

Access and Benefit Sharing Toolkit for the Management of Genetic Resources and Associated Traditional Knowledge in Bhutan



National Biodiversity Centre
Ministry of Agriculture and Forests

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National Biodiversity Centre
Ministry of Agriculture and Forests
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Foreword

Access and Benefit Sharing (ABS) is a relatively new concept in the country since it came to the forefront only after the adoption of the Nagoya Protocol in 2010. While there have been several efforts to create awareness on ABS till date, the need to provide holistic information on ABS under one window for the effective implementation of the ABS regime led to the development of this toolkit.

This toolkit provides necessary information on the legal, administrative and policy framework for the implementation of ABS in the country, including national and international experiences. It is aimed at building the capacities of stakeholders involved in accessing Bhutanese genetic resources and/or associated traditional knowledge such as companies/private enterprises, local communities, policy makers, regulators, public and private research institutions and academia; and also to serve as a Communication, Education and Publication Awareness (CEPA) material on ABS.

This toolkit was developed by a core team at the National Biodiversity Centre through a process comprising a desktop review, experiential learning, expert reviews, consultative meetings and stakeholder workshops. It is hoped that the toolkit will serve as a useful guiding document to foster successful ABS projects that will lead to the conservation and sustainable utilization of Bhutanese genetic resources and/or associated traditional knowledge with increased benefits for local communities.

Tashi Delek!



Dr. Tashi Yangzome Dorji
Program Director
National Biodiversity Centre



Alpine meadow covered with *Primula sikkimensis*.

Executive Summary

Chapter I of this toolkit introduces the concept of Access and Benefit Sharing with its various components and provides a brief history on the development of ABS.

Chapter II briefly describes Bhutan's biodiversity, and the policy and legal environment for biodiversity conservation at the national and international levels.

Chapter III outlines the rationale and methodology for the development of the toolkit and specifies the intended users of this toolkit.

Chapter IV describes the scope of ABS implementation in the country and the processes involved, in particular, the institutional arrangements and stakeholders; and procedures established for access and benefit sharing.

Chapter V traces the history of the Bhutan Access and Benefit Sharing Fund, including the rationale for establishing the Fund and its management.

Chapter VI discusses the mechanisms to monitor the access and utilization of genetic resources and/or associated traditional knowledge within the jurisdiction of the provider country as well as transboundary compliance.

Chapter VII explains what biotrade means and how biotrade and ABS differ in terms of access to genetic resources and benefit sharing.

Chapter VIII presents some of the pilot ABS agreements implemented in the country over the last ten years in order to enable the effective implementation of the ABS regime.

Chapter IX presents some examples of ABS implementation globally.

Finally, Chapter X provides opportunity for self assessment to check the level of understanding that this toolkit has created.

“Throughout the centuries, the Bhutanese have treasured their natural environment and have looked upon it as the source of all life. This traditional reverence for nature has delivered us into the twentieth century with our environment still richly intact. We wish to continue living in harmony with nature and to pass on this rich heritage to our future generations.”

His Majesty the Fourth Druk Gyalpo Jigme Singye Wangchuck



Beaumontia grandiflora

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Abbreviations

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
CNA	Competent National Authority
NFP	National Focal Point
MoAF	Ministry of Agriculture and Forests
NBC	National Biodiversity Centre
BAFRA	Bhutan Agriculture and Food Regulatory Authority
DoFPS	Department of Forests and Park Services
COP	Conference of Parties
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MLS	Multilateral System
NBSAP	National Biodiversity Strategies and Action Plans 2014
PIC	Prior Informed Consent
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
SMTA	Standard Material Transfer Agreement
GNH	Gross National Happiness
GR	Genetic Resources
TK	Traditional Knowledge associated with genetic resources
MASL	Metres above sea level
GEF-UNDP	Global Environment Facility, United Nations Development Program
CEPA	Communication, Education and Publication Awareness
ABC of ABS	Access, Benefit Sharing and Compliance
UNDP CO	United Nations Development Program, Country Office
BABS Fund	Bhutan Access and Benefit Sharing Fund
IRCC	Internationally Recognised Certificate of Compliance
STC	Sample Transfer Certificate
MoA	Memorandum of Agreement
MSPCL	Menjong Sorig Pharmaceuticals Corporation Ltd.
SBC	Sarawak Biodiversity Centre
CSIR	South African Council for Scientific and Industrial Research
MoU	Memorandum of Understanding
BMC	Business Management Committee
EWC	Eudafano Women's Cooperative (EWC)
FoB	Freight on Board
NBA	National Biodiversity Authority
HPFI	Health and Performance Food International
EBI	Ethiopian Biodiversity Institute
TBGRI	Jawaharlal Nehru Tropical Botanic Garden and Research Institute

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Awareness workshop on ABS and Traditional Knowledge for local Communities.



Awareness workshop on ABS and Trational Knowledge for students.

Chapter I: Introduction to Access and Benefit Sharing

1.1. Access and Benefit Sharing Concept

Access and Benefit Sharing refers to the way in which genetic resources and/or associated traditional knowledge are accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries providing it (providers) (NEMA 2014). It is based on the principle of a ‘Prior Informed Consent (PIC)’ being granted by a provider to a user and ‘Mutually Agreed Terms (MAT)’ that ensure that the benefits from the use of genetic resources and/or associated traditional knowledge are shared equitably as enshrined in the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

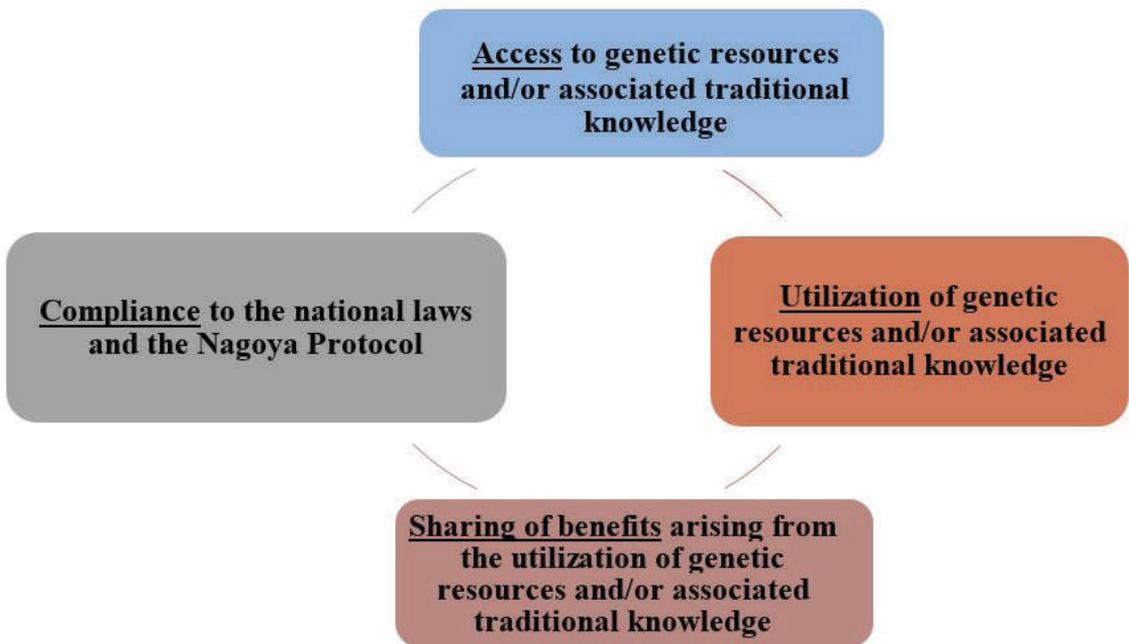


Figure 1: ‘ABC’ of Access and Benefit Sharing

The concept of ABS came to the forefront during the process of negotiations for the CBD in 1992. Prior to that, biodiversity was considered as a ‘common heritage of humanity’, and genetic resources and/or associated traditional knowledge was often taken by companies and academic institutions from communities for research and development (Nijar 2011, UNCTAD 2017). Inventions were made, patented and benefits were enjoyed by these companies/countries without being shared with the communities from where the genetic resources and/or associated traditional knowledge was accessed. This monopolization of benefits created friction between the providers and users thus restricting access to genetic resources and/or associated traditional knowledge. After the adoption of the CBD in 1993, a new paradigm emerged wherein individual countries could affirm their exclusive rights to regulate and set up conditions for the access and use of their biodiversity, particularly their genetic resources and/or associated traditional knowledge

through access and benefit sharing regulations contrary to the so-called concept of the ‘common heritage of humanity’ (UNCTAD 2017). By recognizing the sovereign rights of states over their resources, and requesting users to share benefits from the use of those resources, the CBD created a mechanism which enabled states to secure additional resources to support conservation and sustainable use of biodiversity (Williams et al. 2017).

The provisions that establish the foundation for Access and Benefit Sharing are laid out in Article 15 of the CBD which mandates that “each contracting party should create systems that facilitate access to genetic resources for environmentally sound purposes and ensure that benefits resulting from their use are shared fairly and equitably between users and providers”. It recognizes the sovereignty of states over their biological diversity and provides that access to biological/genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources. It also states that access shall be based on mutually agreed terms in order to ensure the sharing of benefits arising from the commercial or other utilization of these genetic resources with the Contracting Party providing such resources.

Although the CBD was adopted in 1992, the work to operationalize the provisions of CBD especially the third objective began only by 1999. The ‘Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization’ was adopted as a voluntary guidelines during the 6th Conference of Parties (COP) meeting at Bonn, Germany in 2002. The Bonn Guidelines aimed to assist/guide contracting parties to develop national legislative, policy and administrative measures to implement access and benefit sharing at domestic level (BG 2002). The Bonn Guidelines was the first step towards implementing the third objective of the CBD. Although the guidelines provided guidance in developing national measures, they were voluntary guidelines and not legally binding. Thus, during the 7th COP meeting in 2004, the Ad-Hoc Open-ended working group was formed to negotiate an international legally binding instrument on ABS. After six years of intense negotiations, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was finally adopted during the 10th COP meeting at Nagoya, Japan in 2010 (Table 1). The Protocol entered into force during the 12th COP meeting at Pyeongchang, South Korea in 2014 and has 104 Parties including Bhutan (accessed at www.cbd.int on 16th November 2017). The Nagoya Protocol builds on the ABS provisions of the CBD and further offers a transparent legal framework to support the implementation of its third objective: fair and equitable benefit sharing (NP 2010, UNCTAD 2017).

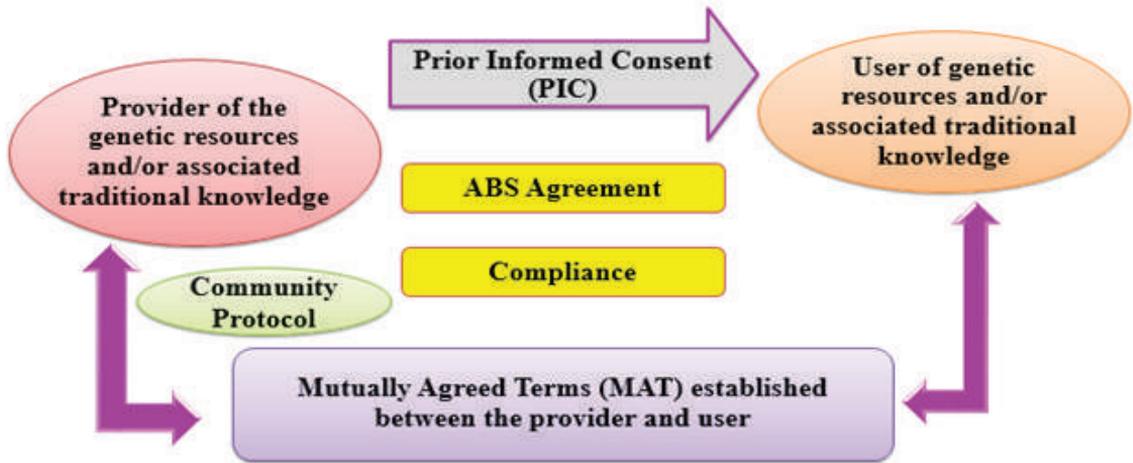


Figure 2: Illustration of the basic components of Access and Benefit Sharing.



Local community of Langthel Gewog processing Indian Gooseberry (*Phyllanthus emblica*).

1.2. Chronological events in the development of the ABS regime

Table 1: Summary of the chronological events in the development of the ABS regime

Year	Particulars
1992	CBD opened for signature.
1993	CBD came into force on 29 December.
2000	COP5 established ABS working group to develop guidance for implementing ABS.
2001	ABS working group was formed to draft Bonn Guidelines.
2002	COP6 adopted the Bonn Guidelines.
2002	World Summit on Sustainable Development called for new international regime on ABS.
2004	COP7 sets terms of reference for negotiations.
2006	COP8 sets 2010 deadline for end of negotiations.
2017 - 2009	Technical expert groups met to discuss certificates of origin, legal terms and concepts, compliance and traditional knowledge.
2009 - 2010	ABS working group met 3 more times to negotiate text.
2010	COP10 adopted the Nagoya Protocol.
2014	Nagoya Protocol came into force on 12 October; first meeting of its governing body, the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP) was held.
2016	Second meeting of its governing body of Nagoya Protocol and, the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP) was held.

1.3. Different components under the concept of Access and Benefit Sharing.

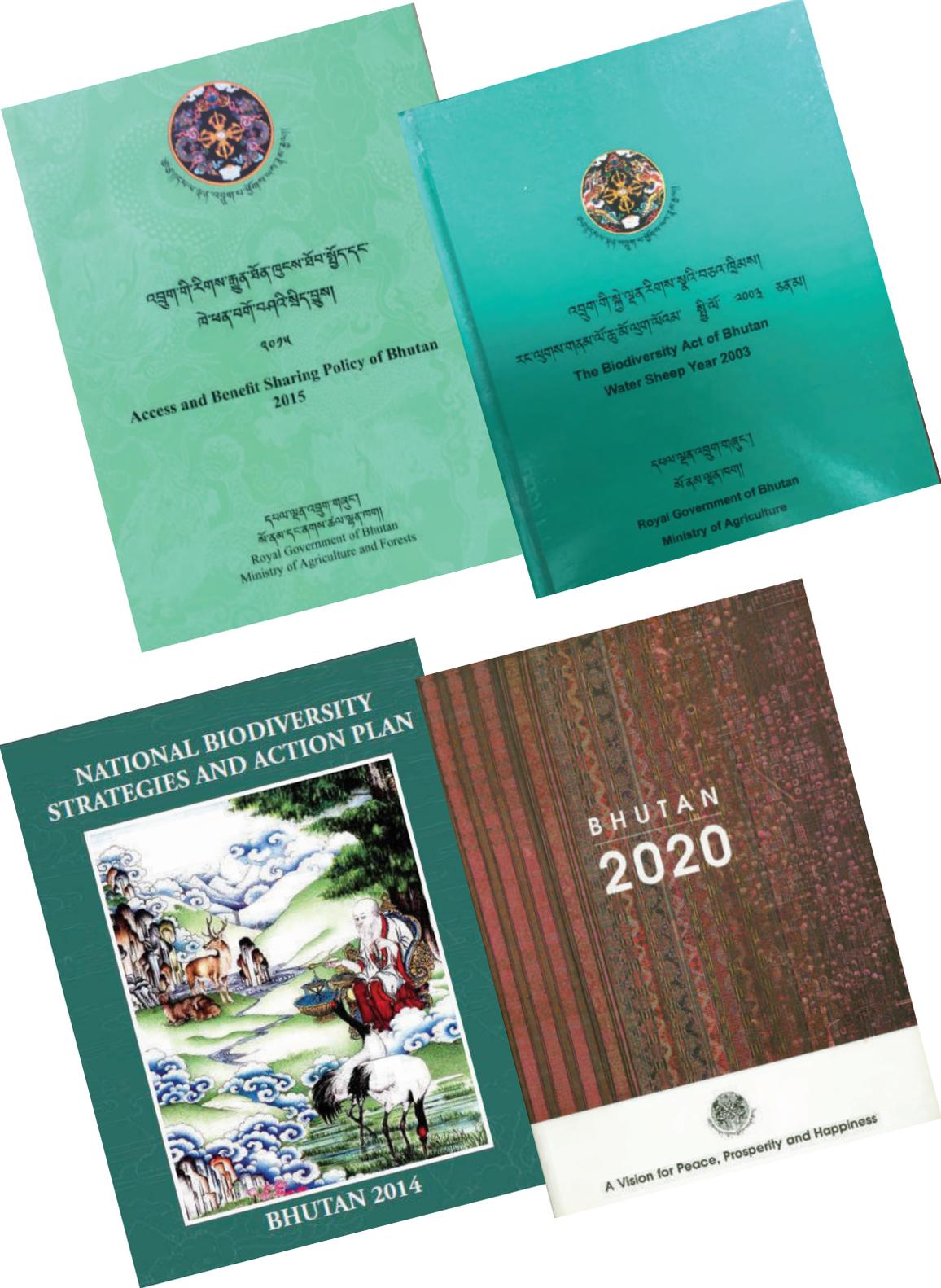
- **Genetic resources:** It refers to the material of plant, animal, microbial or other origin containing a functional unit of heredity and include the biochemical composition of genetic resources, genetic information and derivatives. Genetic resources can be both in-situ (those found in their natural habitat) as well as ex-situ (those found outside their natural habitat such as botanical garden, herbarium, gene bank etc.).
- **Traditional knowledge associated with genetic resources:** It refers to the knowledge, innovations and practices of local communities that are related to the utilization of biodiversity and is not limited to knowledge relating to the genetic structure of biological resources.
- **Access to genetic resources:** It means the utilization of genetic resources irrespective of whether they are accessed in-situ or ex-situ for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including

through the application of biotechnology. Access to genetic resources also includes the conducting of any research and development on derivatives of biological or genetic resources.

- **Access to traditional knowledge associated with genetic resources:** It means the utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and development.
- **Prior Informed Consent:** It is a process through which the National Focal Point seeks the consent of the providers of genetic resources or holders of associated traditional knowledge prior to giving access to genetic resources and associated traditional knowledge after fully disclosing all the required information that permits access to their genetic resources and associated traditional knowledge.
- **Mutually Agreed Terms:** It is an agreement reached between the providers of genetic resources and users on the conditions of access and use of the resources, and the benefits to be shared between both parties.
- **Community Protocols:** Community Protocols are protocols developed by local custodians of genetic resources and/or associated traditional knowledge, through a participatory process based on customary laws and values and detailing the process for acquiring prior informed consent and establishing mutually agreed terms and benefit sharing with respect to utilization of their resources and knowledge.
- **Community Forest Management Group:** Community Forest Management Group are the groups managing the community forests and also refers to community to have the gathering rights for the collection and sale of non-wood forest produce.
- **Commercial utilization of genetic resources and associated traditional knowledge:** “Commercial utilization” includes applying for, obtaining or transferring intellectual property rights by sale or license or in any other manner, or commencement of product development, conducting market research or the sale of any resulting product.
- **Non-commercial utilization:** The utilization of genetic resources without commercial intent.
- **Access and Benefit Sharing (ABS) Agreement:** An ABS Agreement means a contract between the user and providers of genetic resources and/or associated traditional knowledge or both consisting of Prior Informed Consent and Mutually Agreed Terms.
- **Benefit Sharing:** It refers to the sharing of benefits that are derived from access to genetic resources and/or associated traditional knowledge and can be monetary or non-monetary benefits.



Capacity building of local community in Loggchina Gewog on the cultivation of *Zingiber cassumunar*.



Some of the legal documents for biodiversity conservation and ABS in Bhutan.

Chapter II: Legal and Policy Environment for the Conservation of Biodiversity and Implementation of ABS in Bhutan

2.1. An overview of Bhutan and its biodiversity

Bhutan is one of the smallest countries in the world with an area of 38394 sq. km located in the Eastern Himalayas, with China to the North and India to the South, East and West. Bhutan's elevation rises from 150 metres to more than 7500 metres above sea level within 220 kilometres between the southern and northern borders. Bhutan is part of the Eastern Himalayan region which contains three global biodiversity hotspots and counted among the 234 globally outstanding eco-regions of the world according to a comprehensive analysis of global biodiversity by the World Wildlife Fund. Currently, Bhutan has more than 70 percent (DoFPS 2016a) of its land area under forest cover with over 50 percent of the total area secured as protected areas, biological corridors and conservation areas (NECS 2016; DoFPS 2016b). Furthermore, Bhutan is committed to maintaining at least 60 percent of its total land under forest cover for perpetuity as enshrined in the Constitution. Bhutan also committed to remain carbon neutral during the United Nations Climate Change Conference, COP15 at Copenhagen. Bhutan emits approximately 1.5 million tonnes of carbon annually, and its forests absorb approximately 6.3 million tonnes, leaving it with a carbon emission of -4.7 million tonnes, setting it apart as one of the few countries in the world with negative carbon emissions and identifying it as a globally important carbon sink (MoAF 2011).

Bhutan has some of the most pristine and natural landscapes, characterized by a rich species diversity of about 5600 seed plant species, close to 200 species of mammals including 27 globally threatened species and approximately 700 bird species of which 18 are globally threatened (NBSAP 2014). Bhutan is also referred to as “Lhomenjong” (southern valley of medicinal herbs) because of the huge diversity of medicinal plants that are found at different altitudes ranging from 150 to 7500 meters above sea level. There are more than 300 species of medicinal and aromatic plants found in Bhutan.

Bhutan's current status of biodiversity conservation is a result of the far-sighted vision and leadership of our Kings and our rich tradition of living in harmony with nature throughout the centuries. Biodiversity conservation has always occupied a pivotal place in the country's development and this has been further strengthened through the formal adoption of the development philosophy of Gross National Happiness (GNH), which establishes environmental conservation as one of the four pillars of Gross National Happiness.

2.2. Policy and Legal Environment

2.2.1. Policy and Legal Environment at the International level

At an international level, the Convention on Biological Diversity, the International Treaty on Food and Agriculture (ITPGRFA) and the Nagoya Protocol on Access to Genetic Resources and the Fair

and Equitable Sharing of Benefits Arising from their Utilization are the three legal instruments that are relevant to access and benefit sharing.

Convention on Biological Diversity: The United Nations Convention on Biological Diversity is a multilateral treaty with 196 contracting parties which was opened for signature at the Earth Summit at Rio de Janeiro in 1992 and entered into force in 1993. Bhutan became a party to the Convention in 1995 after ratification by the 73rd session of the Parliament of Bhutan. The list of parties to the Convention is available at <https://www.cbd.int/information/parties>¹. The Convention is recognized as one of the key instruments guiding countries towards sustainable development and the effective management of biological diversity. It ascertains the ‘sovereign right’ of each country over its biological resources and/or associated traditional knowledge and guides the fair and equitable sharing of benefits arising from their access. The Convention has three main objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the utilization of genetic resources as indicated in figure 3.

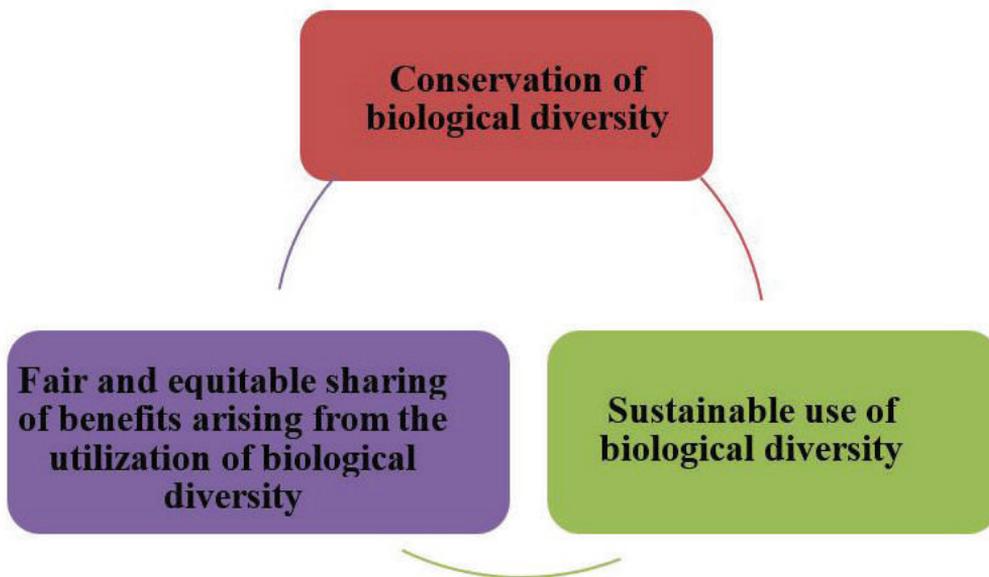


Figure 3: Three objectives of the Convention on Biological Diversity

¹ See annex 1 for the list of signatories to the CBD.

International Treaty on Plant Genetic Resources for Food and Agriculture: The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) popularly known as the International Treaty, is a legal instrument to ensure global food security through the conservation, exchange and sustainable use of the world’s plant genetic resources for food and agriculture as well as the fair and equitable sharing of benefits arising from its use. The Treaty was opened for signature in 2001 and came into force in 2004 while Bhutan ratified the Treaty in 2003. The list of countries that are party to the Treaty can be found at <http://www.fao.org/plant-treaty/countries/membership/en/>. The Treaty introduced the innovative mechanism of access and benefit sharing through the Multilateral System (MLS) wherein a list of 64 species of the most important food and forage crops essential for food security and interdependence, are made accessible through a facilitated plant germplasm exchange and benefit sharing process².

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization: The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity which provides a transparent legal framework to ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. Access, benefit sharing and compliance are the three essential components of the Protocol – the ‘ABC of ABS’ (Nijar 2011). The Protocol was adopted in 2010 and entered into force in 2014. Bhutan signed the Protocol in 2011 and became a party after ratification by the 9th session of the 1st Parliament of Bhutan in 2012. The list of signatories to the Nagoya Protocol is available at <https://www.cbd.int/abs/nagoya-protocol/signatories>³.

2.2.2 Policy and Legal Environment at the National level

Constitution of the Kingdom of Bhutan: Article 1.12 of the Constitution of the Kingdom of Bhutan states that “the rights over mineral resources, rivers, lakes and forests shall vest in the State and are the properties of the State, which shall be regulated by law”. Further, Article 5.1 affirms that “Every Bhutanese is a trustee of the Kingdom’s natural resources and environment for the benefit of the present and future generations and it is the fundamental duty of every citizen to contribute to the protection of the natural environment, conservation of the rich biodiversity of Bhutan and prevention of all forms of ecological degradation including noise, visual and physical pollution through the adoption and support of environment friendly practices and policies.” In addition, Article 5.2 (c) requires the government to secure ecologically balanced sustainable development while promoting justifiable economic and social development (NBSAP 2014).

Forest and Nature Conservation Act of Bhutan 1995: It covers forest management, prohibitions and concessions in government reserve forests, forestry leases, social and community forestry, transport and trade of forestry produce, protected areas, wildlife conservation, soil and water conservation, and forest fire prevention.

² See annex 9 for the list of crops.

³ See annex 2 for the list of signatories to the Nagoya Protocol.

Bhutan 2020-A Vision for Peace, Prosperity and Happiness: Vision 2020 encourages the wise use of natural resources as a development asset to contribute to the sustainable social and economic development of the country and the benefit of humankind.

Biodiversity Action Plans of 1997, 2002 and 2009: These were amongst the earliest documents to recognize bioprospecting as one of the measures for the conservation and sustainable utilization of biological resources and stressed the need to develop a comprehensive policy and legal framework for research and commercial utilization of Bhutan's genetic resources and associated traditional knowledge (NBSAP 2014).

National Biodiversity Strategies and Action Plans 2014: This guiding document underpins the need for a holistic, concerted and effective approach towards biodiversity management for the economic, environmental and social well-being of the present and future generations. It has 20 national targets aligned to the global biodiversity targets, out of which two (targets 16 and 18) are specific to ABS and the protection of Traditional knowledge⁴.

Biodiversity Act of Bhutan 2003: This Act provides a legal foundation for the conservation and sustainable utilisation of biological resources and associated traditional knowledge and the protection of plant varieties through a Sui Generis system. It is currently under revision to align with the national vision and priorities on Access and Benefit Sharing and with the Nagoya Protocol.

Access and Benefit Sharing Policy of Bhutan 2015: This policy guides access to Bhutan's genetic resources and associated traditional knowledge and the fair and equitable sharing of benefits arising from their research and commercial utilization. It upholds the spiritual, cultural and traditional values of the Bhutanese people and it also promotes the ploughing back of benefits secured from access to Bhutan's biodiversity into conservation efforts.

⁴ See annex 13 for the 20 targets of NBSAP.



Eighty two years old man from Tsirang sharing his traditional knowledge with the National Biodiversity Centre.

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Chapter III: An Overview of the Access and Benefit Sharing Management Toolkit

3.1. Rationale

The concept of ABS was introduced to the country in the early 2000s with the enactment of the Biodiversity Act of Bhutan 2003 but the implementation of ABS gained momentum only after the adoption of the Nagoya Protocol in 2010. While there have been numerous activities to create awareness on ABS till date, the need was felt to provide holistic information on ABS under one window for the effective implementation of the ABS regime and increased awareness, leading to the development of this toolkit. This toolkit provides relevant information on the legal, administrative and policy measures, and standard procedures on access and benefit sharing in the country, along with national experiences on the implementation of ABS and allows self-assessments by the toolkit users as well. It is intended to build the capacity of stakeholders involved in the ABS process and also serve as a Communication, Education and Publication Awareness (CEPA) material on ABS.

In addition, this toolkit also fulfils Article 20 of the Nagoya Protocol which states “Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit sharing”.

The specific aim of the development of this toolkit is to enhance understanding of the:

- Concept of ABS.
- Procedures for accessing genetic resources and/or and associated traditional knowledge.
- Procedures and mechanisms for sharing benefits accrued from the access and utilization of genetic resources and/or associated traditional knowledge.

3.2. Methodology

This toolkit was developed by a core team at the National Biodiversity Centre. The process for the development of this toolkit involved various approaches including desktop review of documents, hands-on experience in ABS implementation, expert reviews, consultative meetings and stakeholder workshops.

The process commenced in October 2017 with a review of available toolkits, policies and practices on ABS and knowledge gained from hands-on experiences in ABS implementation by the members of the core team, leading to the development and adoption of the toolkit framework in November 2017. The initial draft of the toolkit was developed and reviewed in January 2018. The comments received were incorporated and further reviewed by the core team in February 2018.

The toolkit underwent a series of consultation with relevant stakeholders involved in the implementation of ABS in the country in order to reach consensus on the information in the toolkit followed by expert reviews.

3.3. Target group: Who can use the ABS Management Toolkit?

This toolkit is intended for use by stakeholders involved in access to genetic resources and/or associated traditional knowledge but not limited to the following:

- Companies/private enterprises such as pharmaceuticals, nutraceuticals, cosmeceuticals, biotechnology companies, etc.
- Local communities
- Policy makers
- Regulators
- Public and private research institutions
- Academia and students
- Individuals



Representative from the National Biodiversity Centre interacting with TK holders.

Chapter IV: ABS Implementation Mechanism in Bhutan

4.1. Institutional Arrangements

The following are the formally designated entities for the implementation of ABS in the country:

- **Competent National Authority (CNA):** The Ministry of Agriculture and Forests, Royal Government of Bhutan is the Competent National Authority for discharging the functions⁵ conferred on it through the Secretary and is the final authority on access proposals.
- **National Focal Point (NFP):** The National Biodiversity Centre, Ministry of Agriculture and Forests is the National Focal Point and the first contact point for access proposals. It receives, reviews and processes access proposals as well as makes information on ABS available for users and liaises with the CBD Secretariat in matters pertaining to Nagoya Protocol as required by the Article 13 of the Nagoya Protocol⁶.
- **Clearing House-Publishing Authority:** The National Biodiversity Centre, Ministry of Agriculture and Forests is the designated Clearing House-Publishing Authority for information related to access and benefit sharing in Bhutan as required by the Article 14 of the Nagoya Protocol.
- **ABS Checkpoints:** The Department of Intellectual Property, Bhutan Agriculture and Food Regulatory Authority and the National Biodiversity Centre are the designated checkpoints to monitor and support compliance of ABS requirements in line with the requirements of Article 17 of the Nagoya Protocol. The designated checkpoints will collect/receive information related to access and utilization of genetic resources and/or associated traditional knowledge ranging from prior informed consent, source of the genetic resources/associated traditional knowledge to establishment of mutually agreed terms and make such information available to the National Focal Point, the Competent National Authority and to the ABS Clearing House, as appropriate⁷.

4.2. Providers of genetic resources and/or associated traditional knowledge

While the state maintains sovereign rights and authority over the management of its genetic resources and recognises the rights of holders of Traditional Knowledge, the following are identified as the provider of genetic resources and/or associated traditional knowledge within the ABS framework.

⁵ See annex 10 for the functions of the Competant National Authority.

⁶ See annex 11 for the functions of the National Focal Point.

⁷ See annex 12 for the functions of the ABS checkpoint.

- **Department of Forests and Park Services:** The Department of Forests and Park Services is the provider of genetic resource from government reserved forests and/or the protected area system.
- **Community Forest Management Group:** A Community Forest Management Group is recognized as the provider when the genetic resource is accessed from a community forest.
- **National Focal Point in consultation with the relevant community custodians or individuals:** The National Focal Point in consultation with the relevant community custodians or individuals is the provider for *in-situ* genetic resources for food and agriculture and genetic resources from private forestry.
- **National Focal Point:** The National Focal Point is the provider when the genetic resources are from *ex-situ* collections such as national gene banks, botanical gardens, national herbarium, etc. In the event that a provider of genetic resources and/or associated traditional knowledge is not identifiable, the National Focal Point is deemed to be the provider.
- **Local Community:** A local community is the provider of traditional knowledge held within a community unless an individual is recognised as the holder of the knowledge by that community. In cases where the traditional knowledge associated with genetic resources is held by more than one community, these communities are recognised as joint providers of traditional knowledge. Where there is no identifiable provider, the National Focal Point is deemed to be the provider.

4.3. Access to Bhutanese genetic resources and/or associated traditional knowledge

Access to Bhutanese genetic resources and/or associated traditional knowledge for research and commercial utilization is guided by the Access and Benefit Sharing Policy of Bhutan 2015 and Biodiversity Act of Bhutan 2003. Access is divided into two phases: a Scoping Phase and an Actualization Phase with differing conditions for each phase.

Scoping Phase: The Scoping Phase refers to the period before the Actualization Phase during which the user is granted access to genetic resources and/or associated traditional knowledge for the initial exploratory phase of research and development with the aim of establishing market or research potential. The Scoping Phase is permitted through a Scoping Agreement executed between the National Focal Point and the user once the access proposal is received and reviewed by the National Focal Point and approved by the Competent National Authority.

Actualization Phase: The actualization phase refers to the period when specific steps are undertaken to commercialize or engage in focused research on genetic resources and/or associated traditional knowledge. It includes, but is not limited to applications for intellectual property rights, product development, and testing and marketing. It is governed by the ABS Agreement which is executed between the users and the providers of genetic resources and/or associated traditional knowledge, under the guidance of the National Focal Point.

4.3.1. Procedures for Access

Any user seeking access to the genetic resources and/or associated traditional knowledge has to submit an access proposal⁸ to the National Focal Point, who will review and assess the proposal for submission to the Competent National Authority for appropriate action. If the access proposal is rejected, the National Focal Point will communicate the decision to the user. If the access proposal is approved, the National Focal Point will facilitate access through execution of one of the following agreements:

1. Scoping Agreement
2. ABS Agreement
3. Material Transfer Agreement
4. Standard Material Transfer Agreement

The Scoping agreement, ABS agreement and Material Transfer agreement are model agreements that have been developed and used for implementing ABS in the country. Each agreement contains clauses which are termed ‘model contractual clauses’, which are the minimum requirements that should be included in these agreements to allow access and utilization of genetic resources and/or associated TK.

1. Scoping Agreement: A Scoping Agreement is executed between the users of genetic resources and associated traditional knowledge, and the National Focal Point to permit the Scoping phase, after the payment of a processing fee of Ngultrum 35,000.00 and a commitment fee of Ngultrum 350,000.00. A Scoping Agreement⁹ shall either be a standard contract or a negotiated contract or amongst others include the following model contractual clauses:

- Conditions for access and utilization
- Specification and quantity of genetic resources
- Information on collection sites of genetic resources
- Confidentiality
- Change of intent
- Sharing of research information and results
- Transfer of research results or accessed genetic resources to third parties
- Benefit sharing

2. ABS Agreement: An ABS Agreement¹⁰ is drawn between the provider and user of genetic resources and/or associated traditional knowledge with the guidance of the National Focal Point in the actualisation phase. A user may also directly enter into an ABS agreement without entering into a Scoping Agreement, where the National Focal Point and the user considers it appropriate. An ABS agreement is conditional to the payment of a processing fee of Ngultrum 35,000.00 if it follows a Scoping agreement. In cases where an ABS agreement is directly executed, then the commitment fee of Ngultrum 350,000.00 is also payable.

⁸ See annex 3 for the sample of an application for access proposal.

⁹ See annex 9 for the sample of the Scoping Agreement.

An ABS agreement shall amongst others include the following model contractual clauses:

- Conditions for access and utilization
- Specification and quantity of genetic resources
- Information on collection sites of genetic resources
- Benefit sharing
- Intellectual property rights
- Confidentiality
- Change of intent
- Sharing of product related information
- Transfer of research results or accessed genetic resources to third parties
- Such other clauses as the Competent National Authority may consider

3. Material Transfer Agreement: A Material Transfer Agreement is a contract which is executed between the person seeking access to the material (applicant) and the recipient of the material with validation by the National Focal Point. It is an expedited form of access when sought for non-commercial purposes such as academic research, exchange of samples between national and international institutions, sample testing for specific purposes if deemed appropriate by the National Focal Point and approved by the Competent National Authority and such other cases as may be determined by the Competent National Authority.

The Material Transfer Agreement¹¹ contains the following model contractual clauses:

- Details of the applicant and recipient of genetic resources
- Description of the genetic resources
- Place of collection
- Destination of the material
- Terms of use of the genetic resources
- Intellectual property rights
- Change of intent
- Confidentiality
- Sharing of research information and results
- Transfer of research results or accessed genetic resources to third parties
- Benefit sharing

4. Standard Material Transfer Agreement¹²: A Standard Material Transfer Agreement (SMTA) is a standard contract developed by the secretariat of the International Treaty for Plant Genetic Resources for Food and Agriculture for use by parties wishing to provide and receive material under the multilateral system. It contains standard terms and conditions that ensures that the relevant provisions of the International Treaty are followed by individual providers and recipients of plant genetic material.

¹⁰ See annex 7 for the sample of the ABS Agreement

4.4. Exemptions under the ABS legislations in the country (Biodiversity Act of Bhutan 2003 and the ABS Policy of Bhutan 2015)

The Biodiversity Act of Bhutan 2003 and the ABS Policy of Bhutan 2015 covers the research and commercial utilization of Bhutan's genetic resources, their derivatives and/or associated traditional knowledge but does not apply to the access of human genetic resources. Biological resources when traded, shared, exchanged and used as commodities are also exempted from the scope of ABS legislations. However, if these biological resources are later utilized as genetic resources for research and/or commercial purposes, such utilization is not exempted.

Further, the use, sharing and exchange of traditional knowledge within and between local communities is exempted from the scope of ABS legislations unless such knowledge is utilized beyond its traditional context for commercial and/or research purposes.

¹¹ See annex 4 for the sample of an application form and annex 5 for the sample of the Material Transfer Agreement.

¹² See annex 8 for the sample of the Standard Material Transfer Agreement.

MATERIAL TRANSFER AGREEMENT

The Material Transfer Agreement is executed in fulfillment of Article 9 of the Biodiversity Act of Bhutan, 2003 and in concurrence to the Executive Order of the Honorable Secretary, Ministry of Agriculture and Forests, designating the National Biodiversity Centre (NBC) as authorized agency for implementing the Material Transfer Agreements (MTA).

1. What is a Material Transfer Agreement?
 A Material Transfer Agreement is a written contract, which defines the rights, obligations and restrictions for both the Provider and the Recipient with respect to the materials or any derivatives, and any confidential information exchanged with the material. It addresses issues such as ownership of materials and rights over the inventions resulting from the use of the materials, transfer and use of the material and any resulting publications or intellectual property rights.

2. Why do we need a Material Transfer Agreement?
 We need to execute Material Transfer Agreements to regulate and streamline access to Bhutanese Genetic resources in order to:

- ✓ Ensure that access results in the fair and equitable sharing of benefits.
- ✓ Avoid unregulated access taking place.
- ✓ Facilitate research collaborations with national capacity building.
- ✓ Fix accountability on the part of the Provider as well as Recipient of the material.
- ✓ Enable generation of information and knowledge sharing.

3. When do we need to execute a Material Transfer Agreement?
 A Material Transfer Agreement is executed when Bhutanese biological resources are transferred to other countries for research and commercialization. It excludes biological resources which are traded as commodity for direct consumption. However, if the materials traded as commodity are later intended to be used for research and commercialization, a Material Transfer Agreement has to be executed. The access to duly registered ex situ collection of genetic resources under Annex-1 of the ITPGRFA shall be in accordance with the terms and conditions of the multilateral system (MLS).

4. Who are the Provider and the Recipient?
 Anyone sending the material is a Provider and anyone receiving the material is a Recipient.

5. What types of materials are being transferred at present?
 The types of materials typically transferred under Material Transfer Agreements include biological resources, such as plants and their extracts, insect vectors, soil and their derivatives, fungi, blood samples etc. Those species listed under Schedule-I of the Forest and Nature Conservation Act of Bhutan are totally protected and not permitted for transfer.



6. How should we process for a Material Transfer Agreement?
 A written application shall be submitted to the Program Director, National Biodiversity Centre, Serbithang covering the following details:

- ✓ Intended purpose of material transfer.
- ✓ Mention types and numbers of material to be transferred (type, quality etc.)
- ✓ Detail address should be provided for final destination of the material.
- ✓ Details of the provider and recipient, including proper mailing address.
- ✓ A Copy of Citizenship ID card for Bhutanese and copy of passport or national ID card for non-Bhutanese.

7. How long does it take to obtain a Material Transfer Agreement?
 A minimum of 10 working days is required to process a Material Transfer Agreement.

8. What are the obligations in relation to materials transferred under a Material Transfer Agreement?
 It is the responsibility of the Recipient to safeguard and protect the transferred materials from misuse and prevent third party transfer without the prior consent and written approval of RGoB. It is also the responsibility of the Recipient to bring the notice of relevant authorities of their organization about the conditions set in the agreement and usage of the transferred materials.

9. How do we track the progress of the executed Material Transfer Agreements?
 The Recipient and the Provider shall provide updates on the progress of the study to the MoAF through NBC. The full study results including confidential information shall be submitted to NBC upon completion of the study. In the event that the Provider and the Recipient fail to report on the progress, NBC shall bring this to the notice of the MoAF for appropriate action.

10. Who holds the right for inventions resulting from the use of the transferred materials?
 In case of inventions resulting from the use of the transferred materials, the recipient and provider shall inform MoAF through NBC, since the ownership of the transferred materials is vested with RGoB. The rights over the inventions will be based on mutually agreed terms and conditions between RGoB and the party concerned.



Figure 5: Procedures involved in the execution of Material Transfer Agreement

4.5. Benefit-Sharing

Benefit-sharing refers to the sharing of benefits accrued from the access and utilization of genetic resources and/or associated traditional knowledge in a fair and equitable manner based on mutually agreed terms, between the providers and users. The National Focal Point is responsible for providing oversight during the negotiation process to ensure the fair and equitable sharing of benefits between the providers of such resources/associated traditional knowledge and the users. Benefits can be monetary or non-monetary in nature as listed below.

4.5.1. Monetary Benefits

The monetary benefits consist of any or a combination of the following:

- Fees
- Up-front payments
- Milestone payments
- Payment of royalties
- License fees in case of commercialization
- Contribution to the Bhutan Access and Benefit Sharing Fund
- Research funding
- Joint ownership of relevant intellectual property rights
- Other monetary benefits

4.5.2. Non-Monetary Benefits

The non-monetary benefits consist of any or a combination of the following;

- Institutional capacity building
- Technology transfer and strengthening capacities for technology transfer
- Collaboration, cooperation and contribution in education and training
- Capacity building of local communities
- Other non-monetary benefits



Farmers from Loggchina visiting ARDC, Wengkhar to learn cultivation practices of *Z. cassumunar*.



An orchid propagation house at Samtengang, Wangdue Phodrang supported by the Bhutan Access and Benefit Sharing Fund.

Chapter V: Bhutan Access and Benefit Sharing (BABS) Fund

5.1. Brief Background

The Bhutan Access and Benefit Sharing Fund was established in 2010 with approval from the Ministry of Finance to receive monetary benefits derived from the research and commercial utilization of Bhutan's genetic resources and/or associated traditional knowledge, in order to support the conservation and sustainable use of Bhutan's biodiversity and enhancement of rural livelihoods and offer a sustainable initiative to complement and offset the costs of conservation in the country. The first contribution to the Fund was made from the payment received from allowing access to genetic resources, in this case, *Cymbidium erythraeum* to a user company in order to operationalize and understand the ABS regime.

5.2. Rationale

The primary objective behind the Fund is to ensure that access to genetic resources and/or associated traditional knowledge results in the fair and equitable sharing of benefits arising from their utilization, which in turn strengthens biodiversity conservation, promotes ownership and enhances community livelihoods.

The BABS fund is also an effective tool to garner support from local communities for the conservation and sustainable utilization of biological resources and/or associated associated traditional knowledge, since communities can see tangible benefits of conservation, which further motivates them to participate in conservation efforts and also promote conservation stewardship.

5.3. Fund Management

The National Biodiversity Centre as the National Focal Point for ABS manages the BABS Fund, under the supervision of the Competent National Authority. Funds are received by the NBC and deposited in the BABS fund. Disbursement of the fund is through joint signatures of the Accounts section and the Program Director, upon approval by the Competent National Authority. The day-to-day functioning of the BABS fund is under the purview of the NBC management. The Fund is subject to auditing by the Royal Audit Authority of Bhutan, as and when required. The fund is used only for the conservation and sustainable use of Bhutan's biodiversity and/or associated traditional knowledge and enhancement of rural livelihoods. It can be used to support community conservation initiatives through capacity building, supply of inputs, infrastructure support etc. as well as to support research initiatives of high value, poorly understood biological resources and/or associated traditional knowledge in the country.

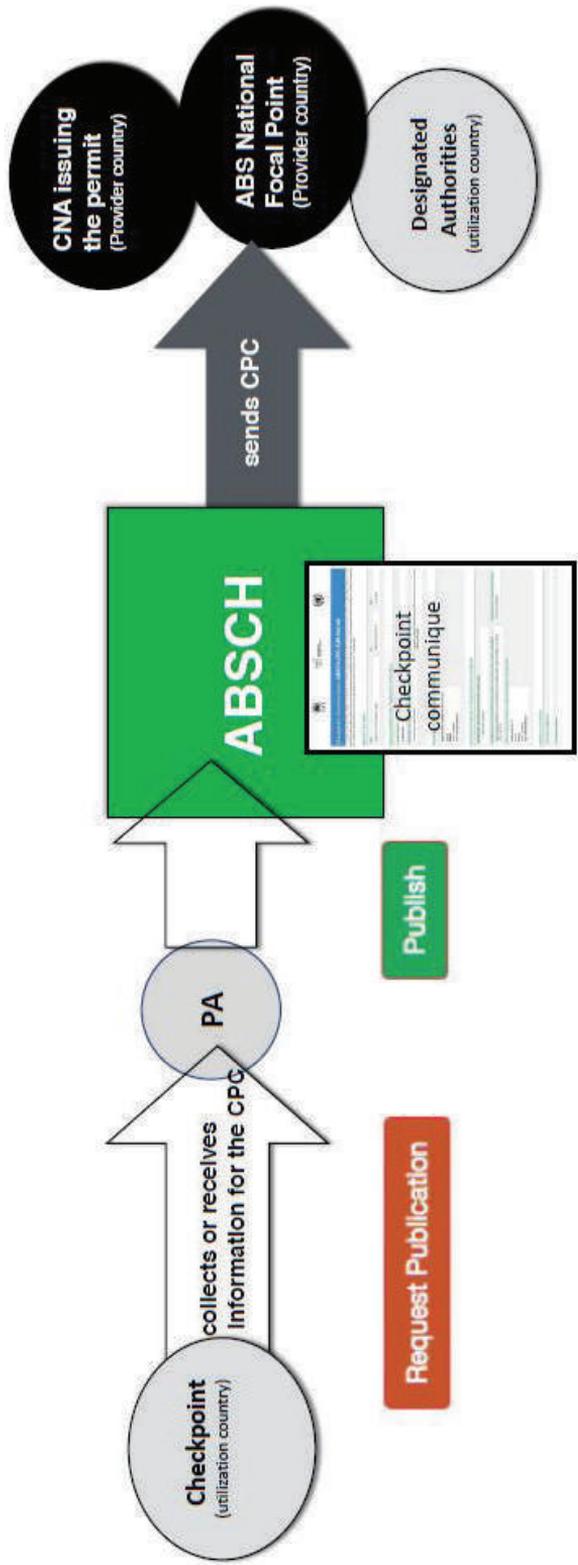
5.4. Contributions to the Fund

The Fund is made up of various contributions namely:

- Monetary benefits arising out of research and commercial utilization of genetic resources from government-reserved forests, protected area system and ex-situ collections.
- Monetary benefits arising from the research and commercial utilization of genetic resources from community forestry including genetic resources related to food and agriculture developed and sustained by the communities.
- Monetary benefits arising from the research and commercial utilization of traditional knowledge associated with genetic resources.
- Processing fee, commitment fee and up-front payments payable at the scoping phase or during the execution of an ABS Agreement.
- Grants, donations or financial assistance from domestic or external sources.
- Such other sources as may be determined by the Competent National Authority.



Research and development work at the bioprospecting laboratory, NBC.



Mechanisms to monitor and track genetic resources and associated traditional knowledge adopted by ABSCH, CBD.

Chapter VI: Compliance Mechanism

6.1. National mechanisms to monitor and track Bhutanese genetic resources and associated traditional knowledge

As per the obligation of the Nagoya Protocol, each contracting party should have appropriate legal, policy and administrative measures to ensure monitoring and tracking of the access and utilization of genetic resources and/or associated traditional knowledge within its jurisdiction and cooperate with other contracting parties to ensure trans-boundary compliance. Accordingly, the measures instituted in the country are as follows:

6.1.1. Designation of ABS Checkpoints

The National Biodiversity Centre, Department of Intellectual Property and Bhutan Agriculture and Food Regulatory Authority are the designated ABS checkpoints. The checkpoints are required to collect or receive information related to the following as appropriate:

- Country of origin of genetic resources or associated traditional knowledge
- Identification of the User
- Prior informed consent
- Establishment of mutually agreed terms
- Utilization of genetic resources or associated traditional knowledge

6.1.2. Issuance of certificate of compliance

The Competent National Authority issues a certificate of compliance¹³ to the user, through the National Focal Point. A certificate of compliance serves as evidence that the genetic resources and associated traditional knowledge have been accessed in accordance with the provisions of the ABS legislation in the country. It can be in the form of a certificate, a permit or equivalent document issued by the Competent National Authority. A certificate of compliance also acts as “passports” along the supply chain of the accessed genetic resources and/ or associated traditional knowledge (UEBT 2010). A certificate of compliance must have the following information:

- Name and signature of the issuing authority
- Date of issuance
- Name of the genetic resources
- Name of the provider
- Name of the user
- Purpose of the access
- Confirmation that mutually agreed terms were established
- Confirmation that prior informed consent was obtained

¹³ See annex 15 for the sample of certificate of compliance.

6.1.3. Generation of Internationally Recognised Certificate of Compliance (IRCC)

An IRCC is generated by the Access and Benefit-sharing Clearing-House under the CBD Secretariat to the user of the genetic resource and/or associated traditional knowledge, the Competent National Authority and the National Focal Point of the provider country, once the Clearing House-Publishing Authority of the provider country uploads information related to the access of genetic resources and/or traditional knowledge to the ABS clearing house. This certificate can be declared at checkpoints as an evidence of Prior Informed Consent, Mutually Agreed Terms and source of the genetic resources and/or associated traditional knowledge.

6.1.4. Sample Transfer Certificate

A Sample Transfer Certificate¹⁴ is a certificate issued by the National Focal Point to accompany the transfer of samples of genetic material out of the country once access has been granted under any one of the following procedures: a Scoping Agreement, an Access and Benefit Sharing Agreement, a Material Transfer Agreement or a Standard Material Transfer Agreement under the ABS regime. Such a certificate along with the samples to be transferred is to be presented at the designated checkpoints or any other relevant organization, as appropriate. A sample transfer certificate is not a substitute for other permits required to be obtained under other relevant laws in the country.

6.2. Transboundary Compliance

Transboundary compliance refers to the cooperation between countries that are party to the Nagoya Protocol to ensure compliance with respective legislation of member countries relating to access to genetic resources and/or associated traditional knowledge.

6.3. Non-compliance

If the National Focal Point or the Competent National Authority or the designated checkpoints become aware of non-compliance by a user or a provider, such situations will be dealt with as per the ABS legislation in the country and with due reverence to the agreements executed between the parties, where appropriate. Examples of non-compliance include accessing genetic resources and/or associated traditional knowledge without PIC and MAT or not upholding the terms and conditions of the agreement granting access to genetic resources and/or associated traditional knowledge and/or its utilization.

¹⁴ See annex 14 for the Sample Transfer Certificate.

Chapter VII: Biotrade and ABS

7.1. Biotrade vs ABS

Biotrade is any activity relating to the commercial collection, processing and sale of products derived from biodiversity. It is often associated with the trade/utilization of biological resources as a whole and as a commodity such as plant material for use as ingredients or inputs for food, cosmetic or industrial products. It refers to all activities involved in a value chain of biodiversity-based products and services, from collection and cultivation through to the different stages of transformation and production and, finally, the marketing and sale of intermediary and consumer products (UNCTAD 2017).

While biotrade and ABS normally differ in terms of objectives, partners involved, the scientific or technological sector they pertain to, and the ways in which biological resources and its components are accessed and utilized (UNCTAD 2017), there is increasing convergence around ABS between sectors using genetic resources and/or associated traditional knowledge and those using raw materials as commodities (Laird et al. 2008), making it important to define whether and when a particular access should be considered under biotrade or ABS.

Under the national ABS regime, any access to biological resources when traded as commodities is considered as biotrade and does not fall under the purview of the ABS policy and legal framework in the country. If biological resources traded as commodities are later utilized as genetic resources for research and/or commercial purposes, such utilization shall be considered as ABS.

The key guiding questions that determine if access falls under biotrade or ABS are:

1. What is the biological resource for which access is sought and for what purpose?
2. Is there a fair and equitable sharing of benefits resulting from the access given under biotrade?
3. Is there ploughing back of benefits accrued from the access under biotrade into conservation initiatives?
4. Has there been an evolution in the utilization of biological resources for which access was given under biotrade?
5. Is there a change in the benefits accrued if access is given under ABS instead of biotrade?



H.E. Prime Minister of Bhutan, Dasho Tshering Tobgay and Resident Coordinator of UN Bhutan, Mr. Gerald Daly at the launch of nature-based products developed in line with the ABS framework on 5th April 2018 in Thimphu, Bhutan.



Nine nature-based products developed from *Rhododendron anthopogon*, *Curcuma longa*, *Sapindas rarak*, *Phyllanthus emblica* and *Z. cassumunar*.

Chapter VIII: Examples of Pilot ABS Agreements Implemented in Bhutan

8.1. Examples of pilot ABS agreements

There are four examples of ABS agreements implemented in the country till date as follows:

1. Bipartite ABS agreement which is between the government and an international company or between the government and the local community.
2. Tripartite ABS agreement which is between the government, a national private company and the local community; and between two government entities and the local community.

There is also ongoing scoping work between the government and an international company with the involvement of the local community which could result in a tripartite ABS agreement down the line and serve as another example of ABS agreement.

8.1.1. Example of a bipartite ABS agreement between the government and an international company.

An international company and NBC entered into a ‘Memorandum of Agreement (MoA) on biodiscovery research and benefit sharing’ allowing the company access to processed orchid flowers from a local community-based natural resources management group for the production of an anti-wrinkle cream.

The monetary benefits received for the processed orchid flowers is channeled into the BABS fund while the royalty from the sale of products is deposited in the government treasury. The money in the BABS fund is used to support community-based conservation initiatives such as capacity building of local communities in orchid propagation and management.



Cymbidium erythraeum flower for the development of cosmetic product.

8.1.2. Example of a bipartite ABS agreement between the government and the local community.

This is an ABS initiative implemented by NBC with the *Dzedokha Phacheng Detshen*, a local community holding traditional knowledge related to a local ginger species, through the Nagoya Protocol Implementation Fund project funded by GEF-UNDP. In this ABS agreement, NBC is the user accessing the genetic resource and associated TK from the provider, who is the *Dzedokha Phacheng Detshen* for developing wellness products. The local community and the NBC agree on the conditions of access and utilization of the genetic resource and associated traditional knowledge through a series of negotiations, guided by the community protocol and the principles of ABS, as enshrined in the ABS policy of Bhutan 2015 and the Nagoya Protocol.

Some of the initial benefits ensuing from this ABS agreement to the local community are: capacity building of the local community in ABS as well as the cultivation and management of the ginger crop; and payment of premium prices for the harvested crop. It is foreseen that the community will reap additional benefits later when the product is commercialised. A portion of the benefit will also be channeled into the BABS fund as a symbolic contribution to the conservation of biodiversity as agreed in the ABS agreement.

8.1.3. Example of a tripartite ABS agreement between the government, a national private company and the local community.

This is also an initiative supported by the GEF-UNDP funded NPIF project wherein BioBhutan has access to the leaves of a *Rhododendron sp.* supplied through a local community group called



Zingiber cassumunar cultivated at Loggchina Gewog.



Massage balm and liniment developed from *Z. cassumunar*.

Dzomdagam Ngomen Tshogpa facilitated by NBC for natural product development. The mutually agreed benefits received by the local community group through negotiations guided by their community protocol and overseen by the NBC are: payment of premium prices by BioBhutan for the genetic resource; capacity building for sustainable harvesting; and sharing of a percentage of the annual gross profit from the sale of the products with the community. Additionally, a portion of the monetary benefit resulting from this ABS agreement will be received by the BABS fund as mutually agreed between the parties.



Products developed under the tripartite ABS agreement by BioBhutan.

8.1.4. Example of a tripartite ABS agreement between two government entities and the local community.

This is also an initiative implemented with support from the GEF-UNDP funded NPIF project wherein NBC and Menjong Sorig Pharmaceuticals Corporation Ltd. (MSPCL) are partnering with two local community groups called *Namther Throgmen Tshogpa* and *Tserim Yugel Sngomen Tshogpa*. MSPCL has access to three different plant species for the production of natural products. MSPCL is granted access to the genetic resource based on mutually agreed terms and conditions through negotiations with the local community groups with NBC maintaining oversight. The benefits received by the community groups in these ABS agreements are: payment of premium prices for the genetic resource accessed by MSPCL; capacity building for sustainable harvesting; and sharing of a percentage of the annual gross ex-factory sales of the products with the community groups.

Additionally, a portion of the monetary benefit resulting from the ABS agreements will be received by the BABS fund as mutually agreed between the parties.



Products developed by MSPCL under the tripartite ABS agreement.

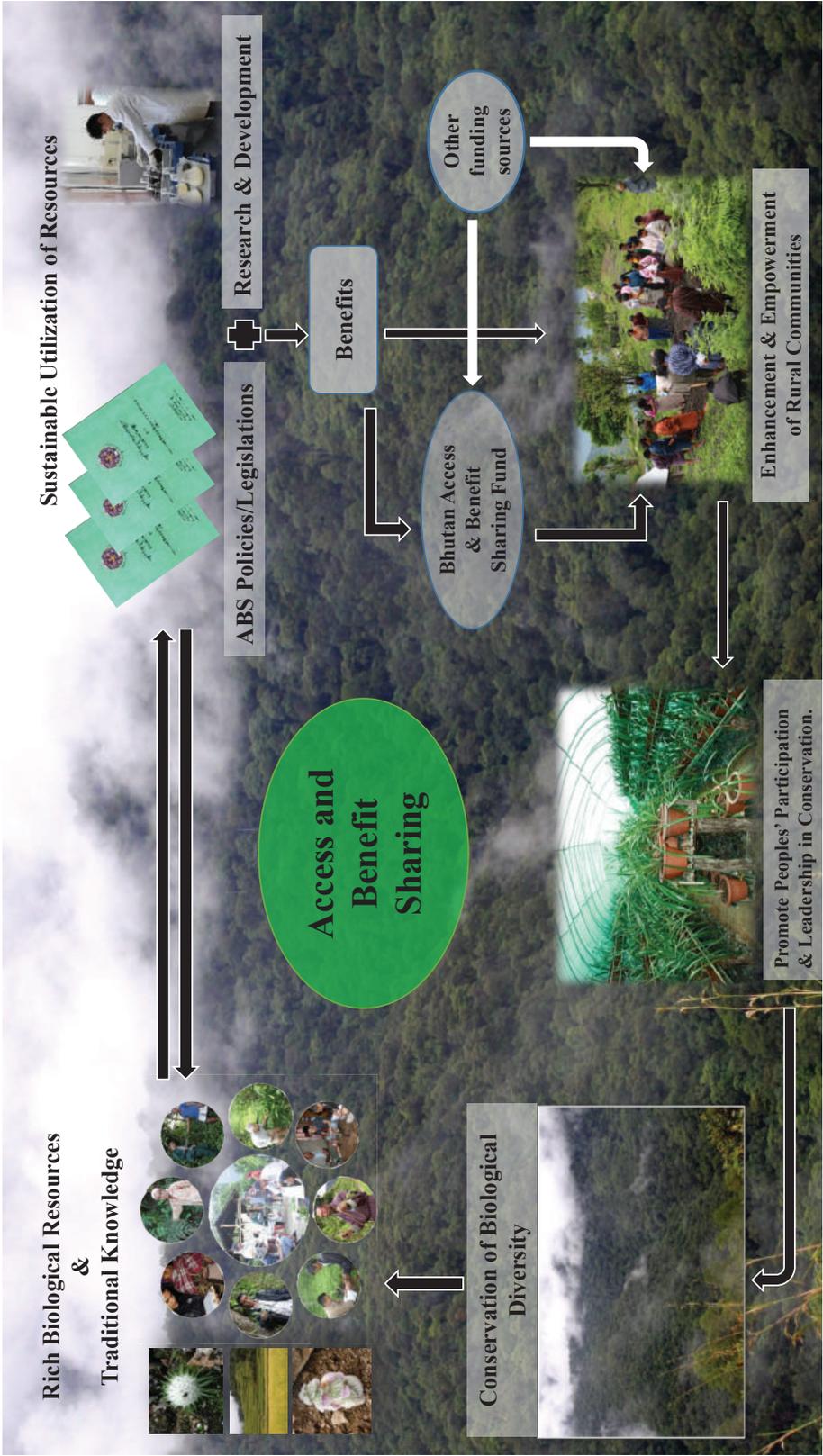


Figure 6: Illustration of the Bhutan Access and Benefit Sharing model.

Chapter IX: Global Examples of ABS Implementation

9.1 Malaysia

Malaysia ratified the CBD in 1994 and but is yet to become a party to the Nagoya Protocol. The Biodiversity and Forestry Management Division, Ministry of Natural Resources and Environment is the National Focal Point for the Nagoya Protocol.

LitSara Project: *Litsea cubeba* has been traditionally used by the indigenous communities in Sarawak, Malaysia as food and medicine for stomach ache and backache. The essential oil extracted from the leaves and fruits has antimicrobial properties that makes it suitable as an active ingredient in personal care products. The Sarawak Biodiversity Centre (SBC), Malaysia learnt about the use of the plant during its traditional knowledge documentation program and is currently working with the local communities; Bidayuh of Kampung Kiding, Lun Bawang in Long Semadoh and the Kelabit of Bario and has developed products under the brand name ‘ LitSara’. Within the Litsara Project, SBC has signed an agreement with Interhill Group for the launch and marketing of LitSara products (IG 2018). Further, the plant *Litsea cubeba* is registered as a Geographical Indication and the Essential oil from the plant is trademarked as LitSara® (SBC 2018).

The research and development of LitSara is one of the pioneer projects that provides benefits to the local communities. An equitable portion of the proceeds from the sale of the products is shared with the indigenous communities of Sarawak who contributed to the development of these products, resulting in improved livelihoods as well as preservation of their traditional knowledge (LitSara® 2018).

9.2 South Africa

South Africa became Party to CBD in 1995 and ratified the Nagoya Protocol in 2014. The Department of Environmental Affairs is the Competent National Authority as well as National Focal Point to the Nagoya Protocol.

1. Hoodia Case: This is a case from the early 2000s for the commercial development of the succulent plant Hoodia ‘*Hoodia gordonii*’ which was used by the indigenous San community of Kalahari Desert, South Africa to suppress their hunger and thirst. The San community used the bitter flesh of the Hoodia plant for centuries to suppress their feeling of hunger and to give them energy while hunting or on long trips across their inhospitable land. This practice was brought to the attention of the South African Council for Scientific and Industrial Research (CSIR) which began to take an interest in the properties of the Hoodia. The work resulted in finding that certain properties of Hoodia (called “P57”) had potential as an appetite-suppressant and anti-obesity drug. Initially, the CSIR was criticized for exploiting the San community’s knowledge without appropriate recognition and acknowledgement as well as sharing of benefits. However, the role of San community’s traditional knowledge and innovative activity in the initial discovery and

development of the properties of the Hoodia were later recognized and acknowledged by the CSIR, which led to the signing of a memorandum of understanding (MoU) with the San community (WIPO 2008). The MoU was followed by a benefit sharing agreement between CSIR and the San community providing San community eight percent of all milestone payments received from the licensee by CSIR as well as six percent of any royalties CSIR received from the sales of the final product (Wynberg et al. 2009). As the CSIR did not have adequate technical capacity to further develop and market a new drug, it licensed its patent to Phytopharm, a UK-based company. The development of this Hoodia-derived product has helped in setting up the ‘San Hoodia Benefit Sharing Trust’, which ensures that the benefits received are used for the general development and training of the San community (WIPO 2008). The Hoodia case exemplifies the significance of the ABS principles and the importance of protection of traditional knowledge to ensure that the holders of such knowledge receive fair benefits (Prip et al. 2015).

2. Rooibos Tea case: A Rooibos tree ‘*Aspalathus linearis*’ meaning “red bush” is a broom-like plant growing in South Africa. The ancient San and Khoi communities of South Africa are believed to be the first to discover that rooibos can be used as a refreshing brew. The plant was then used by the early settlers as an alternative for black tea and for a range of medicinal practices. Rooibos tea is one of South Africa’s oldest and most successful indigenous plant products and has been cultivated on a commercial basis since the 1920s and has become increasingly popular as a health tea as it contains no harmful stimulants and is caffeine-free (Wynberg et al. 2009). Rooibos is endemic to South Africa and only grown in the Cederberg Mountains in the Western Cape Province of the country. In 2009, Nestec S.A., a subsidiary of Nestle filed three patent applications on specific uses of Rooibos for certain medicinal/cosmetic compositions and among other, the prevention of inflammatory disorders (Natural Justice, 2010). Since the plant is endemic to South Africa and according to South African law, their use for the purpose of bioprospecting requires a permit, which Nestec S. A. failed to obtain (Natural Justice, 2010), The Berne Declaration and Natural Justice supported by ABS Initiative worked together with the Khoi and San communities and carried out many advocacy works around this issue in order to secure a fair share for them in line with the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. This resulted in the grant of patents being withheld and brought multinational Nestlé to the negotiating table, which enabled the Khoi and San communities to sign an agreement making Nestlé share the benefits arising from the utilisation of Rooibos.

The key outcome of the process was the development of a community protocol by the National Khoisan Council outlining the identification of 6-8 priorities i.e. recognition, land, healings, traditional knowledge/ABS, youth/women, indigenous languages. Further, traditional knowledge holders associated with rooibos were identified and formally endorsed by the South African government. Subsequently, the first historic benefit sharing agreement on red cappuccino product using rooibos was executed between Nestle and rooibos TK holders (San Council and National Khoisan Council). Currently, only monetary benefits are included but the agreement has a provision for future reviews to explore other non-monetary options such as employment, bursaries and community programs. As of February 2017 two instalments of benefits have been paid via South

Africa Bioprospecting Fund, of which 50 percent was distributed to the San Council and other 50 percent to the National Khoisan Council. In addition, South Africa is in the process of bringing the entire South African Rooibos industry to comply with their benefit sharing obligations under the ABS framework.

9.3 India

India became party to the Convention on Biological Diversity in 1994 and ratified the Nagoya Protocol in 2014. The National Biodiversity Authority is the Competent National Authority and the Ministry of Environment, Forests and Climate Change is the National Focal Point for the Nagoya Protocol.

1. Kani Tribe and Jeevani Case: Kani is a tribe living in the Western Ghats area of Kerala, India and popular for their knowledge of anti-fatigue/anti-stress properties from a particular berry '*Trichopus zeylanicus*' locally known as "arogyapacha". Scientists from the Jawaharlal Nehru Tropical Botanic Garden and Research Institute (TBGRI), India accessed this knowledge and after years of phytochemical and pharmacological research on the plant, isolated twelve active chemical compounds with properties like anti-stress, immune stimulator, stamina booster, fatigue reliever and anti-tumor. They used extracts from this plant to create the herbal formulation 'Jeevani' and filed patent. TBGRI entered into a licensing agreement with an Indian herbal pharmaceutical company 'Arya Vaidya Pharmacy' for marketing the final product (IP4GROWTH 2018). TBGRI also entered into a benefit-sharing agreement with the Kani people. Fifty families from Kani community were given approximately US\$ 40 each for cultivating the plant, and further, after cultivation five tonnes of the leaves per month was bought by TBGRI for the production of Jeevani (IP4GROWTH 2018). A Charitable Trust 'Kerala Kani Samudaya Kshema Trust' was established to receive the royalties from the sale of the products. The Trust's objectives are to promote welfare and development activities for Kani community, to prepare a biodiversity register to document their traditional knowledge, and to promote sustainable use and conservation of biological resources. In 1999, Kani Community received the first payment of US\$ 12,500 from the benefit sharing agreement executed with TBGRI (IP4GROWTH 2018). Funds from the Trust were used for a variety of projects such as installation of telephone booth, creation of an insurance scheme for pregnant women, etc. In 2006, TBGRI invited Kani community to form a Business Management Committee (BMC) which sets minimum conditions for the benefit sharing agreement, such as provision for an increase in license and royalty payments.

The United Nations Environment Program and the World Trade Organization have described the benefit sharing agreement between TBGRI and Kani community as a global model, for recognizing the traditional knowledge and intellectual property of indigenous people in accordance with the guidelines of the CBD. In 2002, TBGRI received the United Nations Equator Prize for its work for the Kani community.

2. Kappaphycus Case: The seaweed '*Kappaphycus alvarezii*' which is renowned for its additive properties in food, pharmaceuticals and cosmetic industries is grown by the fishermen community

in Tamil Nadu, India. The Pepsico India Holdings Pvt. Ltd and Ganesan and Sons, an Indian firm accessed the seaweed from coastal districts of Tamil Nadu for commercial applications (CBD 2018). An ABS agreement was signed between the National Biodiversity Authority (NBA) and the companies for access and utilization of the seaweed. Based on the agreement, a royalty of five percent of Freight on Board (FoB) amounting to Rs. 3.9 Million was paid by the companies to NBA, to be ploughed back to the beneficiaries. Efforts are being made by the State Biodiversity Board to form Biodiversity Management Committees of the 74 benefit claimers spread across four districts of Tamil Nadu. The companies have also trained the Women Self Help Groups for the collection, cleaning and baling of seaweed. However, due to the claims that this particular seaweed is becoming invasive, NBA has currently stopped the access permit (CBD 2018).

9.4 Ethiopia

Ethiopia ratified the CBD in 1994 and became party to the Nagoya Protocol in 2014. The Genetic Resource Access and Benefit Sharing Directorate, Ethiopian Biodiversity Institute (EBI) is the National Focal Point for the Nagoya Protocol.

Teff case: The cereal crop '*Eragrostis tef*' commonly known as a 'teff' is one of Ethiopia's most significant crop species, having gluten-free grains with various other attributes of interest to the food industry. In 2005, a ten-year ABS agreement was signed between the Institute of Biodiversity Conservation, Ethiopia, the Agricultural Research Organization, Ethiopia, and the Netherlands-based company 'Health and Performance Food International (HPFI)' for further breeding and development of teff (Prip et al. 2015). According to the agreement, Ethiopian government gave HPFI access to 12 Ethiopian teff varieties for the development of new teff-based products for the European market. As per the agreement, HPFI was supposed to share the benefits with Ethiopia. However, it did not happen since the company went bankrupt in 2009.

The company had also obtained patent rights for processing teff flour in Europe, which was later transferred to a series of new companies set up by the same owners. The Ethiopian government has been trying to reclaim the patent rights but so far they have not been successful. The teff case exemplifies the complexities of an ABS regime as well as non-compliance of an ABS agreement (for more details please see the article by Andersen et al. 2005).

9.5 Namibia

Namibia became party to CBD in 1997 and ratified the Nagoya Protocol in 2014. The Directorate of Environmental Affairs, Ministry of Environment and Tourism is the National Focal Point for the Nagoya Protocol, while Competent National Authority is yet to be designated.

Marula Case: Women in Namibia have used Marula "*Sclerocarya birrea*" in a variety of ways for generations. A brew made from the bark of the plant has been traditionally administered as a cleansing ritual prior to marriage. Marula oil is also used as meat preservative, skin moisturizer and ingredient for popular foods such as jam and alcoholic beverages (local marula beer) (IP4GROWTH

2018). The marula plant was later used by the South African Distell Group to make ‘Amarula Cream alcoholic drink’ popular in South Africa. With the help of Namibian government, women from rural villages formed Eudafano Women’s Cooperative (EWC) to market marula products for local and international markets. In 2000, EWC became the exclusive provider of marula oil to The Body Shop/African Botanics. In 2008, the cooperative consisted of over 5,000 women in 22 groups producing marula oil from wild trees and in 2010, EWC was the second largest producer of marula products in southern Africa. Currently, over 140 of The Body Shop’s products contain Namibian marula produced by EWC (IP4GROWTH 2018). EWC became a member of PhytoTrade, Africa, a non-profit trade association of the natural products industry in South Africa and through its membership in PhytoTrade, EWC receives fair prices for the marula products it produces for international markets (IP4GROWTH 2018). The partnership also helps to ensure that such knowledge continues to be passed on to younger generations. EWC and PhytoTrade also formed a joint partnership with a specialized international Research and Development company- Aldivia S.A. which specializes in producing natural and organic ingredients for cosmetic manufacturers. With further research and development, an active chemical ingredient ‘Maruline’ was isolated by Aldivia S.A. from Marula Oil with enhanced antioxidant properties creating a viable international market for marula and Maruline. The retail prices for cosmetics with marula is four times more than products without it. Through this partnership, Marula producers receive over US\$ 60,000 annually (IP4GROWTH 2018).



Ja Karpo, Naro Gewog Thimphu covered with *Meconopsis paniculata*

Chapter X: Guiding Questions for Self-Assessment

10. 1 Guiding questions for self-assessment

Section I

1. When did the Convention on Biological Diversity (CBD) enter into force?
 - a. 1990
 - b. 2010
 - c. 1993
 - d. 1992

2. What are the objectives of the Convention on Biological Diversity (CBD)?
 - a. Conservation of biodiversity, sustainable use, benefit sharing
 - b. Conservation, restoration, sustainable use
 - c. Benefit sharing, control of access to genetic resources, capacity building
 - d. Access to genetic resources, technology transfer, capacity building

3. When did Bhutan ratify the CBD?
 - a. 1992
 - b. 1993
 - c. 1994
 - d. 1995

4. Which protocol under the CBD protects the sovereign rights of member countries over their genetic resources and /or associated traditional knowledge?
 - a. Nagoya Protocol
 - b. Cartagena Protocol
 - c. Nagoya Kuala-Lumpur Supplementary Protocol
 - d. None of the above

5. Which year was the Nagoya Protocol adopted?
 - a. 2010
 - b. 2011
 - c. 2012
 - d. 2013

6. Which year was the Nagoya Protocol entered into force?
 - a. 2010
 - b. 2011
 - c. 2012
 - d. 2013

7. Under the Nagoya Protocol what does ABS stands for?
 - a. Agreements and Biodiversity Systems
 - b. Access and Benefit Sharing
 - c. Access to Biological Services
 - d. Access to Genetic Resources

8. Which of the following is the correct definition of ABS under the Nagoya Protocol?
 - a. Fair and equitable sharing of benefits arising from the utilisation of genetic resources
 - b. Sharing of access and benefits to everyone who wants them
 - c. Fair and equitable sharing of benefits from research on human genetic resources
 - d. None of the above

9. What is ABC of the ABS under the Nagoya Protocol?
 - a. Access, Benefit Sharing and Compliance
 - b. Access, Benefit Sharing and Cooperation
 - c. Agreements, Benefit Sharing and Compliance
 - d. None of the above

10. Which year did Bhutan ratified the Nagoya Protocol?
 - a. 2011
 - b. 2012
 - c. 2013
 - d. 2014

11. When was ABS Policy of Bhutan endorsed?
 - a. 2011
 - b. 2012
 - c. 2013
 - d. 2015

12. Who has “sovereign rights” over biological resources in Bhutan as per the Constitution?
 - a. Local Communities
 - b. Private Citizens
 - c. The State
 - d. All of the above

13. Which of the following is exempted from the scope of ABS legislations in Bhutan?
 - a. Genetic resources
 - b. Traditional knowledge associated with genetic resources
 - c. Human genetic resources
 - d. None of the above

14. What are the phases of Access in Bhutan?
 - a. Scoping Phase
 - b. Actualization Phase
 - c. Both Scoping and Actualization Phase
 - d. None of the above

15. What are the different ways to access genetic resources and/or associated traditional knowledge from Bhutan?
 - a. Scoping Agreement
 - b. ABS agreement
 - c. Material Transfer Agreement
 - d. Standard Material Transfer Agreement
 - e. All of the above

16. When is Prior Informed Consent and Mutually Agreed terms required in Bhutan?
 - a. Prior to accessing genetic resources and/or associated traditional knowledge for research and commercial utilization
 - b. After accessing genetic resources and/or associated traditional knowledge for research and commercial utilization
 - c. After development of products through research and commercial utilization
 - d. None of the above

17. Which party listed below will not be involved in the signing of ABS agreement as per ABS legislation in Bhutan?
 - a. State
 - b. Researchers
 - c. Communities
 - d. Judiciary

18. What type of benefits are generated through ABS?
 - a. Monetary only
 - b. Non-monetary only
 - c. Both monetary and non-monetary
 - d. None of the above

19. Choose the monetary benefits from the following? [please tick as appropriate]
 - a. Institutional capacity building
 - b. Payment of royalties
 - c. Technology transfer and strengthening capacities for technology transfer
 - d. License fees in case of commercialization

20. Choose the non-monetary benefit from the following?
 - a. Milestone payments
 - b. Research funding
 - c. License fees in case of commercialization
 - d. Technology transfer and strengthening capacities for technology transfer

21. Choose the forms of contribution to the Bhutan Access and Benefit Sharing Fund.
 - a. Monetary benefits arising out of research and commercial utilization of genetic resources and/or associated traditional knowledge
 - b. Processing fee, commitment fee and up-front payments payable at the scoping phase or during the execution of an ABS Agreement
 - c. Grants, donations or financial assistance from domestic or external sources
 - d. All of the above

22. What are the national mechanisms put in place to monitor and track Bhutanese genetic resources and associate traditional knowledge?
 - a. Designation of ABS Checkpoint
 - b. Sample Transfer Certificate
 - c. Issuance of Certificate of Compliance
 - d. Generation of Internationally Recognized Certificate of Compliance
 - e. All of the above

23. What are the core institutional arrangements required for the implementation of ABS?
 - a. Competent National Authority
 - b. National Focal Point
 - c. Clearing House Publishing Authority
 - d. ABS checkpoints
 - e. All the above

24. Who has the authority to provide a certificate of compliance?
 - a. Competent National Authority
 - b. National Focal Point
 - c. Designated checkpoints
 - d. All of the above

25. What is an ABS Clearing House?
 - a. It is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the Nagoya Protocol
 - b. It is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the Cartagena Protocol
 - c. It is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the CBD
 - d. All the above

Section II

1. List down and define the different components under the concept of ABS.
2. Which are the three main international legal frameworks for ABS?
3. Note some of the important national policies and legal instruments for ABS.
4. Which are the designated entities for implementation of ABS in Bhutan and what are their roles?
5. List down the identified providers of genetic resources and/or associated traditional knowledge as per ABS legislation in Bhutan.
6. Briefly describe the two phases of access and ways in which access is granted in Bhutan?
7. What are the fees involved for executing an access agreement? Is there a fee for executing Material Transfer Agreement and Standard Material Transfer Agreement?
8. What is benefit sharing and what are some of the monetary and non-monetary benefits?
9. What is the objective of the Bhutan Access and Benefit Sharing Fund?
10. Describe national mechanisms instituted to monitor and track Bhutanese genetic resources and associated traditional knowledge.
11. What do you mean by transboundary compliance?
12. What are the examples of non-compliance and how are they dealt?
13. What is Biotrade? What is the main difference between ABS and Biotrade?
14. Detail at least two examples of pilot ABS agreements implemented in Bhutan.
15. Highlight at least two global examples of ABS agreements implemented.

Answers (Section I)

- 1. c
- 2. a
- 3. b
- 4. a
- 5. a
- 6. c
- 7. b
- 8. a
- 9. a
- 10. b
- 11. d
- 12. c
- 13. c
- 14. c
- 15. e
- 16. a
- 17. d
- 18. c
- 19. b, d
- 20. d
- 21. d
- 22. e
- 23. e
- 24. a
- 25. a

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Annexures

Annex. 1. List of countries who are party to the Convention on Biological Diversity

1	Afghanistan	41	Costa Rica	81	Iran	121	Nauru	162	South Africa
2	Albania	42	Côte d'Ivoire	82	Iraq	122	Nepal	163	South Sudan
3	Algeria	43	Croatia	83	Ireland	123	Netherlands	164	Spain
4	Andorra	44	Cuba	84	Israel	124	New Zealand	165	Sri Lanka
5	Angola	45	Cyprus	85	Italy	125	Nicaragua	166	State of Palestine
6	Antigua and Barbuda	46	Czech Republic	86	Jamaica	126	Niger	167	Sudan
7	Argentina	47	Democratic Peoples of Republic of Korea	87	Japan	127	Nigeria	168	Suriname
8	Armenia	48	Democratic Republic of Congo	88	Jordan	128	Niue	169	Swaziland
9	Australia	49	Denmark	89	Kazakhstan	129	Norway	170	Sweden
10	Austria	50	Djibouti	90	Kenya	130	Oman	171	Switzerland
11	Azerbaijan	51	Dominica	91	Kiribati	131	Pakistan	172	Syrian Arab Republic
12	Bahamas	52	Dominican Republic	92	Kuwait	132	Palau	173	Tajikistan
13	Bahrain	53	Ecuador	93	Kyrgyzstan	133	Panama	174	Thailand
14	Bangladesh	54	Egypt	94	Lao PDR	134	Papua New Guinea	175	Republic of Macedonia
15	Barbados	55	El Salvador	95	Latvia	135	Paraguay	176	Timor-Leste
16	Belarus	56	Equatorial Guinea	96	Lebanon	136	Peru	177	Togo
17	Belgium	57	Eritrea	97	Lesotho	137	Philippines	178	Tonga
18	Belize	58	Estonia	98	Liberia	138	Poland	179	Trinidad and Tobago
19	Benin	59	Ethiopia	99	Libya	139	Portugal	180	Tunisia
20	Bhutan	60	European Union	100	Liechtenstein	140	Qatar	181	Turkey
21	Bolivia	61	Fiji	101	Lithuania	141	Republic of Korea	182	Turkmenistan
22	Bosnia and Herzegovina	62	Finland	102	Luxembourg	142	Republic of Moldova	183	Tuvalu
23	Botswana	63	France	103	Madagascar	143	Romania	184	Uganda
24	Brazil	64	Gabon	104	Malawi	145	Rwanda	185	Ukraine

25	Brunei Darussalam	65	Gambia (the)	105	Malaysia	146	Saint Kitts and Nevis	186	United Arab Emirates
26	Bulgaria	66	Georgia	106	Maldives	147	Saint Lucia	187	United Kingdom of Great Britain and Northern Ireland
27	Burkina Faso	67	Germany	107	Mali	148	Saint Vincent and the Grenadines	188	United Republic of Tanzania
28	Burundi	68	Ghana	108	Malta	149	Samoa	189	Uruguay
29	Cabo Verde	69	Greece	109	Marshall Islands	150	San Marino	190	Uzbekistan
30	Cambodia	70	Grenada	110	Mauritania	151	Sao Tome and Principe	191	Vanuatu
31	Cameroon	71	Guatemala	111	Mauritius	152	Saudi Arabia	192	Venezuela
32	Canada	72	Guinea	112	Mexico	153	Senegal	193	Viet Nam
33	Central Africa Republic	73	Guinea-Bissau	113	Micronesia (Federated State of)	154	Serbia	194	Yemen
34	Chad	74	Guyana	114	Monaco	155	Seychelles	195	Zambia
35	Chile	75	Haiti	115	Mongolia	156	Sierra Leone	196	Zimbabwe
36	China	76	Honduras	116	Montenegro	157	Singapore	** United States of America and Holy See are the only two countries which are not party yet.	
37	Colombia	77	Hungary	117	Morocco	158	Slovakia		
38	Comoros	78	Iceland	118	Mozambique	159	Slovenia		
39	Congo	79	India	119	Myanmar	160	Solomon Islands		
40	Cook Islands	80	Indonesia	120	Namibia	161	Somalia		

Annex. 2. List of countries who are party to the Nagoya Protocol

S. No.	Country Name	Signed	Ratification		Party
1.	Albania		2013-01-29	acs	2014-10-12
2.	Angola		2017-02-06	acs	2017-05-07
3.	Antigua and Barbuda	2011-07-28	2016-12-12	rtf	2017-03-12
4.	Argentina	2011-11-15	2016-12-09	rtf	2017-03-09
5.	Belarus		2014-06-26	acs	2014-10-12
6.	Belgium	2011-09-20	2016-08-09	rtf	2016-11-07
7.	Benin	2011-10-28	2014-01-22	rtf	2014-10-12
8.	Bhutan	2011-09-20	2013-09-30	rtf	2014-10-12
9.	Bolivia		2016-10-06	acs	2017-01-04
10.	Botswana		2013-02-21	acs	2014-10-12
11.	Bulgaria	2011-06-23	2016-08-11	rtf	2016-11-09
12.	Burkina Faso	2011-09-20	2014-01-10	rtf	2014-10-12
13.	Burundi		2014-07-03	acs	2014-10-12
14.	Cambodia	2012-02-01	2015-01-19	rtf	2015-04-19
15.	Cameroon		2016-11-30	acs	2017-02-28
	Chad	2012-01-31	2017-10-11	rtf	2018-01-09
16.	China		2016-06-08	acs	2016-09-06
17.	Comoros		2013-05-28	acs	2014-10-12
18.	Congo	2011-09-23	2015-05-14	rtf	2015-08-12
19.	Côte d'Ivoire	2012-01-25	2013-09-24	rtf	2014-10-12
20.	Croatia		2015-09-02	acs	2015-12-01
21.	Cuba		2015-09-17	acs	2015-12-16
22.	Czech Republic	2011-06-23	2016-05-06	rtf	2016-08-04
23.	Democratic Republic of the Congo	2011-09-21	2015-02-04	rtf	2015-05-05
24.	Denmark	2011-06-23	2014-05-01	apv	2014-10-12
25.	Djibouti	2011-10-19	2015-10-01	rtf	2015-12-30
26.	Dominican Republic	2011-09-20	2014-11-13	rtf	2015-02-11
	Ecuador	2011-04-01	2017-09-20	rtf	2017-12-19
27.	Egypt	2012-01-25	2013-10-28	rtf	2014-10-12
28.	Ethiopia		2012-11-16	acs	2014-10-12
29.	European Union	2011-06-23	2014-05-16	apv	2014-10-12
30.	Fiji		2012-10-24	acs	2014-10-12
31.	Finland	2011-06-23	2016-06-03	acp	2016-09-01
32.	France	2011-09-20	2016-08-31	rtf	2016-11-29
33.	Gabon	2011-05-13	2011-11-11	acp	2014-10-12
34.	Gambia (the)		2014-07-03	acs	2014-10-12
35.	Germany	2011-06-23	2016-04-21	rtf	2016-07-20
36.	Guatemala	2011-05-11	2014-06-18	rtf	2014-10-12
37.	Guinea	2011-12-09	2014-10-07	rtf	2015-01-05

S. No.	Country Name	Signed	Ratification		Party
38.	Guinea-Bissau	2012-02-01	2013-09-24	acp	2014-10-12
39.	Guyana		2014-04-22	acs	2014-10-12
40.	Honduras	2012-02-01	2013-08-12	rtf	2014-10-12
41.	Hungary	2011-06-23	2014-04-29	rtf	2014-10-12
42.	India	2011-05-11	2012-10-09	rtf	2014-10-12
43.	Indonesia	2011-05-11	2013-09-24	rtf	2014-10-12
44.	Japan	2011-05-11	2017-05-22	acp	2017-08-20
45.	Jordan	2012-01-10	2012-01-10	rtf	2014-10-12
46.	Kazakhstan		2015-06-17	acs	2015-09-15
47.	Kenya	2012-02-01	2014-04-07	rtf	2014-10-12
48.	Kuwait		2017-06-01	acs	2017-08-30
49.	Kyrgyzstan		2015-06-15	acs	2015-09-13
50.	Lao PDR		2012-09-26	acs	2014-10-12
	Lebanon	2012-02-01	2017-10-13	rtf	2018-01-11
51.	Lesotho		2014-11-12	acs	2015-02-10
52.	Liberia		2015-08-17	acs	2015-11-15
53.	Luxembourg	2011-06-23	2016-10-25	rtf	2017-01-23
54.	Madagascar	2011-09-22	2014-07-03	rtf	2014-10-12
55.	Malawi		2014-08-26	acs	2014-11-24
56.	Mali	2011-04-19	2016-08-31	rtf	2016-11-29
57.	Malta		2016-12-01	acs	2017-03-01
58.	Marshall Islands		2014-10-10	acs	2015-01-08
59.	Mauritania	2011-05-18	2015-08-18	rtf	2015-11-16
60.	Mauritius		2012-12-17	acs	2014-10-12
61.	Mexico	2011-02-24	2012-05-16	rtf	2014-10-12
62.	Micronesia	2012-01-11	2013-01-30	rtf	2014-10-12
63.	Mongolia	2012-01-26	2013-05-21	rtf	2014-10-12
64.	Mozambique	2011-09-26	2014-07-07	rtf	2014-10-12
65.	Myanmar		2014-01-08	acs	2014-10-12
66.	Namibia		2014-05-15	acs	2014-10-12
67.	Netherlands	2011-06-23	2016-08-19	acp	2016-11-17
68.	Niger	2011-09-26	2014-07-02	rtf	2014-10-12
69.	Norway	2011-05-11	2013-10-01	rtf	2014-10-12
70.	Pakistan		2015-11-23	acs	2016-02-21
71.	Panama	2011-05-03	2012-12-12	rtf	2014-10-12
72.	Peru	2011-05-04	2014-07-08	rtf	2014-10-12
73.	Philippines		2015-09-29	acs	2015-12-28
74.	Portugal	2011-09-20	2017-04-11	apv	2017-07-10
75.	Qatar		2017-01-25	acs	2017-04-25

S. No.	Country Name	Signed	Ratification		Party
76.	Republic of Korea	2011-09-20	2017-05-19	rtf	2017-08-17
77.	Republic of Moldova	2012-01-25	2016-08-24	rtf	2016-11-21
78.	Rwanda	2011-02-28	2012-03-20	rtf	2014-10-12
79.	Samoa		2014-05-20	acs	2014-10-12
80.	Sao Tome and Principe		2017-01-10	acs	2017-04-10
81.	Senegal	2012-01-26	2016-03-03	rtf	2016-06-01
82.	Seychelles	2011-04-15	2012-04-20	rtf	2014-10-12
83.	Sierra Leone		2016-11-01	acs	2017-01-30
84.	Slovakia		2015-12-29	acs	2016-03-28
85.	South Africa	2011-05-11	2013-01-10	rtf	2014-10-12
86.	Spain	2011-07-21	2014-06-03	rtf	2014-10-12
87.	Sudan	2011-04-21	2014-07-07	rtf	2014-10-12
88.	Swaziland		2016-09-21	acs	2016-12-20
89.	Sweden	2011-06-23	2016-09-08	rtf	2016-12-07
90.	Switzerland	2011-05-11	2014-07-11	rtf	2014-10-12
91.	Syrian Arab Republic		2013-04-05	acs	2014-10-12
92.	Tajikistan	2011-09-20	2013-09-04	acs	2014-10-12
93.	Togo	2011-09-27	2016-02-10	rtf	2016-05-10
94.	Uganda		2014-06-25	acs	2014-10-12
95.	United Arab Emirates		2014-09-12	acs	2014-12-11
96.	United Kingdom of Great Britain and Northern Ireland	2011-06-23	2016-02-22	rtf	2016-05-22
97.	Uruguay	2011-07-19	2014-07-14	rtf	2014-10-12
98.	Vanuatu	2011-11-18	2014-07-01	rtf	2014-10-12
99.	Viet Nam		2014-04-23	acs	2014-10-12
100.	Zambia		2016-05-20	acs	2016-08-18

*** acs: accession (ratified after the protocol's entry into force) ; rtf: ratification (ratified before the protocol's entry into force in 2014)

Annex. 3. Sample of a form for Access Proposal

<p>Form for Access Proposal (<i>Information included in this Form shall be in sufficient detail to enable the relevant authorities to make a decision whether to grant or refuse Access</i>)</p>
<p>Section 1. Applicant Name: _____ Address: _____ Work Tel _____ Home Tel _____ E-mail address: _____ Mobile No: _____ Name and address of principal researcher: Address of the contact person/agent if any in Bhutan: _____</p>
<p>Section 2. Category (<i>Tick the relevant box</i>)</p> <p><i>Type of Phase</i> <input type="checkbox"/> Scoping <input type="checkbox"/> Access and Benefit Sharing</p> <p><i>Type of Resources</i> <input type="checkbox"/> Genetic Resources <input type="checkbox"/> Associated Traditional Knowledge <input type="checkbox"/> Others (specify)</p>
<p>Section 3. Application Checklist</p> <p><i>The following list outlines all of the information necessary to provide a timely decision on your application. All items on the list must be provided with the application. We are unable to accept applications that do not have all of the required items.</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Profile of the organization. <input type="checkbox"/> Copy of Company Incorporation Certificate or equivalent/CV of Foreign applicant in case of individual. <input type="checkbox"/> Copy of passport of foreign applicant (if investor is individual). <input type="checkbox"/> Power of Attorney for the authorized representative/contact person. <input type="checkbox"/> Identity and responsibilities of all entities and individual persons who will be involved in the activities. <input type="checkbox"/> Annual turnover of the organization in Nu/US dollars (including Tax return/audited accounts of foreign investor (s) for last 3 years). <input type="checkbox"/> Equipments and laboratories relevant to the activity. <input type="checkbox"/> Description of all previous genetic resource collection activities in Bhutan or elsewhere. <input type="checkbox"/> Provide complete information about existing or proposed contracts between the applicant and any third party relating to the use of any information and products resulting from the access activity.

Section 4: Proposal

The proposal shall include:

1. Identification (scientific name) of genetic resource and its use or description/nature of traditional knowledge (oral/documented)
2. Geographical location of proposed collection.
3. Any identified individual/community holding the traditional knowledge.
4. Quantity of biological resources to be collected.
5. Provide information on the arrangements made within Bhutan to facilitate the collection.
6. Time span in which genetic resources is proposed to be collected.
7. Purpose for which access is requested including the type and extent of research, mechanism for sharing of results, commercial use being derived and expected to be derived from it and any other benefits anticipated.
8. Provide information if collection of the resource endangers any component of biological diversity and the risks which may arise from the access where available.
9. Nature of legal rights including any intellectual property rights the applicant intends to seek over the accessed genetic resources and ensuing innovations.
10. Indicate the work plan and time frame within which the project is to be completed.

Section 5. Others

1. Provide information on:
 - The primary destination of the resources and any expected subsequent destinations of the resources.
 - Intended distribution/sharing of the accessed resources and list actual or potential beneficiaries.
2. Details and responsibilities of collaborating national institution/s, scholars, scientists, students, farmers and farmer groups in Bhutan in the field mission and/or its follow-up activities.
3. Economic and other benefits including those resulting from any Intellectual Property Rights (IPR) and 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.

Section 6. Declaration

I/We, the undersigned, being duly authorized, declare to the best of my/our knowledge and belief that the information contained in this application is correct and complete and I/We authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application. In case the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed: _____
 Date: _____
 Name: _____
 In the capacity of: _____

Annex. 4. Sample of an application form for execution of Material Transfer Agreement

Application form for Material Transfer Agreement	
Section 1. Details of the User	
Name: _____	
Address: _____	
Work Tel.: _____ Home Tel.: _____	
E-mail address: _____	
Mobile No.: _____	
Section 2. Purpose <i>(tick the relevant box)</i>	
<input type="checkbox"/> specific academic research	<input type="checkbox"/> exchange of samples
<input type="checkbox"/> sample testing	<input type="checkbox"/> others (specify
Section 3: Details of the Genetic Resources	
1. Scientific description of genetic resources	
a. If it is for academic research	
i) name of the university;	
ii) name of the institution;	
iii) location of the institution;	
iv) name of the supervisor;	
v) purpose of the study;	
vi) affidavit from the institution affirming that it shall not be put to commercial use;	
b. If it is for exchange of samples	
i) name of the institution providing the genetic resources;	
ii) name of the institution receiving the genetic resources;	
iii) location of the institution;	
iv) affidavit from the institution affirming that it shall not be put to commercial use.	
c. If it is for sample testing	
i) purpose of the testing;	
ii) name of the laboratory;	
iii) location of the laboratory;	
iv) affidavit from the user affirming that it shall not be put to commercial use.	

Section 4. Declaration

I/We, the undersigned, being duly authorized representative, declare to the best of my/our knowledge and belief that the information contained in this application is correct and complete and I/We authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application. In case the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed: _____

Date: _____

Name: _____

In the capacity of: _____

Annex. 5. Sample of a Material Transfer Agreement

Material Transfer Agreement

Reference No: NBC/ BRD/7/2017-2018/

Article 1 – Parties to the Agreement

1.1. This Agreement is made between:

National Biodiversity Centre (NBC), Ministry of Agriculture and Forests (MoAF), Serbithang, Thimphu, Post Box No. 875. (*National Focal Agency on Access to Genetic Resources and execution of Material Transfer Agreement*).

Applicant:Name of the organization....., represented by, bearing CID No.:(hereinafter referred to as “Applicant”).

And

Recipient:, bearing CID No.:..... (hereinafter referred to as “Recipient”).

Article 2 – Preamble

- 2.1. The Material Transfer Agreement is executed in fulfillment of Article 9 of the Biodiversity Act of Bhutan 2003 and based on the Ministry’s approval note-sheet No: dated
- 2.2. The Applicant and the Recipient acknowledge that the Royal Government of Bhutan (hereinafter referred to as RGoB) retains legal ownership of the Material. The Applicant is authorized to transfer to the Recipient the Material specified under Article 4 of this agreement upon execution of this Material Transfer Agreement (MTA) between the Applicant and the Recipient.
- 2.3. The Applicant and Recipient shall jointly be referred to as “Parties”.

Article 3– Definitions

- 3.1. In this Agreement the expression set out below shall have the following meaning:
 - “**Material**” shall mean, as mentioned in article 4.1 of this Agreement.
 - “**Applicant**” means the person/institution providing the material and for this agreement, Mr.....
 - “**Recipient**” means the person receiving the material and for this agreement, Mr.

Article 4 - Subject Matter of the Material Transfer Agreement

- 4.1.**description and quantity of the material**..... hereby transferred from the Applicant to the Recipient subject to the terms and conditions set in this Agreement. The detail of the subject matter is indicated in the table below;

Article 5 – Destination

5.1.Details of the final destination.....

Article 6 -Terms and Conditions

- 6.1. The Applicant and Recipient understands and undertakes that, the transferred material shall be used only for The transferred material shall be used only for the aforementioned purpose, in case of change of intent, the Recipient and the Applicant shall seek the prior written approval from the MoAF through NBC.
- 6.2. The Recipient shall take full responsibility for the safety and protection of the material and shall be liable of misuse by any third party. The materials shall be properly destroyed upon successful completion of the study.
- 6.3. The Recipient shall submit the full study results including confidential information to the MoAF through NBC upon completion of the study or not later than failing to do so will restrict them to get future access.
- 6.4. Any publications related to this collaboration shall be jointly co-authored by the appropriate Bhutanese counterpart.
- 6.5. It is the responsibility of the Recipient to bring to the notice of relevant authorities of the receiving authority....., about the conditions set in the agreement and the usage of the transferred material.
- 6.6. In case of new discovery (ies), the Recipient and the Applicant shall inform the MoAF through NBC of such discovery (ies) immediately without fail. The Recipient and the Applicant shall not apply for any intellectual property rights without prior written approval from the MoAF.
- 6.7. NBC makes no warranties as to the safety of the material, nor so to the accuracy of any passport or other data provided with the material. Neither does it make any warranties as to the quality, or purity (genetic or mechanical) of the Material being supplied. The Recipient assumes full responsibility for complying with the counterpart nation’s quarantine and biosafety regulations and rules as to the import of the material.

Article 7 – Settlement

- 7.1. The Parties shall discuss sincerely and settle amicably on matters which are not stipulated in this Agreement or interpretation of this Agreement.
- 7.2. This Agreement shall be governed by and construed in accordance with the laws of Bhutan.

Article 8 – Signature and Acceptance

IN WITNESS THEREOF, the parties have executed this Material Transfer Agreement on the dates set forth below:

For the National Biodiversity Centre:

Seal & Signature [_____]

Date:

Name:

Designation:

Contact Number:

Mailing Address:

For the Applicant: I, _____, represent and warrant that, I have the authority to execute this Agreement on behalf of the Applicant.

Seal & Signature [_____]

Date

Name:

Designation:

Mailing Address:

Contact Number:

For the Recipient: I, _____, represent and warrant that, I have the authority to execute this Agreement on behalf of the Recipient and acknowledge to abide by the provisions of this Agreement, both by letter and in principle, in order to promote the conservation and sustainable use of biological resources and sharing of benefits derived thereof.

Seal & Signature [_____]

Date:

Name:

Designation:

Mailing Address:

Annex. 6. Sample of a Scoping Agreement

AGREEMENT FOR GRANTING ACCESS TO GENETIC RESOURCES FROM BHUTAN FOR THE SCOPING PHASE OF SUCH RESOURCES

This Agreement is entered on the day of 2013 at Thimphu, Bhutan.

Between

Ministry of Agriculture and Forests, Royal Government of Bhutan acting through and represented by the **Program Director, National Biodiversity Centre** being the authorised officer of the Authorized Agency (AA) having its office at Serbithang, Thimphu, Bhutan (hereinafter referred to as “the AA”)

And

.....**Name of the Company**....., established and existing under the laws of **Name of the country**..... with a capital of**USD**..... having its registered**address of the company**..... (hereinafter referred to as)

Whereas:

The **AA** has been established by the Royal Government of Bhutan under the powers granted to it by Section 5 of the Biodiversity Act of Bhutan 2003 (hereafter referred to as the Act) and the Access and Benefit Sharing Policy of Bhutan 2015. Under which, the **AA** is the authority to permit access to any genetic resources and /or associated traditional knowledge found within the territory of Bhutan.

Name of the Company..... seeks to engage in the scoping phase of the utilization of Bhutan’s genetic resources and has made an application to the **AA** to seek its approval under Section 6 of the Act.

This Agreement is for granting approval for the scoping phase of access to Bhutan’s genetic resources described under Section 5 of this Agreement.

The Parties hereto agree as follows:

1. Definitions

In this Agreement, unless the context otherwise requires:

Genetic Resources means all material of plant, animal, microbial or other origin containing functional units of heredity and include the biochemical composition of genetic resources, genetic information and derivatives.

Traditional Knowledge associated with genetic resources means the knowledge, innovations and practices of Bhutanese communities that is related to the utilization of biodiversity and is not limited to knowledge relating to genetic structure of biological resources.

Access to Genetic Resources means the utilization of genetic resources from Bhutan irrespective of whether they are accessed in situ or ex situ for the purpose of conducting any research and/ or development on the genetic and/ or biochemical composition of genetic resources including through the application of biotechnology. Access to genetic resources also includes the conducting

of any research and development on derivatives of biological or genetic resources from Bhutan.

Access to Traditional Knowledge associated with genetic resources means the utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and development.

Bhutan Access and Benefit Sharing Fund (BABS Fund) means a fund established to receive monetary benefits derived from the research and commercial utilization of Bhutan's genetic resources and/or associated traditional knowledge including processing fee and the cash deposit payable at the Scoping phase for strengthening the sustainable conservation initiatives of biological resources.

Act means the Biodiversity Act of Bhutan 2003.

Policy means the Access and Benefit Sharing Policy of Bhutan 2015.

The scoping phase of utilization of genetic resources and/or associated traditional knowledge means the initial exploratory phase of research and development with the aim of establishing market or research potential.

The actualization phase of utilization of genetic resources and/or associated traditional knowledge means the phase when specific steps are undertaken to commercialize or engage in focused research on such resources and/or knowledge. The actualization phase includes, but is not limited to applications for intellectual property rights, product development and testing and marketing.

2. Preamble

- 2.1. Access to Bhutan's genetic resources shall be divided in two phases: *a Scoping Phase* and an *Actualization Phase* with differing conditions for each phase.
- 2.2 The Scoping Phase to conduct exploratory research will require Scoping Permit which shall be in a form of a Scoping Agreement and contain a set of conditions for utilization of such resources.
- 2.3. Based on the outcome of the Scoping Phase if**Name of the Company**.... intends to undertake any step to commercialize or engage in focused research on such resources and/or research results which may include but is not limited to applications for intellectual property rights, product development and testing and marketing; **Name of the Company**..... shall enter into an ABS Agreement and secure Actualization Permit prior to engaging in such steps or the Actualization Phase of utilization of such resources.
- 2.4. Benefit sharing under the ABS Agreement during Actualization Phase shall be based on each party's contribution, fairness and mutual consensus.

3. Grant of Approval

- 3.1. The AA hereby grants approval for access to genetic resources for the scoping phase subject to the terms and conditions set forth in this Agreement.

- 3.2. Any activity/usage involving the genetic resources that is not expressly authorized by the provisions of this Agreement and any additional annexure (s) hereto is deemed as prohibited.
- 3.3. **Name of the Company**..... hereby agrees that, this Agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Parties hereto or make them in any way liable as partners or as agents for one another. No Party has the authority to act for or to assume any obligation or responsibility on behalf of the other Party and the relationship between the Parties is that of a legal or natural person and a statutory authority competent to approve access to genetic resources under the Act.

4. Assignment

- 4.1. Without the prior written approval of the AA in each instance, neither this Agreement nor the approval granted hereunder shall be transferred or assigned in whole or in part by **Name of the Company**..... to any natural or legal person whether voluntarily or involuntarily, by operation of act or omission on the part of **Name of the Company**..... or otherwise.
- 4.2. In the event of any substantial changes in the management or shareholding of **Name of the Company**....., that alters the control structure of **Name of the Company**..... and includes changes brought by a transfer of business units, merger, demerger or any other kind of corporate restructuring, **Name of the Company**..... shall ensure that the obligations under this agreement perpetuate and provide written notice to the AA not less than **thirty (30)** days prior to initiating such changes.

5. Conditions for Access to Genetic Resources

- 5.1. **Name of the Company**..... shall have access only to the biological resources approved by the AA and listed under Annex-1 of this agreement. The approved resources shall be made available to **Name of the Company**..... by National Biodiversity Centre (NBC).
- 5.2. The initial processing of the biological resources listed under Annex-1 of this agreement shall be done at Bioprospecting Laboratory, NBC, Serbithang, Thimphu as per the protocols of **Name of the Company**..... and shall be transferred to **Name of the Company** for advanced research.
- 5.3. **Name of the Company**..... undertakes to abide with the provisions of the Act and other related legislations in force in Bhutan and as amended in the future.
- 5.5. **Name of the Company**..... undertakes to facilitate measures for the conservation and sustainable use of genetic resources and to minimize any negative environmental or social impact of the collecting and research activities.
- 5.6. **Name of the Company**..... shall not distribute, transfer or part with the accessed genetic resources and associated information to any third party without prior written approval of AA nor engage in the ‘actualization phase’ of the accessed resources under this Agreement and signing of appropriate Agreement and issuance of Actualization Permit.
- 5.7. **Name of the Company**..... undertakes to submit status report in English on yearly basis on the progress of the scoping phase to the AA by 15th of December.

- 5.8. The AA reserves its right to supervise the access process to the genetic resources and the research as it may deem fit.
- 5.9. Any violation of above conditions will be deemed to be material breach of this Agreement making the Agreement voidable at the option of the AA.

6. Other conditions

- 6.1. **Name of the Company**..... shall submit in English a hard and soft copy of its scoping findings in the form of reports, publications, thesis or any other documents to the AA as soon as the scoping is completed or published or expiry of the term of the Agreement whichever is earlier. The AA will have full ownership of the results of the scoping phase if **Name of the Company**..... decides not to enter into an ‘actualization phase’ of the utilization of Bhutan’s genetic resources.
- 6.2. **Name of the Company**shall pay such sum of Nu. 35000.00 (thirty-five thousand only) as a processing fee for the Scoping Permit/Agreement. This fee will be deposited in Bhutan ABS Fund for strengthening the sustainable conservation initiatives of biological resources.
- 6.3. **Name of the Company**..... shall pay such sum of Nu. 350,000.00 (Three lakhs fifty thousand only) to the AA as a guarantee deposit.

7. Liabilities and Indemnification

- 7.1. **Name of the Company**.... shall be solely responsible for any claims by third parties arising from the **Name of the Company**acts or omissions in the course of performing this Agreement and under no circumstances shall the AA be held responsible or liable for any claims by such third parties.
- 7.2. **Name of the Company**..... shall indemnify and protect the AA and its employees from and against all claims, demands, losses, damages, costs (including attorney fees), actions, suits or other proceedings, all in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of**Name of the Company**....., its employees or agents, (whether by reason of negligence or otherwise) in the performance by or on behalf of **Name of the Company**..... of the provisions of this Agreement or any activity undertaken or purported to be undertaken under **Name of the Company**..... authority or pursuant to the terms of this Agreement.
- 7.3. **Name of the Company**..... undertakes to pay such a sum as determined by AA and mutually agreed for any breach of this agreement and loss incurred in Bhutan.

8. Term of the Agreement and Termination

- 8.1. This Agreement, unless terminated as provided herein, shall remain in effect for a period of **five (5) years** from the date of signing of this Agreement by the Parties. However the obligations of **Name of the Company**..... with respect to the utilization of Bhutan’s genetic resources and/or associated information under this Agreement will remain in perpetuity.
- 8.2. The AA may terminate the rights under this Agreement and revoke the Scoping Permit by a written notice if **Name of the Company**..... defaults in the performance of any

obligations under this Agreement and the default has not been remedied within sixty (60) days after the date of notice in writing of such default by AA.

- 8.3. **Name of the Company**..... agrees to forfeit its deposit in situations where the AA terminates this Agreement and revokes the Scoping Permit under the conditions listed in 8.2.
- 8.4. **Name of the Company**..... may terminate this Agreement by giving sixty (60) days advance written notice stating valid reasons for the same. However, such termination shall come into effect only on acceptance of the same by the AA given in writing not later than thirty (30) days after the notice period and payment of all outstanding dues and submission of mandatory reports on scoping conducted until then by **Name of the Company**.....
- 8.5. **Name of the Company**..... agrees to transfer to the AA all the data/results/ conclusions of the scoping phase in the instance of the termination of this Agreement.
- 8.6. **Name of the Company** agrees to return the genetic resources remaining and/or associated information to the AA no later than thirty (30) days after the termination of this Agreement. The costs incurred in transferring these resources back to the AA will be borne by **Name of the Company**.....
- 8.7. The AA shall not be liable for any loss or damage whatsoever caused to **Name of the Company**..... due to revocation of approval for access and/ or termination of this Agreement on any ground whatsoever.
- 8.8. **Name of the Company**, on termination of the Agreement, agrees not use any of the data/results/conclusions from the research on the accessed material for any purpose whatsoever without the prior approval of the AA.

9. Notice

9.1. Wherever in this Agreement, it is required or permitted that any communication, notice or demand be given or served by either Party to or on the other Party, such communication, notice or demand will be in English and in writing and will be validly given or sufficiently communicated if forwarded by registered post with acknowledgement due, e-mail, telegram, telex or facsimile as follows:

The addresses of the Parties for communication:

The AA	Name of the Company
Program Director National Biodiversity Centre Ministry of Agriculture and Forests P.O. Box 875, Serbithang Thimphu, Bhutan	

- 9.2 Notice will be deemed to have been delivered:
- a. If delivered by hand/courier, upon receipt;
 - b. If sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation weekends and public holidays;
 - c. If sent by certified post, four (4) days after the mailing thereof, provided that if there is a postal strike or other disruption such notice will be delivered by hand or electronic transmission.
- 9.3 The Parties may change their respective addresses for delivery by delivering notice of change no later than thirty (30) days after such change has been undertaken.

10. Confidentiality

- 10.1 Upon request from Name of the Company....., the AA agrees to keep the research being carried out and the progress achieved as confidential. However, confidential information may be disclosed to the extent required by any law or regulation or order of any governmental/administrative/judicial authority having jurisdiction over any of the Parties.
- 10.2 This confidentiality clause does not apply in cases where the AA terminates this Agreement and revokes the Scoping Permit under Section 8.2.

11. Interpretation

Any interpretation of words or phrases of this Agreement shall be in accordance with the purpose, spirit and letter of the Act and as defined in this Agreement.

12. Arbitration

- 12.1 If any difference in interpretation or dispute (hereinafter referred to as a ‘Dispute’) between the Parties arises under this Agreement, any Party may give the other Party a written notice clearly identifying and providing details of the Dispute. On receipt of such notice by the other Party, the Parties shall try to settle the Dispute amicably between them by negotiating in good faith within thirty (30) days of the receipt of such notice.
- 12.2 If the Dispute is not resolved by such negotiations within the period mentioned, the Parties agree to settle the Dispute through arbitration conducted by the sole arbitrator appointed by the AA. The place of arbitration shall be in Thimphu, Bhutan. The language to be used in the arbitration proceedings shall be normally in English.
- 12.3 The Parties agree that the award and determination of the arbitrator shall be final and binding on the Parties.

13. Governing Law and Jurisdiction

This Agreement is governed by and is to be construed in accordance with the laws of Bhutan without regard to the principles of conflict of laws. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the courts in Bhutan.

14. Severability

If any part of this Agreement is declared or held invalid by a court of law for any reason, the invalidity of that part will not affect the validity of the remainder which will continue in full force and effect and be construed as if the Agreement had been executed without the invalid portion.

15. Modification

No amendment or modification to this Agreement shall be valid or binding upon the Parties, unless agreed upon by the Parties, made in writing, and signed on behalf of each Party by their duly and legally authorized signatories and made as annexure to this Agreement.

16. Entirety of Agreement

This Agreement constitutes the culmination of all prior negotiations, understandings, representations and commitments and sets down the complete terms and conditions of Agreement between the parties as to the subject matter.

17. Representations

- 17.1. The Parties represent to each other that they have the legal right and power to enter into this Agreement and to perform its obligations under the terms of this Agreement and its execution, delivery and performance by and has been duly and validly authorized by all necessary corporate action or Government action on its part.
- 17.2. The signatories to this Agreement shall be duly authorized by the Parties and certified copies of such authorization are appended as Annexure (s).

This Agreement has been executed in duplicate, each of which shall be deemed to be original; one shall be retained by the AA and other by **Name of the Company**..... and both shall constitute one and the same instrument.

IN CONFORMITY OF THE ABOVE TERMS AND CONDITIONS, this Agreement has been executed by duly authorized representatives of the Parties on the day and the year first mentioned.

Annex. 7. Sample of an Access and Benefit Sharing Agreement

ABS Agreement

ACCESS AND BENEFIT SHARING AGREEMENT (this “Agreement”) entered into on, among:

1. [insert details of Provider] hereinafter referred to as the “**User**” [hereinafter referred to as the “**User**”]; and
2. [insert details of Provider] [hereinafter referred to as the “**Provider**”]; and
3.[insert details of National Focal Point] [hereinafter referred to as the “**National Focal Point**”];

Hereinafter, the User and the Provider shall collectively be referred to as “Relevant Parties” and individually as “Relevant Party”.

WHEREAS:

- (A) the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) to which Bhutan is a party gives the responsibility to manage biological diversity to ensure fair and equitable sharing of the benefits arising from the use of genetic resources;
- (B) realizing the benefits that the country may accrue from regulating access to its genetic resources and ensuring fair and equitable sharing of benefits, the Biodiversity Act of Bhutan, 2003 was enacted to provide for detailed provisions relating to access to genetic resources and benefit sharing;
- (C) the National Focal Point is the entity vested with the responsibility to regulate the access to genetic resources and benefit sharing in the country;
- (D) the User intends to access genetic resources specified in this Agreement from the Kingdom of Bhutan;
- (E) the Provider through this agreement furnishes the Prior Informed Consent (PIC) granting the access to genetic resources/traditional knowledge associated with genetic resources;
- (F) in consideration of the grant of access to genetic resources, the User is entitled to access and use the biological resource and in accordance with this Agreement and will provide the National Biodiversity Centre and the Provider with the benefits specified herein.

NOW THEREFORE, the parties hereto hereby agree as follows:

1. Definitions

1.1. In this Agreement, unless the context otherwise requires, the following terms shall have the following meanings:

“**Access Area**”: means the area from which the User will have access to biological resources;

“**Access to genetic resources**”: means the collection, transfer, or utilization of genetic resources from Bhutan irrespective of whether they are found in situ or ex situ for the purpose of conducting research or development on genetic or biochemical composition of genetic resources including through the application of biotechnology;

“**Access to traditional knowledge**”: means utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and commercial utilization;

“**Act**”: means the Biodiversity Act of Bhutan, 2003 and includes any subsequent amendment or re-enactment of the Act;

“**Bhutan Access and Benefit Sharing Fund**”: means a fund established to receive monetary benefits derived from the research and commercial utilization of Bhutan’s genetic resources or associated traditional knowledge or both;

“**Biological resources**”: means plant, animal and micro-organism or parts thereof, their genetic material and by products with actual or potential use or value but excluding value added products;

“**Commercial utilization**”: includes applying for, obtaining or transferring intellectual property rights by sale or license or in any other manner, or commencement of product development, conducting market research or the sale of any resulting product;

“**Genetic resources**”: means all material of plant, animal, microbial or other origin containing functional units of heredity and includes the biochemical composition of genetic resources, genetic information regardless of the manner in which the genetic information is stored or knowledge of how the hereditary material works in an organism and derivatives;

“**Product**”: means material produced, obtained, extracted or derived through research and development activity;

“**Prior Informed Consent**”: means a process through which the National Focal Point seeks the consent of the providers of genetic resources or holders of associated traditional knowledge;

“**Provider**”: means a person (individual or organization) named as Provider and includes their authorized representative, where the context permits;

“**Third Party**”: means any person or institution other than the Provider, the User or any collaborator under their control or supervision;

“**User**”: means a person (individual or organization) named as the User and includes their authorized representative, where the context permits;

2. Interpretation

- 2.1. Clause heading are inserted for convenient reference only and have no effect in limiting or extending the language of provisions to which they refer.
- 2.2. Words importing a person include a partnership and a body whether corporate or otherwise.
- 2.3. A reference to any legislation includes any statutory modification substitution or re-enactment of such legislation.
- 2.4. The schedules form an integral part of this Agreement.

3. Prior Informed Consent

- 3.1. This Agreement is made pursuant to the Prior Informed Consent (PIC) given by the Provider granting the access to genetic resources.

4. Access

- 4.1. The User shall have access to the Genetic Resources as specified in Schedule A of this Agreement.
- 4.2. The User shall pay a sum of Nu. 35,000.00 as processing fee to the National Focal Point at the time of execution of this agreement.

5. Access Use Conditions

- 5.1. The User shall have access only to the genetic resource/associated traditional knowledge specified in Schedule A of this Agreement and undertakes to access the same in accordance with the conditions specified in this Agreement.
- 5.2. The User shall attach details of the commercial utilization of the genetic resources/associated traditional knowledge accessed in accordance with Schedule B of this Agreement.
- 5.3. Any use involving the genetic resource/associated traditional knowledge that is not expressly authorized by the provisions of this agreement shall be deemed to be expressly prohibited.
- 5.4. The User undertakes that it shall not allow any persons other than its authorized employees under its direct control and supervision to have access to the genetic resource.
- 5.5. The User shall not obtain, transfer, and distribute any form of intellectual property rights associated with the genetic resource/associated traditional knowledge accessed under this agreement in any manner without obtaining the prior written consent of the National Focal Point.
- 5.6. The User shall not transfer the results of research relating to any genetic resource/associated traditional knowledge that is the subject of this Agreement to a third party without obtaining the approval of the National Focal Point.

5.7. The User undertakes to comply with the existing national laws, regulatory mechanisms and international agreements or treaties for the access to genetic resources.
 Provided that in case of conflict between the national laws and international agreement, the national laws shall prevail.

6. Access Permits and Approval

6.1. The approval given under this agreement is without prejudice to any other permits or approval that may be required for the purpose of access to the genetic resource/associated traditional knowledge from any other authorities under any other laws in force in the territory of Bhutan.

6.2. The failure to acquire such permit or approval under clause 6.1 shall be deemed as a material breach of this agreement and shall result in the termination of this agreement. However, upon an application by the User, the User may be given the opportunity to rectify the default and obtain the required permit or approval within such time as maybe granted by the National Focal Point.

7. Third Party Transfer

7.1. Without the prior written consent of the National Focal Point, neither this agreement nor the approval granted hereunder shall be transferred or assigned in whole or in part by the User to a third party.

7.2. In the event of any substantial changes in the management or shareholding of the User that alters the organizational or control structure of the User and includes changes brought by acquisition, merger, demerger or any other kind of corporate restructuring, the User shall ensure that the obligations under this agreement perpetuate and provide written notice to the National Focal Point not less than thirty (30) days prior to initiating such changes.

8. Liabilities and Indemnification

8.1. A Relevant Party shall be solely responsible for any claims by third parties arising from its acts or omissions in the course of performing this agreement and under no circumstances shall the other Relevant Party be held responsible or liable for any such claims by third parties.

8.2. A Relevant Party shall indemnify the other Relevant Party and its employees from and against all claims, losses, damages, costs (including attorney fees), actions, suits or other proceedings, in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of the Relevant Party, its employees or agents, (whether by reason of negligence or otherwise) in the performance by or on behalf of the Relevant Party of the provisions of this agreement or any activity undertaken or purported to be undertaken pursuant to the terms of this agreement.

9. Benefit Sharing

9.1. The User shall pay to the Provider of annual gross ex-factory sales of the product on such date as may be agreed between the relevant parties.

9.2. % of the total monetary benefits specified in clause 9.1 shall be paid to the Bhutan Access and Benefit Sharing Fund.

10. Obligation of the Provider

10.1. The Provider has the obligation to facilitate access to the genetic resources/associated traditional knowledge which includes the facilitation in acquisition of permits required in accordance with the relevant national laws.

11. Termination

11.1. This agreement, unless terminated as provided herein, shall remain in effect for a period of 5 years from the date of signing this agreement. In case the User continues the commercial utilization of the genetic resource/associated traditional knowledge mentioned in the agreement beyond the period initially agreed upon, the User shall apply for renewal to the National Focal Point for subsequent required period at which time a new agreement has to be effected with relevant provisions agreed mutually.

11.2. The Relevant Parties may terminate this Agreement at any time by mutual agreement in writing by giving sixty (60) days advance written notice of termination. or either Relevant Party may terminate this agreement by a written notice on the happening of any of the following:

- a) if the User does not make a payment due and fails to clear such non-payment within thirty (30) days after the date of notice in writing of such non-payment; or
- b) if the User becomes insolvent or has a petition in bankruptcy, winding up filed for or against it, such termination shall be effective immediately upon the National Focal Point giving written notice to the User.

11.3. The National Focal Point may revoke access or approval granted to the applicant, if any of the following circumstances arise:

- a) on the basis of reasonable belief that the person accessing the said genetic resource has violated any of the provisions of the Act or the condition on which approval was granted;
- b) when the person has failed to comply with the terms of the agreement;
- c) on failure to comply with any of the use conditions; or
- d) on account of overriding public interest with reference to protection of environment and conservation of biological diversity and protection of the rights, livelihoods and knowledge of communities.

In the event of revocation of access or approval as mentioned above, this agreement shall automatically stand terminated.

11.4. Upon termination of this agreement, the User shall cease all use of the genetic resource/ associated traditional knowledge and shall, upon request, return or destroy (at the option of the National Focal Point) all genetic resources under its control or in its possession. The costs in this regard shall be borne by the User.

11.5. The National Focal Point shall not be liable for any loss or damage whatsoever caused to the User due to revocation of approval for access and/ or termination of this agreement as provided in clause 11.3.

11.6. The User upon termination of the Agreement, agrees not use any of the data, results, or conclusions from the research on the accessed material for any purpose whatsoever without

the prior approval of the National Focal Point.

12. Reports and Audit

- 12.1. The User shall submit to the National Focal Point yearly reports on the following:
 - a) the quantity of Genetic resource accessed;
 - b) the total quantity of the products produced by the use of the accessed genetic resources/ associated traditional knowledge;
 - c) audited financial statements; and
 - d) any other related information sought by the National Focal Point by a written notice.
- 12.2. The User shall keep accurate records (together with supporting documentation) appropriate to determine all amounts due to the Provider. Such records shall be retained for at least three years following the end of the reporting period to which they relate.
- 12.3. In conducting audits in pursuant to clause 12, such person shall have access to all records which he reasonably believes to be relevant to the calculation of monetary benefit.

13. Confidentiality

- 13.1. The Provider and the National Focal Point agrees to treat as confidential all confidential information marked as “CONFIDENTIAL” by the User and agrees that information disclosed in pursuance of this agreement relating to the formulations, including efforts to commercialize the formulations, shall be deemed confidential information.
- 13.2. The Provider and the National Focal Point shall, upon due review of the need for confidentiality, maintain the confidentiality of information pertaining to the User at the written request of the User.
- 13.3. Notwithstanding clause 13.1 and 13.2, confidential information may be disclosed to the extent required by any law or regulation or order of any governmental, administrative, or judicial authority having jurisdiction over any of the Parties.

14. Notice

- 14.1. Wherever in this agreement, it is required or permitted that a communication, notice or demand be given or served on any party, such communication, notice or demand will be given in writing and in English and will be validly given or sufficiently communicated if forwarded by Registered post or e-mail:

For the National Focal Point:

.....
 Post Box No.
 Email address:.....
 Email address:.....

For the Provider:

.....
Post Box No.
Email address:.....
Email address:.....

For the User:

.....
Post Box No.
Email address:.....
Email address:.....

14.2. Notice will be deemed to have been delivered:

- a) if delivered by hand, upon receipt;
- b) if sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation of weekends and public holidays; or
- c) if sent by post, seven (7) days after the mailing thereof.

14.3. The Parties may change their respective addresses for delivery by delivering notice of change as provided in this paragraph.

15. Governing Law and Jurisdiction

15.1. This agreement is governed by and is to be construed in accordance with the laws of Bhutan

16. Arbitration

16.1. Subject to clause 15.1 any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination shall try to settle the dispute amicably between them by negotiating in good faith.

16.2. If the dispute is not resolved under clause 16.1, the Parties agree to settle the dispute through arbitration. The arbitration shall be governed by the Alternate Dispute Resolution Act of Bhutan, 2013. The place of arbitration shall be in Thimphu, Bhutan. The language to be used in the arbitration proceedings shall be in English

17. Severability

17.1. If at any time, any provision of this Agreement is or becomes illegal, invalid or unenforceable, either the legality, validity or enforceability of the remaining provisions will in any way be affected or impaired.

18. Modification

18.1. No amendment or modification of this agreement shall be valid or binding upon the parties, unless agreed upon by both parties, made in writing, and signed on behalf of each of the Parties by their authorized representatives.

19. Benefit of Agreement

19.1. This Agreement shall bind and inure to the benefit of the successors and assignees of the

parties. However, none of the Relevant Parties may assign or delegate any of its rights or obligations herein without the prior written consent of other relevant party and the National Focal Point.

20. Representations

20.1. Either Relevant Party represents to each other Relevant Party that it has the legal right and power to enter into this agreement or to perform its obligations under the terms of this agreement and the execution, delivery and performance of this agreement by it has been duly and validly authorized by all necessary action on its part.

21. Miscellaneous

21.1. The User hereby agrees that this agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Relevant Parties hereto or make them in any way liable as partners of or as agents for one another.

21.2. The documents attached hereto as Schedules form an integral part of this agreement, and consists of:

Schedule A: Access to Genetic Resources/associated traditional knowledge

Schedule B: Details of Commercial Utilization of genetic resources/associated traditional knowledge

Schedule C: Details of Benefit Sharing mutually agreed and delivery mechanism

21.3. Payments to be made under this Agreement shall be channeled through banking instruments excepting payment in cash.

IN WITNESS WHEREOF the parties hereto, acting through their duly authorized representatives, have caused this Agreement to be signed in their respective names as of the day and year first above written.

[NAME OF PROVIDER]
.....

Witnessed by.....

Name:
[NAME OF USER]
.....

Witnessed by.....

Name:
Details;
NATIONAL FOCAL POINT
.....

Witnessed by.....

Name:
Details;

Schedule A: Access to Genetic Resources

Sample of biological resources to be collected and associated Traditional Knowledge: [include name of species or lowest level of taxon, to which the resources belong; mention form of biological resource to be collected (leaves, stem, flower, roots etc.)]

Access Area: [state the area from which the sample will be taken]

Time and Frequency of entry to access area: [state the anticipated dates and times of entry to access area]

Purpose of Access: [provide a brief description of the purpose(s) of collecting samples including end products.]

Labelling of Samples: [include a statement setting out the means of labelling the samples]

Schedule B : Details of Commercial Utilization of Genetic Resources

Schedule C : Details of Benefit Sharing Mutually Agreed and Delivery Mechanism

Annex. 8. Sample of a Standard Material Transfer Agreement

Standard Material Transfer Agreement

PREAMBLE

WHEREAS

The International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as “the Treaty” was adopted by the Thirty-first session of the FAO Conference on 3 November 2001 and entered into force on 29 June 2004;

The objectives of the Treaty are the conservation and sustainable use of Plant Genetic Resources for Food and Agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security;

The Contracting Parties to the Treaty, in the exercise of their sovereign rights over their Plant Genetic Resources for Food and Agriculture, have established a Multilateral System both to facilitate access to Plant Genetic Resources for Food and Agriculture and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis;

Articles 4, 11, 12.4 and 12.5 of the Treaty are borne in mind;

The diversity of the legal systems of the Contracting Parties with respect to their national procedural rules governing access to courts and to arbitration, and the obligations arising from international and regional conventions applicable to these procedural rules, are recognized;

Article 12.4 of the Treaty provides that facilitated access under the Multilateral System shall be provided pursuant to a Standard Material Transfer Agreement, and the Governing Body of the Treaty, in its Resolution 1/2006 of 16 June 2006, adopted the Standard Material Transfer Agreement.

I Note by the Secretariat: as suggested by the Legal Working Group during the Contact Group for the Drafting of the Standard Material Transfer Agreement, defined terms have, for clarity, been put in bold throughout.

** In the event that the SMTA is used for the transfer of Plant Genetic Resources for Food and Agriculture other than those listed in Annex I of the Treaty:*

The references in the SMTA to the “Multilateral System” shall not be interpreted as limiting the application of the SMTA to

Annex I Plant Genetic Resources for Food and Agriculture, and in the case of Article 6.2 of the SMTA shall mean “under this Agreement”;

The reference in Article 6.11 and Annex 3 of the SMTA to “Plant Genetic Resources for Food and Agriculture belonging to the same crop, as set out in Annex I to the Treaty” shall be taken to mean “Plant Genetic Resources for Food and Agriculture belonging to the same crop”.

ARTICLE 1 — PARTIES TO THE AGREEMENT

1.1. The present Material Transfer Agreement (hereinafter referred to as “this Agreement”) is the Standard Material Transfer Agreement referred to in Article 12.4 of the Treaty.

1.2. This Agreement is:

BETWEEN: (name and address of the provider or providing institution, name of authorized official, contact information for authorized official) (hereinafter referred to as “the Provider”),
AND: (name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official*) (hereinafter referred to as “the Recipient”).

1.3. The parties to this Agreement hereby agree as follows:

ARTICLE 2 — DEFINITIONS

In this Agreement the expressions set out below shall have the following meaning:

“Available without restriction”: a Product is considered to be available without restriction to others for further research and breeding when it is available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the Treaty.

“Genetic material” means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.

“Governing Body” means the Governing Body of the Treaty.

“Multilateral System” means the Multilateral System established under Article 10.2 of the Treaty.

“Plant Genetic Resources for Food and Agriculture” means any genetic material of plant origin of actual or potential value for food and agriculture.

“Plant Genetic Resources for Food and Agriculture under Development” means material derived from the Material, and hence distinct from it, that is not yet ready for commercialization and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the Plant Genetic Resources for Food and Agriculture under Development shall be deemed to have ceased when those resources are commercialized as a Product.

“Product” means Plant Genetic Resources for Food and Agriculture that incorporate the Material or any of its genetic parts or components that are ready for commercialization, excluding commodities and other products used for food, feed and processing.

“Sales” means the gross income resulting from the commercialization of a Product or Products, by the Recipient, its affiliates, contractors, licensees and lessees.

“To commercialize” means to sell a Product or Products for monetary consideration on the open market, and “commercialization” has a corresponding meaning. Commercialization shall not include any form of transfer of Plant Genetic Resources for Food and Agriculture under Development.

ARTICLE 3 — SUBJECT MATTER OF THE MATERIAL TRANSFER AGREEMENT

The Plant Genetic Resources for Food and Agriculture specified in Annex 1 to this Agreement (hereinafter referred to as the “Material”) and the available related information referred to in Article 5b and in Annex 1 are hereby transferred from the Provider to the Recipient subject to the terms and conditions set out in this Agreement.

ARTICLE 4 — GENERAL PROVISIONS

- 4.1. This Agreement is entered into within the framework of the Multilateral System and shall be implemented and interpreted in accordance with the objectives and provisions of the Treaty.
- 4.2. The parties recognize that they are subject to the applicable legal measures and procedures, that have been adopted by the Contracting Parties to the Treaty, in conformity with the Treaty, in particular those taken in conformity with Articles 4, 12.2 and 12.5 of the Treaty.
- 4.3. The parties to this Agreement agree that (the entity designated by the Governing Body), acting on behalf of the Governing Body of the Treaty and its Multilateral System, is the third party beneficiary under this Agreement.
- 4.4. The third party beneficiary has the right to request the appropriate information as required in Articles 5e, 6.5c, 8.3 and Annex, 2 paragraph 3, to this Agreement.
- 4.5. The rights granted to the (the entity designated by the Governing Body) above do not prevent the Provider and the Recipient from exercising their rights under this Agreement.

ARTICLE 5 — RIGHTS AND OBLIGATIONS OF THE PROVIDER

The Provider undertakes that the Material is transferred in accordance with the following provisions of the Treaty:

- a) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;
- b) All available passport data and, subject to applicable law, any other associated available non-confidential descriptive information, shall be made available with the Plant Genetic Resources for Food and Agriculture provided;
- c) Access to Plant Genetic Resources for Food and Agriculture under Development, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development;
- d) Access to Plant Genetic Resources for Food and Agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;
- e) The Provider shall periodically inform the Governing Body about the Material Transfer Agreements entered into, according to a schedule to be established by the Governing Body. This information shall be made available by the Governing Body to the third party beneficiary.

ARTICLE 6 — RIGHTS AND OBLIGATIONS OF THE RECIPIENT

- 6.1. The Recipient undertakes that the Material shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. Such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses.
- 6.2. The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System.
- 6.3. In the case that the Recipient conserves the Material supplied, the Recipient shall make the

Material, and the related information referred to in Article 5b, available to the Multilateral System using the Standard Material Transfer Agreement.

- 6.4. In the case that the Recipient transfers the Material supplied under this Agreement to another person or entity (hereinafter referred to as “the subsequent recipient”), the Recipient shall
- a) do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement; and
 - b) notify the Governing Body, in accordance with Article 5e.

On compliance with the above, the Recipient shall have no further obligations regarding the actions of the subsequent recipient.

6.5. In the case that the Recipient transfers a Plant Genetic Resource for Food and Agriculture under Development to another person or entity, the Recipient shall:

5 Note by the Secretariat: The Standard Material Transfer Agreement makes provision for information to be provided to the Governing Body, in the following Articles: 5e, 6.4b, 6.5c and 6.11h, as well as in Annex 2, paragraph 3, Annex 3, paragraph 4, and in Annex 4. Such information should be submitted to:

The Secretary
International Treaty on Plant Genetic Resources for Food and Agriculture
Food and Agriculture Organization of the United Nations
I-00100 Rome, Italy

- a. do so under the terms and conditions of the Standard Material Transfer Agreement, through a new material transfer agreement, provided that Article 5a of the Standard Material Transfer Agreement shall not apply;
- b. identify, in Annex 1 to the new material transfer agreement, the Material received from the Multilateral System, and specify that the Plant Genetic Resources for Food and Agriculture under Development being transferred are derived from the Material;
- c. notify the Governing Body, in accordance with Article 5e; and
- d. have no further obligations regarding the actions of any subsequent recipient.

6.6. Entering into a material transfer agreement under paragraph 6.5 shall be without prejudice to the right of the parties to attach additional conditions, relating to further product development, including, as appropriate, the payment of monetary consideration.

6.7. In the case that the Recipient commercializes a Product that is a Plant Genetic Resource for Food and Agriculture and that incorporates Material as referred to in Article 3 of this Agreement, and where such Product is not available without restriction to others for further research and breeding, the Recipient shall pay a fixed percentage of the Sales of the commercialized Product into the mechanism established by the Governing Body for this purpose, in accordance with Annex 2 to this Agreement.

6.8. In the case that the Recipient commercializes a Product that is a Plant Genetic Resource for Food and Agriculture and that incorporates Material as referred to in Article 3 of this Agreement and where that Product is available without restriction to others for further research and breeding, the Recipient is encouraged to make voluntary payments into the mechanism established by the Governing Body for this purpose in accordance with Annex 2 to this Agreement.

6.9. The Recipient shall make available to the Multilateral System, through the information system provided for in Article 17 of the Treaty, all non-confidential information that results from

research and development carried out on the Material, and is encouraged to share through the Multilateral System non-monetary benefits expressly identified in Article 13.2 of the Treaty that result from such research and development. After the expiry or abandonment of the protection period of an intellectual property right on a Product that incorporates the Material, the Recipient is encouraged to place a sample of this Product into a collection that is part of the Multilateral System, for research and breeding.

6.10. A Recipient who obtains intellectual property rights on any Products developed from the Material or its components, obtained from the Multilateral System, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of this Agreement to that third party.

6.11. The Recipient may opt as per Annex 4, as an alternative to payments under Article 6.7, for the following system of payments:

- a. The Recipient shall make payments at a discounted rate during the period of validity of the option;
- b. The period of validity of the option shall be ten years renewable in accordance with Annex 3 to this Agreement;
- c. The payments shall be based on the Sales of any Products and of the sales of any other products that are Plant Genetic Resources for Food and Agriculture belonging to the same crop, as set out in Annex 1 to the Treaty, to which the Material referred to in Annex 1 to this Agreement belongs;
- d. The payments to be made are independent of whether or not the Product is available without restriction;
- e. The rates of payment and other terms and conditions applicable to this option, including the discounted rates are set out in Annex 3 to this Agreement;
- f. The Recipient shall be relieved of any obligation to make payments under Article 6.7 of this Agreement or any previous or subsequent Standard Material Transfer Agreements entered into in respect of the same crop;
- g. After the end of the period of validity of this option the Recipient shall make payments on any Products that incorporate Material received during the period in which this Article was in force, and where such Products are not available without restriction. These payments will be calculated at the same rate as in paragraph (a) above;
- h. The Recipient shall notify the Governing Body that he has opted for this modality of payment. If no notification is provided the alternative modality of payment specified in Article 6.7 will apply.

ARTICLE 7 — APPLICABLE LAW

The applicable law shall be General Principles of Law, including the UNIDROIT Principles of International Commercial Contracts 2004, the objectives and the relevant provisions of the Treaty, and, when necessary for interpretation, the decisions of the Governing Body.

ARTICLE 8 — DISPUTE SETTLEMENT

8.1. Dispute settlement may be initiated by the Provider or the Recipient or the (the entity designated by the Governing Body), acting on behalf of the Governing Body of the Treaty and its Multilateral System.

- 8.2. The parties to this Agreement agree that the (the entity designated by the Governing Body), representing the Governing Body and the Multilateral System, has the right, as a third party beneficiary, to initiate dispute settlement procedures regarding rights and obligations of the Provider and the Recipient under this Agreement.
- 8.3. The third party beneficiary has the right to request that the appropriate information, including samples as necessary, be made available by the Provider and the Recipient, regarding their obligations in the context of this Agreement. Any information or samples so requested shall be provided by the Provider and the Recipient, as the case may be.
- 8.4. Any dispute arising from this Agreement shall be resolved in the following manner:
- a. Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation.
 - b. Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed.
 - c. Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. Either party to the dispute may, if it so chooses, appoint its arbitrator from such list of experts as the Governing Body may establish for this purpose; both parties, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

ARTICLE 9 — ADDITIONAL ITEMS

Warranty

- 9.1. The Provider makes no warranties as to the safety of or title to the Material, nor as to the accuracy or correctness of any passport or other data provided with the Material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Material being furnished. The phytosanitary condition of the Material is warranted only as described in any attached phytosanitary certificate. The Recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material.

Duration of Agreement

- 9.2. This Agreement shall remain in force so long as the Treaty remains in force.

ARTICLE 10 — SIGNATURE/ACCEPTANCE

The Provider and the Recipient may choose the method of acceptance unless either party requires this Agreement to be signed.

Option 1 –Signature*

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute this Agreement on behalf of the Provider and acknowledge my institution's responsibility and obligation to abide by the provisions of this Agreement, both by letter and in principle, in order to promote the conservation and sustainable use of Plant Genetic Resources for Food and Agriculture.

Signature..... Date.....
Name of the Provider

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute this Agreement on behalf of the Recipient and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement, both by letter and in principle, in order to promote the conservation and sustainable use of Plant Genetic Resources for Food and Agriculture.

Signature..... Date.....
Name of the Recipient.....

Option 2 – Shrink-wrap Standard Material Transfer Agreements*

The Material is provided conditional on acceptance of the terms of this Agreement. The provision of the Material by the Provider and the Recipient’s acceptance and use of the Material constitutes acceptance of the terms of this Agreement.

Option 3 – Click-wrap Standard Material Transfer Agreement*

I hereby agree to the above conditions.

Where the Provider chooses signature, only the wording in Option 1 will appear in the Standard Material Transfer Agreement. Similarly, where the Provider chooses either shrink-wrap or click-wrap, only the wording in Option 2 or Option 3, as appropriate, will appear in the Standard Material Transfer Agreement. Where the “click-wrap” form is chosen, the Material should also be accompanied by a written copy of the Standard Material Transfer Agreement.

Annex 1:

LIST OF MATERIALS PROVIDED

This Annex contains a list of the Material provided under this Agreement, including the associated information referred to in Article 5b.

This information is either provided below or can be obtained at the following website: (URL). The following information is included for each Material listed: all available passport data and, subject to applicable law, any other associated, available, non-confidential descriptive information.

Annex. 9. List of Annex I crops under the Multilateral System of ITPGRFA

Food Crops	
Crop	Genus
Breadfruit	<i>Artocarpus</i>
Asparagus	<i>Asparagus</i>
Oat	<i>Avena</i>
Brassica complex	<i>Brassica et al.</i>
Pigeon Pea	<i>Cajanus</i>
Chickpea	<i>Cicer</i>
Citrus	<i>Citrus</i>
Beet Beta	<i>Beta</i>
Coconut	<i>Cocos</i>
Major aroids	<i>Colocasia, Xanthosoma</i>
Carrot	<i>Daucus</i>
Yams	<i>Dioscorea</i>
Finger Millet	<i>Eleusine</i>
Strawberry	<i>Fragaria</i>
Sunflower	<i>Helianthus</i>
Barley	<i>Hordeum</i>
Sweet Potato	<i>Ipomoea</i>
Grass pea	<i>Lathyrus</i>
Lentil	<i>Lens</i>
Apple	<i>Malus</i>
Cassava	<i>Manihot (Manihot esculenta only)</i>
Banana / Plantain	<i>Musa (Except Musa textilis)</i>
Rice	<i>Oryza</i>
Pearl Millet	<i>Pennisetum</i>
Beans	<i>Phaseolus (Except Phaseolus polyanthus)</i>
Pea	<i>Pisum</i>
Rye	<i>Secale</i>
Potato	<i>Solanum (Section tuberosa included, except Solanum phureja)</i>
Eggplant	<i>Solanum (Section melongena included)</i>
Sorghum	<i>Sorghum</i>
Triticale	<i>Triticosecale</i>
Wheat	<i>Triticum et al. (Including Agropyron, Elymus, and Secale)</i>
Faba Bean / Vetch	<i>Vicia</i>
Cowpea	<i>Vigna</i>
Maize	<i>Zea (Excluding Zea perennis, Zea diploperennis, and Zea luxurians)</i>

Legumes Forages	
Genus	Species
<i>Astragalus</i>	<i>chinensis, cicer, arenarius</i>
<i>Canavalia</i>	<i>varia</i>
<i>Coronilla</i>	<i>ensifolmis</i>
<i>Hedysarum</i>	<i>coronarium</i>
<i>Lathyrus</i>	<i>cicera, ciliolatus, hirsutus, ochrus, odoratus, sativus</i>
<i>Lespedeza</i>	<i>cuneata, striata, stipulacea</i>
<i>Lotus</i>	<i>corniculatus, subbiflorus, uliginosus</i>
<i>Lupinus</i>	<i>albus, angustifolius, luteus</i>
<i>Medicago</i>	<i>arborea, falcata, sativa, scutellata, rigidula, truncatula albus, officinalis</i>
<i>Melilotus</i>	<i>albus, officinalis</i>
<i>Onobrychis</i>	<i>viciifolia</i>
<i>Ornithopus</i>	<i>sativus</i>
<i>Prosopis</i>	<i>affinis, alba, chilensis, nigra, pallida</i>
<i>Pueraria</i>	<i>phaseoloides</i>
<i>Trifolium</i>	<i>alexandrinum, alpestre, ambiguum, angustifolium, arvense, agrocicerum, hybridum, incarnatum, pratense, repens, resupinatum, rueppellianum, semipilosum, subterraneum, vesiculosum</i>
Grass Foragess	
Genus	Species
<i>Andropogon</i>	<i>gayanus</i>
<i>Agrostis</i>	<i>stolonifera, tenuis</i>
<i>Alopecurus</i>	<i>pratensis</i>
<i>Arrhenatherum</i>	<i>elatius glomerata</i>
<i>Dactylis</i>	<i>arundinacea, gigantea, heterophylla, ovina, pratensis, rubra</i>
<i>Festuca</i>	<i>hybridum, multiflorum, perenne, rigidum, temulentum</i>
<i>Lolium Phalaris</i>	<i>aquatica, arundinacea</i>
<i>Phleum</i>	<i>pratense</i>
<i>Atriplex</i>	<i>halimus, nummularia</i>

Annex. 10. Functions of the Competent National Authority for ABS in Bhutan

The functions of the Competent National Authority shall be to:

- Ensure enforcement of the ABS Policy of Bhutan 2015, Biodiversity Act of Bhutan 2003 and any other subsidiary Acts and Rules.
- Approve or reject access proposal based on recommendation of the National Focal Point.
- Endorse Scoping Agreement and Access and Benefit Sharing Agreement;
- Issue directives to the National Focal Point.
- Create favourable conditions and incentives that foster the conservation and sustainable use of genetic resources and associated traditional knowledge.

Annex. 11. Functions of the National Focal Point for ABS in Bhutan

The functions of the National Focal Point shall be to:

- Administer the implementation of the provisions ABS Policy of Bhutan 2015, Biodiversity Act of Bhutan 2003 and any other subsidiary Acts and Rules.
- Receive and process access proposal for genetic resources or associated traditional knowledge or both.
- Conduct negotiations and execute Scoping Agreement, Access and Benefit Sharing Agreement, Material Transfer Agreement and Standard Material Transfer Agreement upon the approval of the Competent National Authority.
- Negotiate and provide oversight to ensure fair and equitable sharing of benefits arising from research or commercial utilization of genetic resources or associated traditional knowledge or both.
- Make recommendations to the Competent National Authority regarding approval or rejection of access proposal.
- Establish measures with the aim of monitoring and tracking of genetic resources and associated traditional knowledge.
- Create awareness and promote education on access to and utilization of genetic resources to the stakeholders and public.

Annex. 12. The core functions of the Designated ABS checkpoints

The core functions of the designated checkpoints are to collect or receive, as appropriate, relevant information related to:

- Prior informed consent, and the establishment of mutually agreed terms.
- The source of the genetic resource and associated traditional knowledge.
- The utilization of genetic resources, as appropriate.

Annex. 13. National Targets under the National Biodiversity Strategies and Action Plans, 2014

Following are the National targets under the National Biodiversity Strategies and Action Plans, 2014. These targets are based on the issues, threats, gaps and opportunities identified through a series of stakeholder consultation workshops carried out throughout the country. It is also based on the result of the review of the past Biodiversity Action Plans and guided by the national priorities and Aichi Biodiversity targets.

National Target 1: By 2018, at least 60 per cent of the population is aware of values of biodiversity and steps they can take to conserve and use it sustainably.

National Target 2: By 2018, national capacity is established for valuation of biodiversity and ecosystem services to integrate into national development planning and policy-making process and national accounting system, as appropriate.

National Target 3: By 2020, incentives harmful to biodiversity are reformed and positive incentives are enhanced.

National Target 4: By 2020, relevant stakeholders adopt the principles of sustainable production and consumption of natural resources and have kept the impacts of use of natural resources well within safe ecological limits.

National Target 5: By 2018, high-biodiversity value habitats are mapped, the rate of loss is accounted, trends monitored and overall loss and fragmentation reduced.

National Target 6: By 2020, the baseline for fish and key aquatic biodiversity is established for implementation of sustainable management plans, as appropriate.

National Target 7: Areas under agriculture and forestry, including rangeland are managed through the adoption of sustainable management practices, ensuring conservation of biological diversity.

National Target 8: By 2020, pollution from different sources, including from use of fertilizers and agro-chemicals affecting biodiversity and ecosystem functions are maintained within the national environmental standards.

National Target 9: By 2020, invasive alien species and pathways are identified and prioritized, priority species are controlled or eradicated, and measures are in place to manage pathways to prevent their introduction and establishment.

National Target 10: By 2020, the potential impacts of climate change on vulnerable ecosystems are identified and adaptation measures strengthened.

National Target 11: The current Protected Area System is maintained with enhanced management effectiveness and financial sustainability.

National Target 12: By 2020, the information on conservation status of prioritized taxonomic groups is available and actions are taken to improve the status of prioritized species.

National Target 13: By 2020, the genetic diversity of key cultivated plants and domesticated animals, including that of crop wild relatives are documented and conserved.

National Target 14: By 2020, key ecosystems and ecosystem services are identified, assessed and safeguarded for human well-being.

National Target 15: By 2020, priority degraded ecosystems and habitats are identified and rehabilitated through a landscape approach.

National Target 16: By 2015, the Nagoya protocol is implemented through national ABS legislative, administrative and institutional frameworks, which are consistent with the Nagoya Protocol.

National Target 17: By 2015, the revised National Biodiversity Strategies and Action Plan (NBSAP) is adopted as a national guiding document for effective biodiversity management.

National Target 18: By 2020, TK and Customary Practices of communities, relevant to biodiversity conservation and sustainable use are documented and used, and where appropriate revived and protected.

National Target 19: By 2020, science-based knowledge and technologies related to biodiversity are generated, improved, made accessible and applied, where appropriate.

National Target 20: By 2016, the funding requirement for the implementation of the NBSAP is identified and funds mobilized.

Annex. 14. Sample of a Sample Transfer Certificate

Letter Head

NBC/.....

Date:.....

Sample Transfer Certificate

This Certificate is issued pursuant to section 65 of the Biodiversity Act of Bhutan 2018 to _____ (Name) and is hereby permitted to transfer _____ (genetic resources) accessed from _____ (Dzongkhag), Bhutan to _____ (Place of Destination).

The details of the material are as follows:

Material Description:

Quantity of Material to be transferred:

This Certificate is valid for one time transfer of the genetic resources only and is not substitute for other permits or clearances required under other laws in force in the country.

(Signature and Seal)

Annex. 15. Sample of a “Certificate of Compliance” to the ABS legislation in Bhutan

Letter Head

NBC/.....

Date:.....

Certificate of Compliance to the ABS legislation in Bhutan

This is to certify that _____ has legitimately accessed the following genetic resources and/ or associated traditional knowledge in accordance to the Access and Benefit Sharing regime of Bhutan fulfilling the requirement of prior informed consent and mutually agreed terms.

Name of the genetic resources and/ or associated traditional knowledge:

Name of the provider of the genetic resources and/ or associated traditional knowledge:

Purpose of access:

Terms and condition:

This certificate is issued as an evidence of certificate of compliance to the ABS legislations and is not substitute for other permits or clearances required under other laws in force in the country.

(Signature and Seal)

Photo Contributions:

- 1. Dr. Tashi Yangzome Dorji, *NBC*
- 2. Ms. Sangay Dema, *NBC*
- 2. Mr. Chencho Dorji, *NBC*
- 3. Mr. Mani Prasad Nirola, *NBC*
- 4. Mr. Choki Gyeltshen, *NBC*
- 5. Mr. Lhab Tshering, *NBC*



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Resilient nations.*

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