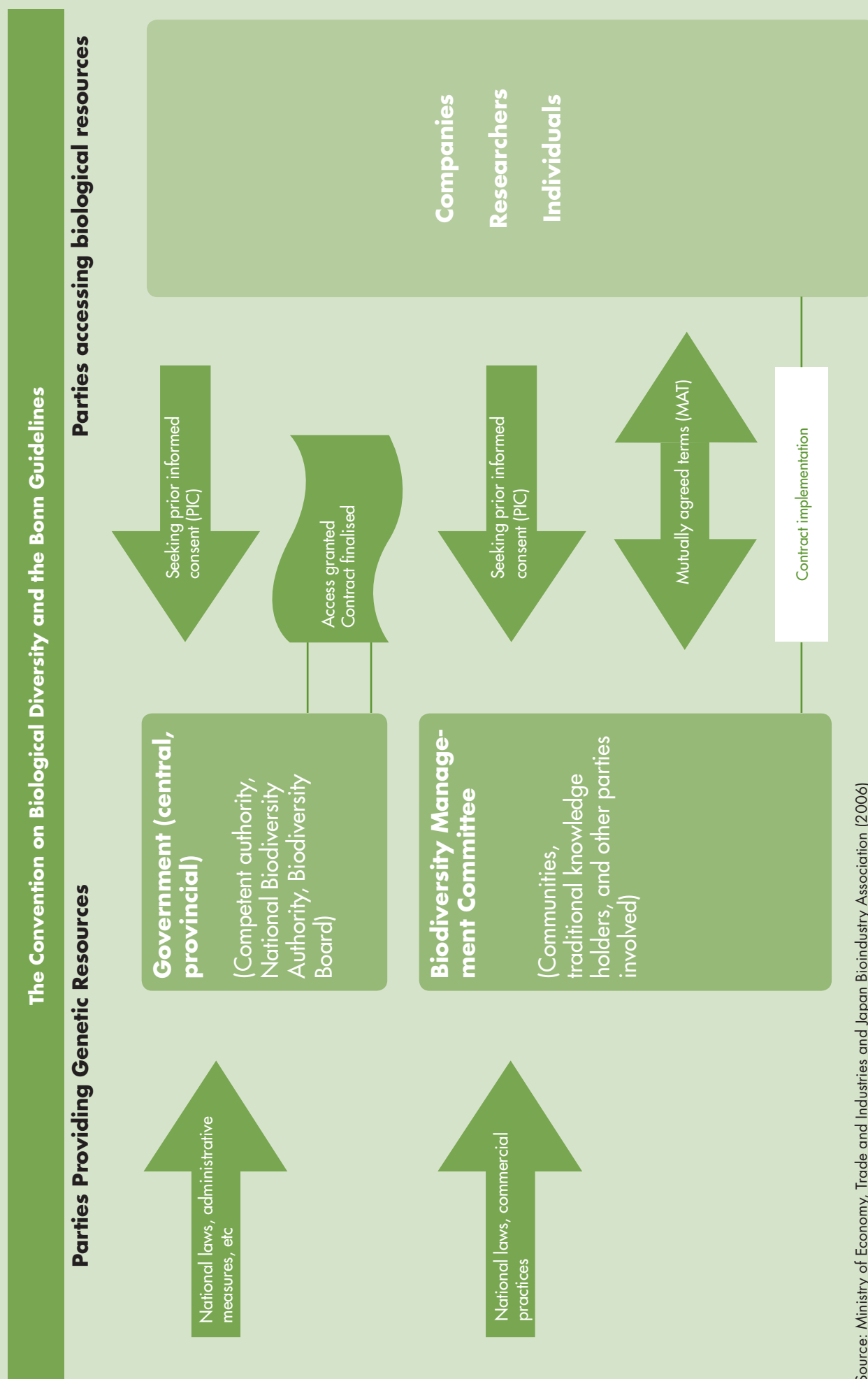
Mapping of ABS Actors



General Legal Process for Access and Benefit Sharing

It is important to understand the general procedure involved in ABS, the legal responsibilities and roles of the providing and accessing parties, and the roles and rights of traditional knowledge holders in the agreement process. Figure 8 provides a diagrammatic representation of the access and benefit sharing process. The parties accessing genetic resources should seek prior informed consent (PIC) from the parties providing genetic resources and from the traditional knowledge holders. Parties should base their access and benefit sharing agreement on mutually agreed terms (MAT). Figure 9 (ABS Poster) depicts the general legal process in most Eastern Himalayan countries for access and benefit sharing from genetic resources and associated traditional knowledge.

Figure 8: Access and Benefit Sharing Process



Source: Ministry of Economy, Trade and Industries and Japan Bioindustry Association (2006)

Figure 9: General Legal Process for Access and Benefit Sharing from Genetic Resources and Associated Traditional Knowledge

Access and Benefit Sharing



1 The area is rich in trees, bushes, herbs, and wildlife (genetic resources)



2 This company is looking to see if there may be useful resources



3 The company decides to apply to the government for a licence to use the biological resources (bioprospecting)



4 They go to the ministry responsible for these decisions (competent authority)



5 They submit the application to the government (competent authority) and discuss it with them



6 Yes/No



7 If access is denied they want to know why; they can seek assistance from the court



8 The application is approved, but there is still work to do



9 The company informs the community, and asks for their permission (prior informed consent, PIC); the community decides if it is good for them



10 Yes/No



11 The company studies the plants and wildlife (genetic resources) in detail and asks the community what they know about them (traditional knowledge)



12 They may look at the likely impact of the proposal on the area (environmental impact assessment)



13 They prepare a detailed proposal with a research and resource use plan



14 The proposal is complete, now the company goes to the designated authority ...



15 ... and submits the detailed proposal



16 Yes/No



17 The proposal is accepted with mutually agreed terms (MAT)



18 They collect samples of plants and animals and document everything including traditional knowledge



19 They send the samples and information to a laboratory ...



20 ... where they are studied in different ways, and plans drawn up for products that can be made from them



21 The company describes the new products, what they will cost and how much profit there may be



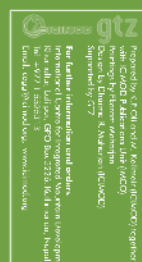
22 The product is made and sold, the company makes money



23 A part of the profit goes to the government (competent authority), which shares it with the local community



24 The community discusses the best way to use the benefits. The money should be used to help conserve the biological resources for the future, as well as to give the community options for development



ABS poster: Access and benefit sharing steps

The ABS Poster (Figure 9) outlines the ABS process step-by-step. The individual steps are outlined in chronological order corresponding to the picture numbers. The detailed procedure can be explained step by step as described below:

Pictures 1 and 2

Bioprospectors who represent companies are aware of the availability of valuable genetic resources in village X of country Y. They express interest in bioprospecting.

Picture 3

The bioprospectors seek prior approval from the competent authority in country Y.

Pictures 4 and 5

The bioprospectors obtain and complete the appropriate PIC application for country Y and submit the application at the biodiversity authority office. The final decision will be announced after the official procedure is complete, within the legally specified time.

Pictures 6, 7 and 8

The competent authority announces the decision, which is either acceptance or rejection. In case of rejection, the bioprospectors may seek review by the court. However, the availability of this option varies from country to country. If the application is approved, the bioprospectors take the next step required by the legislation.

Pictures 9 and 10

The legislation of country Y requires bioprospectors to obtain PIC from the from the communities/traditional knowledge holders of the resources of village X as well as from the State Biodiversity Board (SBB), District Biodiversity Board (DBB), and Biodiversity Management Committee (BMC). Therefore, the bioprospecting team visits the community to obtain PIC from them. While obtaining PIC, the team informs the concerned stakeholders of the details of their bioprospecting plan (what resources they will use, what they will do with the resource, and how they will share the benefits with the national government and the community, and so forth). The community asks the bioprospectors questions about the bioprospectors' proposal. After thorough discussion between the bioprospectors and the community, the community announces their decision to accept or reject the proposal. If they accept, the bioprospecting team takes the next step required by the ABS laws of country Y. If the community rejects the proposal, then the bioprospectors may look to the ABS laws to see if they have any options.

Note: PIC options may vary from country to country. The law in relation to PIC for the particular country needs to be verified.

Pictures 11 and 12

The bioprospecting team gets a green PIC signal from village X. The bioprospectors then conduct preliminary research on the biological resources and associated traditional knowledge in the village. They

also conduct an environmental impact assessment (to understand the potential impact of their work on the ecosystem and local community). The legislation of country Y directs whether or not, and in what situation, this assessment is needed.

Pictures 13, 14, 15 and 16

The bioprospecting team completes its preliminary research in the village. From the findings of their study, they develop a detailed proposal with a research and resource use and benefit sharing plan. They submit the detailed proposal to the competent authority of country Y. The competent authority reviews the proposal. When the reviewing procedure is complete, which may take some time, the authority either accepts or rejects the proposal.

Pictures 17

The competent authority (providing parties) and bioprospecting team (accessing parties) base their ABS agreement on MAT (terms and conditions that both parties agree upon). When the competent authority is satisfied with the MAT, it accepts the proposal.

Pictures 18 and 19

The bioprospecting team then conducts detailed research during which they collect samples of biological resources and document the traditional knowledge in village X of country Y. The physical samples are either sent to a laboratory within country Y or abroad for detailed investigation of the chemical properties and to verify the properties indicated by traditional knowledge.

Pictures 20, 21 and 22

Based on the findings of the detailed investigation of samples or traditional knowledge, the company draws a plan for the kind of products it can develop from the resource. The products may be medicine, food, cosmetics, or other. They then design a business plan for the products that they are going to manufacture from the accessed genetic resources. The products are then marketed and profits generated by the company.

Picture 23 and 24

The bioprospecting team (the company) signs an agreement with the competent authority of country Y based on MAT. A benefit sharing plan is agreed upon by the company. In the agreement. According to the benefit sharing plan, benefits in the form of money, royalties, upfront payments, resources sharing, and technology must be shared by the bioprospectors with the country and community from where the resources were accessed.

After making a profit, the bioprospecting company shares the agreed benefits with the government of country Y, represented by the competent authority. Based on the national legislation of country Y, the competent authority then shares the derived benefits with the community in village X, who are the owners of the accessed resources and traditional knowledge. The community then decides how to utilise the benefits.

Review and Practise of ABS Tools

The ABS/bioprospecting process has several components that are critical to the process. Each component must be complied with by both the providing and accessing parties and the holders of traditional knowledge so as to ensure the fair and equitable sharing of benefits arising out of the utilisation of genetic resources and associated traditional knowledge. Prior informed consent (PIC) must be obtained by the accessing party from the providing party. Both parties are required to formulate a joint agreement to facilitate access to genetic resources and the sharing of benefits arising from their use. Parties are required to base their agreements on mutually agreed terms (MAT). The parties are required to establish legal, administrative, and policy procedures to ensure the fair and equitable sharing of benefits from the utilisation of genetic resources and associated traditional knowledge.

To ensure that parties abide by these requirements, countries in the region are developing administrative measures to facilitate the ABS process. Some have developed measures already, and others are in the process of developing them, including tools such as PIC and Material Transfer Agreement (MTA) forms for research/commercialisation purposes to ensure the smooth implementation of the ABS process. Some of the tools developed in Bhutan and India are provided here as a sample.

Sample 1: PIC Application for research and collecting permit (Bhutan) (in draft rules)

ROYAL GOVERNMENT OF BHUTAN

National Biodiversity Centre

Application for a scientific research and collecting permit

DAY TWO

Select one of the following: <input type="checkbox"/> New application <input type="checkbox"/> Renewal of a previously issued permit <input type="checkbox"/> Modification of a previously issued permit	Please enter existing permit numbers for renewal or modification requests:
Name of principal investigator (last name, first name):	Nationality of principal investigator:
Mailing address of principal investigator:	Legal status of principal investigator:
	Office phone # of principal investigator:
Name and location of institution represented:	Office fax # of principal investigator:
	Office email address of principal investigator:
Additional investigators and institutions (last name, first name, office phone, office fax, office email) (include respective responsibilities):	
Project title:	
Purpose of study (include the purpose and field(s) of the proposed access activity, the type and extent of the research, the teaching or commercial intention of the research, and any expected use(s) to be derived from the research):	
Scientific description of genetic and biological resources to be collected (include taxonomic group or name, sample size, quantity, and frequency of proposed collection):	
Proposed starting date (month/day/year):	Proposed ending date (month/day/year):
Location(s) where activities will take place within Bhutan:	

Provide information on the arrangements made within Bhutan to facilitate the collection work as well as information on the prior informed consent of the relevant stakeholders when necessary (include plans, if any, for cooperation with national institutions, scholars, scientists, students, farmers and farmer groups in Bhutan in the field mission and/or its follow-up activities):

Demonstrate that the collection/access activity will have no negative environmental impact:

Describe the principal investigator's technical and financial capability to conduct the access activity (include descriptions of any previous biological resource collection activities within Bhutan and elsewhere) (Attach Proposal Budget Form):

Provide information about existing or proposed contracts between any applicant(s) relating to the use of any information and products resulting from the access activity:

Describe the economic, social, technical, scientific, environmental, and/or other benefits that this activity intends and that may likely accrue to Bhutan (include an indication of the types of short, medium, and long term benefits to be shared with the RGOB and other relevant stakeholders as well as the proposed benefit sharing mechanisms and arrangements):

I certify that this application is accurate and complete. I agree to abide by the conditions set out by the Competent Authority for collection activities. This includes appropriate arrangements with the Authorized Agency to facilitate the collection mission, including establishing provisional routes, estimated timing, types of material collected and quantities and identification of methods of collection (sampling, harvest and storage methods). I also agree to pay all costs involved in collection, including participation of at least one governmental official of the RGOB in the collection mission.

Signature of principal investigator: _____ Date: _____

Signature of additional investigator: _____ Date: _____

Signature of additional investigator: _____ Date: _____

Signature of principal investigator: _____ Date: _____

(Additional signature pages may be attached.)

For Authorizing Agency use only	Date received	Assigned permit number:
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Sample 2: PIC permit for research (bhutan) (in draft rules)

Scientific research and collecting permit

Grants permission in accordance with the attached general and special conditions

Royal Government of Bhutan
National Biodiversity Centre

Study #:

Permit #:

Start Date #:

Expiration Date #:

COOP Agreement #:

Optional Park Code #:

Name and Contact information of Principal Investigator:

Name of Institution Represented:

Additional Investigators:

Project Title:

Purpose of Study:

Location Authorized:

Transportation Method to Research Site(s):

Collecting of the Following Specimens or Materials, Quantities, and any Limitations on Collecting:

Name of Repository for Specimens or Sample Materials if Applicable:

Specific Conditions or Restrictions (also see attached conditions):

Recommended by park or RGOB official
(Name and Title):

Name

Date

Reviewed by Collections Manager:

Yes _____ No _____

Approved by RGOB official:

Name & Title: _____

Date Approved: _____

I agree to all conditions and restrictions of this permit as specified.
(Not valid unless signed and dated by the Principal Investigator)

(Principal Investigator's Signature)

(Date)

This permit and attached conditions and restrictions must be carried at all times while conducting research activities in the designated area(s)

Sample 3: PIC application for access to biological resources and traditional knowledge (India)

GOVERNMENT OF INDIA
National Biodiversity Authority

FORM I (See Rule 14)

Application form for access to biological resources and associated traditional knowledge

Part A

- i) Full particulars of the applicant
 - ii) Name:
 - iii) Permanent address:
 - iv) Address of the contact person/agent, if any, in India:
 - v) Profile of the organization (personal profile in case the applicant is an individual). Please attach relevant documents of authentication):
 - vi) Nature of business:
 - vii) Turnover of the organization in US\$:
2. Details and specific information about nature of access sought and biological material and associated knowledge to be accessed
 - a) Identification (scientific name) of biological resource and its traditional use:
 - b) Geographical location of proposed collection:
 - c) Description/nature of traditional knowledge (oral/documented):
 - d) Any identified individual/community holding the traditional knowledge:
 - e) Quantity of biological resources to be collected (give the schedule):
 - f) Time span in which the biological resources are proposed to be collected:
 - g) Name and number of persons authorized by the company for making the selection:
 - h) The purpose for which the access is requested including the type and extent of research, commercial use being derived and expected to be derived from it:
 - i) Whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access:
 3. Details of any national institution which will participate in the Research and Development activities.
 4. Primary destination of accessed resource and identity of the location where the R&D will be carried out.
 5. The economic and other benefits including those arriving out of any IPR, patent obtained out of accessed biological resources and knowledge that are intended, or may accrue to the applicant or to the country that he/she belongs.

6. The biotechnological, scientific, social or any other benefits obtained out of accessed biological resources and knowledge that are intended, or may accrue to the applicant or to the country that he/she belongs.
7. Estimation of benefits that would flow to India/communities arising out of the use of accessed bioresources and traditional knowledge.
8. Proposed mechanism and arrangements for benefit sharing.
9. Any other information considered relevant.

Part B

Declaration

I/we declare that:

- Collection of proposed biological resources shall not adversely affect the sustainability of the resources;
- Collection of proposed biological resources shall not entail any environmental impact;
- Collection of proposed biological resources shall not pose any risk to ecosystems;
- Collection of proposed biological resources shall not adversely affect the local communities.

I/we further declare the information provided in the application form is true and correct and I/we shall be responsible for any incorrect/wrong information.

Signed:

Name:.....

Title:.....

Place:.....

Date:.....

Sample 4: PIC application for traditional knowledge access and non-customary use (Bhutan) (in draft rules)

ROYAL GOVERNMENT OF BHUTAN

Ministry of Agriculture

Application for traditional knowledge access and non-customary use

(Please Note: All information provided should be in either Dzongkha or English. Additional pages may be added as needed.)

DAY TWO

Select one of the following: <input type="checkbox"/> New application <input type="checkbox"/> Renewal of a previously issued application <input type="checkbox"/> Modification of a previously issued application	Please enter existing application numbers for renewal or modification requests:
Name of principal researcher (last name, first name):	Nationality of principal researcher:
Mailing address of principal researcher:	Legal status of principal researcher:
	Office phone # of principal researcher:
Name and location of institution represented:	Office fax # of principal researcher:
	Office email address of principal researcher:
Additional researchers and institutions (last name, first name, office phone, office fax, office email) (include respective responsibilities):	
Project title:	
Purpose of study (include the purpose and field(s) of the proposed access activity, the type and extent of the research, the teaching or commercial intention of the research, and any expected use(s) to be derived from the research):	
Description of subject matter and/or types of traditional knowledge to be accessed (include also identity and/or name of community group, geographic location/address, , and subject matter and/or types of traditional knowledge including related biological and/or genetic resources):	
Proposed starting date (month/day/year):	Proposed ending date (month/day/year):
Location(s) where activities will take place within Bhutan:	

Provide information on the arrangements made within Bhutan to facilitate the research as well as information on the prior informed consent of the relevant stakeholders when necessary (include plans, if any, for cooperation with national institutions, scholars, scientists, students, farmers and farmer groups, or other community groups in Bhutan in the field mission and/or its follow-up activities, and proposed methods for protecting the confidentiality of any traditional knowledge accessed):

Demonstrate that the collection/access activity will have no negative environmental impact:

Describe the principal researcher's technical and financial capability to conduct the access activity (identify previous traditional knowledge and related biological resource ('ethno-botanical') research activities within Bhutan and elsewhere) (Attach Proposal Budget Form):

Provide information about existing or proposed contracts between any applicant(s) relating to the use of any information and products resulting from the proposed access activity:

Describe the economic, social, technical, scientific, environmental, and/or other benefits that this activity intends or that could accrue to Bhutan (include an indication of the types of short, medium, and long term benefits to be shared with the RGOB and other relevant stakeholders as well as the proposed benefit sharing mechanisms and arrangements):

I certify that this application is accurate and complete. I agree to abide by the conditions set out by the Competent Authority for the activities described in this Application. This includes appropriate arrangements with the Authorized Agency and appropriate stakeholders to facilitate the collection mission, including establishing provisional routes, estimated timing, types of material collected and quantities and identification of methods of collection (sampling, harvest and storage methods). I also agree to pay all costs involved in collection, including participation of at least one governmental official of the RGOB in the collection mission.

Signature of principal researcher: _____ Date: _____

Signature of additional researcher: _____ Date: _____

Signature of additional researcher: _____ Date: _____

Signature of principal researcher: _____ Date: _____

(Additional signature pages may be attached.)

For Authorizing Agency use only

Date received

Assigned application number:

Sample 5: MTA biological material transfer agreement (Bhutan) (in draft rules)

ROYAL GOVERNMENT OF BHUTAN

National Biodiversity Centre

Biological material transfer agreement (BMTA)

I. Definitions

PROVIDER: The term **“Provider”** means the person(s) providing the **Material**. The name and address of **Provider** is:

(name)

(address)

RECIPIENT: The term **“Recipient”** means the person(s) receiving the **Material**. The name and address of **Recipient** is:

(name)

(address)

TRANSFERRED MATERIAL: The term **“Transferred Material”** means the **Material** being transferred from **Provider** to **Recipient** that is described as follows: _____

MATERIAL: The term **“Material”** means Research Specimens, Replicates, and Derivatives.

RESEARCH SPECIMENS: The term **“Research Specimens”** means biological material in **Provider’s** possession that **Provider** has or had authority to collect under the collection permit or permits issued by [name of authorizing unit of the Royal Government of Bhutan] to **Provider** (copy of permit(s) attached hereto), or which otherwise were originally and lawfully collected from Bhutan and now in **Provider’s** possession.

REPLICATE: The term **“Replicate”** means any biological or chemical substance that represents a substantially unmodified copy of the **Material** such as, but not limited to, substances produced by growth of cells or microorganisms or amplification of the **Material**.

DERIVATIVE: The term “**Derivative**” means substances created from the **Material** that is substantially modified to have new properties such as, but not limited to, recombinant DNA clones.

PRODUCT: The term “**Product**” means any commercially valuable or otherwise useful or potentially useful substance, compound or useful or potentially useful combination of substances or compounds recovered, obtained, derived, resulting, or otherwise isolated by or developed from scientific research conducted on any **Replicate, Derivative, or Research Specimen** originally acquired from Bhutan.

COMMERCIAL PURPOSE: The term “**Commercial Purpose**” means the sale, lease, license, or other transfer of any **Material, Replicate, Derivative, or Product** for value received, including but not limited to scientific research uses of any **Material, Replicate, Derivative, or Product** by any person (including but not limited to **Provider** and **Recipient**) in the performance of any contract research, screening compound libraries, or the conduct of research activities that result in any sale, lease, license, or other transfer of any **Material, Replicate, Derivative, or Product**.

II. Terms and Conditions of this Agreement and Authorization

1. **Provider** and **Recipient** hereby acknowledge that the Royal Government of Bhutan retains ownership of the **Research Specimens** and **Replicates**. **Provider** is authorized to transfer to **Recipient** the specific **Transferred Material** described above in paragraph 1.3 upon execution of this Biological Material Transfer Agreement (BMTA) by **Provider, Recipient**, and [name of authorizing unit of the Royal Government of Bhutan].

Recipient agrees that the Transferred Material:

- a) will be used in compliance with all applicable laws, governmental regulations and guidelines (including but not limited to all applicable terms and conditions of the Permit that governs collection, distribution and use of **Research Specimens** collected from Bhutan (reference copy of applicable Permit terms and conditions attached));
- b) may be used for scientific or educational purposes only, and may not be used for any **Commercial Purpose** without the prior written authorization of the Royal Government of Bhutan; and
- c) may not be sold or otherwise transferred to any other person without the prior written authorization of Royal Government of Bhutan.

Recipient understands and agrees that the Royal Government of Bhutan may seek damages to which it may be entitled including but not limited to injunctive relief for any unauthorized sale, transfer or other use of **Transferred Material**.

Recipient agrees to provide to [name of authorizing unit of the Royal Government of Bhutan] a copy of any interim reports, final reports, publications, and other scholarly materials resulting from use of **Transferred Material**. **Recipient** also agrees to identify in each such written report or other material the project study number (if any) of the Permit-authorized project that collected the original **Research Specimen** from which the **Transferred Material** is derived. In addition, **Recipient** agrees to provide notice in writing to [name of authorizing unit of the Royal Government of Bhutan] not less than sixty (60) days before **Recipient** files an application for a patent or other intellectual property claim resulting from use of **Transferred Material**.

Recipient agrees that the **transferred material** is experimental in nature and is being provided without warranty, express or implied, including any implied warranty of merchantability or fitness for a particular purpose or freedom from infringement of any patent or other proprietary right of a third party.

Recipient agrees to hold harmless and indemnify the royal government of bhutan, any unit thereof, and persons acting on their behalf, for any claim asserted by a third party related to **recipient's** possession, use, storage, or disposal of **transferred material**.

III. Administration

Any correspondence or other notice concerning this agreement should be addressed to: *[insert name and address of authorizing official and unit of the Royal Government of Bhutan]*.

Signatures begin on next page.

SIGNATURE PAGE

Signatures

In Witness Whereof, the parties have executed this **biological material transfer agreement (BMTA)** on the dates set forth below. This BMTA may be signed in counterparts, each of which will be deemed to be an original. All such counterparts shall together constitute a single, executed instrument when all parties have so signed. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the Royal Government of Bhutan:

[name]

Date

[name of authorizing unit of the RGOB]

Mailing Address for Notices: Competent Authority [*name and address*]

For Provider:

[signatory's name]

Date

[title]

[name of Provider (if different from signatory)]

Mailing Address for Notices: [name and address]

For Recipient:

[signatory's name]

Date

[title]

[name of Recipient (if different from signatory)]

Mailing Address for Notices: [name and address]

NOTE: Both **Provider** and **Recipient** should sign this BMTA, and then forward it to [name of authorizing unit of the Royal Government of Bhutan] for approval. A fully executed copy of the completed BMTA will be sent to **Provider** and **Recipient** upon approval. This agreement does not enter into force until signed by the authorizing unit of the Royal Government of Bhutan.

Sample 6: MTA biological material license agreement # 1 (Bhutan) (in draft rules)

THE ROYAL GOVERNMENT OF BHUTAN
National Biodiversity Centre

Biological Materials License Agreement # 1

This Agreement is entered into between the Royal Government of Bhutan (RGOB), through the National Biodiversity Centre (NBC), and _____ ("LICENSEE").

[INSERT NAME, BUSINESS ADDRESS, AND CORPORATE AFFILIATE – IF ANY.]

1. DEFINITIONS

a. **"Materials"** means the following biological materials including all replicates and derivatives.

[Describe licensed Material[s] and location of laboratory.]

b. **"Replicate"** means any biological or chemical material that represents a substantially unmodified copy of the material such as, but not limited to, material produced by growth of cells or microorganisms or amplification of Material.

c. **"Derivative"** means material created from the Material that is substantially modified to have new properties such as, but not limited to, recombinant DNA clones.

d. **"Commercial Purpose"** means the sale, lease, license, or other transfer of any **Materials**, including **Replicates** and **Derivatives**, for value received, including but not limited to scientific research uses of any **Replicates**, **Derivatives**, by LICENSEE in the performance of any research, screening compound libraries, or the conduct of research activities that result in any sale, lease, license, or other transfer of any **Replicates** or **Derivatives**.

e. **"Licensed Products"** means substances created by LICENSEE resulting from use of the Materials.

2. LICENSEE wishes to obtain a license from RGOB to use the **Material[s]** provided under this Agreement in its research or product development and marketing activities. LICENSEE represents that it has the facilities, personnel and expertise to use the Material[s] for research purposes and agrees to expend reasonable efforts and resources to develop the **Material[s]** consistent with this agreement.

3. RGOB hereby grants to LICENSEE a worldwide, non-exclusive license to use the **Material[s]** for scientific research purposes only. The LICENSEE shall not distribute, sell, lend or otherwise transfer the **Material[s]** or **Replicates** for any reason. Any commercial use of the **Material[s]**, **Replicates**, **Derivatives**, and **Licensed Products** is prohibited without RGOB's prior written authorization. If LICENSEE decides to use or sublicense the **Material[s]**, **Replicates**, **Derivatives**, or **Licensed Products** for **Commercial Purposes**, LICENSEE agrees in advance of such use to negotiate in good faith with the RGOB (See RBOB Biological Materials License Agreement #2).
4. In consideration of the grant in Paragraph 3 above, LICENSEE hereby agrees to make the following payments to RGOB:
 - a. Concurrent with its execution of this Agreement, a noncredit able, nonrefundable license issue royalty of _____ **[INSERT CURRENCY TO BE USED]**.
 - b. A nonrefundable minimum annual royalty of _____ **[INSERT CURRENCY TO USED]**, which shall be due and payable on January 1 of each calendar and may be credited against earned royalties due for sales made in that year. The minimum annual royalty for the first calendar year of this Agreement is due and pay able within thirty (30) days from the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1.

[INSERT THE DESIRED METHOD OF PAYMENT IN FULL DETAIL]. If a payment is not made within 15 days of its due date, the LICENSEE will be charged 10% of the unpaid payment. Late charges will be applied to any overdue payments. The payment of such late charges shall not prevent **RGOB** from exercising any other rights it may have as a consequence of the lateness of any payment.
5. LICENSEE agrees to make written license reports to RGOB within sixty (60) days after the end of each calendar year. This report shall describe the use of the **Material[s]** and state the number, and description of **Licensed Products** made, or otherwise disposed of. LICENSEE shall submit each such report along with payment due RGOB for the calendar year to RGOB at the address listed in Paragraph 5 above and shall also send a copy of the report to RGOB at the Mailing Address for Notices indicated on the Signature Page of this Agreement.
6. This Agreement shall become effective on the date when the last party to sign has executed this Agreement and shall terminate _____ () years from this effective date, unless previously terminated under the terms of Paragraphs 11 or 12 below.
7. LICENSEE agrees to retain control over the **Material[s]**, and not to distribute them to any unauthorized parties without the prior written consent of RGOB.
8. No warranties, express or implied, are offered as to the merchantability or fitness for any purpose of the **Material[s]** provided to licensee under this agreement, or that the **Material[s]** or **Licensed Products** may be exploited without infringing the patent rights of any other parties. licensee accepts license rights to the **Material[s]** and **Licensed Products** as "as is," and RGOB does not offer any guarantee of any kind.

9. LICENSEE agrees to indemnify and hold harmless the RGOB from any claims, costs, damages or losses that may arise from or through LICENSEE's use of the **Material[s]** or Licensed Products. LICENSEE further agrees that it will not by its action bring the RGOB government into any lawsuit involving the **Material[s]** or Licensed Products.
10. LICENSEE agrees in its use of any RGOB-supplied **Material[s]** to comply with all applicable statutes, regulations and guidelines, including the NBC and RBOG regulations and guidelines.
11. LICENSEE may terminate this Agreement upon sixty (60) days written notice to RGOB.
12. RGOB may terminate this Agreement if LICENSEE is in default in the performance of any material obligation under this Agreement, and if the default has not been remedied within ninety (90) days after the date of written notice by RGOB of such default.
13. Upon termination of this Agreement, LICENSEE agrees to return all **Material[s]** or provide RGOB with certification of their destruction (if so permitted by the RGOB). Any further use of **Material[s]** by LICENSEE shall constitute a material breach of this agreement.
14. Within ninety (90) days of termination of this Agreement, LICENSEE agrees to submit a final report to RGOB, and to submit payment of any royalties due.
15. LICENSEE is encouraged to publish the results of its research projects using the **Material[s]** or **Licensed Products**. In all oral presentations or written publications concerning the **Material[s]** or **Licensed Products**, LICENSEE will acknowledge the contribution of RGOB (unless requested otherwise by RGOB).
16. This Agreement shall be construed in accordance with the laws of the Royal Government of Bhutan.
17. This Agreement constitutes the entire understanding of RGOB and LICENSEE and supersedes all prior agreements and understandings with respect to the **Material[s]**.
18. The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.
19. Paragraphs 8, 9, and 15 of this Agreement shall survive termination of this Agreement.

Signatures begin on next page.

RGBOB Biological Materials License Agreement

SIGNATURE PAGE

In Witness Whereof, the parties have executed this agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **RGBOB**

[Insert name, address of authorized signature and date of signature].

For **LICENSEE** (The undersigned expressly certifies or affirms that the contents of any statements of **LICENSEE** made or referred to in this Agreement are truthful and accurate.)

Signature Date

Printed Name

Title

Mailing Address for Notices: _____

Sample 7: Community level PIC form traditional knowledge (India)

NATIONAL INNOVATION FOUNDATION

Traditional knowledge – Prior informed consent form

Dear Traditional Knowledge Holder(s),

The Department of Science and Technology, Government of India established the National Innovation Foundation (NIF), in March 2000, as an autonomous society to recognise and promote grassroots innovations and traditional knowledge of individuals/communities. This initiative shall help in reducing the erosion of knowledge, increase the social esteem of the grassroots innovators and knowledge providers and help India become an innovative society. NIF strives to obtain the written consent and authorization from all the innovators/knowledge providers to disclose and/or add value to the innovation/traditional knowledge submitted for inclusion in the National Register of Green Grassroots Technological Innovations and Traditional Knowledge. An explanatory note, describing the implications of various options given in the form, is enclosed along with this form to assist you to fill up the form. NIF assures full compliance with the conditions specified by you and any modification in these conditions will be taken up only after obtaining your written consent.

Reference No.: _____

Title of traditional knowledge/herbal practice: _____

Please tick the appropriate boxes

How did you come to know about the knowledge/practice?

☐ Elder ☐ By Self ☐ Family Tradition ☐ Community

If you have ticked box a, b or c, please fill section A, and if box d, then please fill section B, Section C to be filled by all.

SECTION – A

A. Can NIF share your address with those interested in your traditional knowledge?

(Yes/No): _____

B. Can NIF display/publish your traditional knowledge on the Internet/in Honey Bee magazine or any other media?(Yes/No) _____

C. To what extent can NIF share your traditional knowledge?

a) Partial disclosure/summary OR

b) Full disclosure

D. Would you like NIF to pursue further research on your traditional knowledge (if applicable), if yes, please specify _____

SECTION – B

- A. Name of the community, _____ authorized leader
 a) elected : _____
 b) traditional: _____
- B. Can NIF share the address of the community with those interested? (Yes/No): _____
 Can NIF display/publish the traditional knowledge on the Internet/in Honey Bee magazine or any other media? (Yes/No) _____
- C. To what extent can NIF share the traditional knowledge ?
 a) Partial disclosure/summary OR
 b) Full disclosure
- D. Whether the consent of local community has been taken while submitting the community traditional knowledge to NIF? (Yes/No) _____
- E. To what extent specific traditional knowledge/community knowledge is known and/or practiced within or among the concerned communities?
 a) Known to few Known widely
 b) Practiced by few Practiced widely
- F. Has any improvement been done in the knowledge/practices of the community? (Yes/No)
- If YES, please specify by whom?
- G. Has the concerned community been informed of the improvements made in the traditional knowledge belonging to them ?(Yes/No).....

SECTION- C

Would you prefer non-monetary benefits, if your traditional knowledge is found to be outstanding and worthy of special recognition?

- If Yes, then please tick the suitable option/s.
 - ☐ Honour in a public function at local, state or national level
 - ☐ Recognition in media
 - ☐ Recognition in text books in case of really unique distinction
 - ☐ Travel support for contacting other innovators/traditional knowledge holders
 - ☐ Linkage with R and D institutions for valorization of knowledge
 - ☐ Opportunity to share one's knowledge with others in shodh yatra (journey through the villages on foot) and shodh sankals (workshop of local healers)
 - ☐ Guidance from formal or informal sources to conserve the natural resources used in traditional knowledge
 - ☐ Supply of scientific information in local language about the herbal or other traditional knowledge submitted by you,
 - ☐ Any other, please specify _____

Declaration: I/we have read this Prior Informed Consent Form and have understood the implications of various choices described in the explanatory note. I/We have voluntarily decided to select the option / options which I/we have ticked above in section A and/or section B. I/we further assure NIF that all the information given above is true to the best of my/our Knowledge and belief. I/we acknowledge that if the knowledge innovation/practice contributed by me/us is already in public domain, then the restrictions in the form will not apply.

Name and Address of the Community/Traditional Knowledge Holder:

Signature

Name of the Nominee/Authorized Representative:

Signature

Name and Address of Witness/Collaborator/Scout/NIF Representative:

Signature

Signature of witness

Date (dd/mm/yyyy)

Sample 8: Community level PIC form technological innovations (India)

NATIONAL INNOVATION FOUNDATION

Technological innovations – Prior informed consent form

Dear Innovator(s),

The Department of Science and Technology, Government of India established the National Innovation Foundation (NIF), in March 2000, as an autonomous society to recognise and promote grassroots innovations and traditional knowledge of individuals/communities. This initiative shall help in reducing the erosion of knowledge, increase the social esteem of the grassroots innovators and knowledge providers, and help India become an innovative society.

NIF strives to obtain the written consent and authorization from all the innovators/knowledge providers to disclose and/or add value to the innovation/traditional knowledge submitted for inclusion in the National Register of Green Grassroots Technological Innovations and traditional knowledge. An explanatory note, describing the implications of various options given in the form, is enclosed along with this form to assist you to fill up the form. NIF assures full compliance with the conditions specified by you and any modification in these conditions will be taken up only after obtaining your written consent.

Reference No.: _____

Signature _____

Stamp of NIF _____

Title of Innovation/Idea: _____

We will appreciate if you could tick 'YES' or 'NO' in the appropriate boxes (for items A to F).

A. Can NIF share your address with those interested in your innovation/idea? _____

B. Can NIF display/publish your innovation/idea on the Internet/in Honey Bee magazine or any other media? _____

C. To what extent do you wish NIF to disclose the information furnished by you ?

a) Partial disclosure/summary OR _____

b) Full disclosure _____

If Yes, under which of the following conditions:

i) Only on commercial terms (if the interested party is willing to pay for it) _____

ii) Free of Cost _____

iii) Any other option? Please specify: _____

D. Would you like NIF to add value to your innovation/idea
(Analysis by experts, prototype development, testing etc.) _____

E. Would you like NIF to mediate on your behalf for commercialization (if applicable)
(Developing business plan, market research, technology transfer etc.) _____

F. Would you like NIF to protect intellectual property rights (wherever applicable) _____
Technological Innovations and Ideas

G. In case, your innovation/idea is not eligible for any monetary benefit/awards, would you prefer any non-monetary benefits, if YES then please tick the suitable option/s:

- ☐ Honour in a public function at local, state or national level
- ☐ Recognition in media
- ☐ Recognition in textbooks in case of really unique distinction
- ☐ Travel support for contacting other innovators/traditional knowledge holders
- ☐ Linkage with R and D institutions for valorization of knowledge
- ☐ Opportunity to share one's knowledge with others in *shodh yatra* (journey through the villages on foot) and *shodh sankals* (workshop of local experimenters)
- ☐ Support to the community to share the knowledge with other communities
- ☐ Guidance from formal or informal sources to conserve the natural resources used in traditional knowledge
- ☐ Supply of scientific information in local language about the herbal or other traditional knowledge submitted by you
- ☐ Any other, please specify _____

Declaration : I/we have read this Prior Informed Consent Form and have understood the implications of various choices described in the explanatory note. I/we have voluntarily decided to select the option/ options which I/we have ticked above for questions from A to G. I/we further assure NIF that all the information given above is true to the best of my/our knowledge and belief.

Name and Address of the Innovator(s)

Signature

Name and Address of the Witness/Collaborator/Scout/NIF Representative:

Signature of witness _____

Date: _____