

Biodiversity Bill of Bhutan, 2016

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Biodiversity Bill of the Kingdom of Bhutan, 2016

PREAMBLE

Whereas, in keeping with the constitutional rights vested in the state over natural resources, minerals, rivers, lakes, and forests and the duty of the government to secure ecologically balanced sustainable development, while promoting justifiable economic and social development;

Whereas, recognizing the rich genetic resources which have been protected by the wise and far-sighted leadership of our Kings, Bhutanese traditional beliefs, socio-cultural outlook, and the overarching development philosophy of Gross National Happiness;

Whereas, to secure economic value of Bhutan's genetic resources for national development and biodiversity conservation through sustainable use of genetic resources, in research and development of products, compounds, and substances that have medicinal, industrial, agricultural, and related applications;

Whereas, recognizing the importance of regulating access to and utilization of genetic resources and associated Traditional Knowledge;

Whereas, noting that Bhutan is a party to the Convention on Biological Diversity, and the International Treaty on Plant Genetic Resources for Food and Agriculture, and acknowledging Bhutan's rights and obligations therein;

Parliament of the Kingdom of Bhutan hereby enacts as follows:

CHAPTER 1 PRELIMINARY

Short Title

1. This Act is called the Biodiversity Act of the Kingdom of Bhutan, 2016.

Repeal

2. This Act hereby repeals Biodiversity Act of Bhutan 2003, and subsidiary legislations framed and adopted thereunder, and section 73 of the National Environment Protection Act 2007.

Application

3. This Act applies to:
 - (1) access to, or utilization of genetic resources or its derivatives from Bhutan irrespective of whether they are accessed *in situ* or *ex situ*;
 - (2) biological resources traded, shared, exchanged and used as commodities which are later utilized as genetic resources for research or commercial purposes or both; and
 - (3) access to, and utilization of traditional knowledge associated with genetic resources of Bhutan.
4. This Act does not apply to:
 - (1) biological resources when traded, shared, exchanged and used as commodities for direct use and consumption;
 - (2) the use, sharing and exchange of traditional knowledge within and between local communities as customary practices; or
 - (3) access to human genetic resources.

Objective

5. The objective of this Act is to:
 - (1) ensure national sovereignty and secure trusteeship of the Bhutanese people over its genetic resources;
 - (2) recognize and protect knowledge, innovation, and practice associated with genetic resources;

- (3) secure the value of Bhutan's genetic resources and associated traditional knowledge and promote its conservation and sustainable use;
- (4) regulate access to genetic resources, and associated traditional knowledge for research and commercial purpose; and
- (5) ensure fair and equitable sharing of benefits derived from the use of genetic resources and associated traditional knowledge for research and development.

CHAPTER 2

INSTITUTIONAL ARRANGEMENT

Competent National Authority

6. The Secretary, Ministry of Agriculture and Forests, is the Competent National Authority for the purpose of this Act.

Functions of Competent National Authority

7. The functions of the Competent National Authority shall be to :
 - (1) ensure proper enforcement of this Act;
 - (2) create favorable conditions and incentives that foster the conservation and sustainable use of genetic resources and associated traditional knowledge;
 - (3) approve or reject access proposal based on recommendation of the National Focal Point;
 - (4) endorse Scoping Agreement and Access and Benefit Sharing Agreement;
 - (5) establish advisory committee;
 - (6) issue directives to the National Focal Point; and
 - (7) perform such other functions, as may be necessary, to carry out the provisions of this Act.

National Focal Point

8. The National Biodiversity Centre, Ministry of Agriculture and Forests, is the National Focal Point for the purpose of this Act.
9. The National Focal Point shall be the clearing house for information related to access and benefit sharing.

Functions of the National Focal Point

10. The functions of the National Focal Point shall be to :
 - (1) coordinate the implementation and enforcement of the provisions of this Act;
 - (2) receive and process access proposal for genetic resources from Bhutan or associated traditional knowledge or both;

- (3) 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;
- (4) negotiate and provide oversight to ensure fair and equitable sharing of benefits arising from research or commercial utilization of genetic resources from Bhutan or associated traditional knowledge or both;
- (5) make recommendations to the Competent National Authority regarding approval or rejection of access proposal;
- (6) establish measures with the aim of monitoring and tracking of genetic resources from Bhutan and associated traditional knowledge;
- (7) represent Bhutan under any treaty, agreement, convention, or protocol relating to access and benefit sharing;
- (8) create awareness and education on this Act to the stakeholders and public;
- (9) inform the Competent National Authority within a reasonable period of any offence committed under this Act;
- (10) prepare annual report on access proposals and decisions relating to access proposals; and
- (11) do such other things as it considers fit to enable it to perform its functions effectively or which are incidental to the performance of its functions.

Committee

11. The Competent National Authority may, on the recommendation of the National Focal Point, constitute a committee to provide advice on scientific, technical, and other relevant matters.
12. The head of the National Focal Point shall be the ex-officio Chairperson of such Committee.

CHAPTER 3 CONSERVATION AND SUSTAINABLE USE

Conservation and Sustainable use

13. The Competent National Authority shall promote:
 - (1) continuity of biodiversity conservation and sustainable use;
 - (2) conservation and sustainable use of agro-biodiversity for food and agriculture including crop wild relatives; and
 - (3) traditional informal seed systems under which farmers save, use, exchange and sell farm-saved seeds or propagating material including rights to save, use and exchange protected varieties.
14. The National Focal Point shall, in order to promote conservation and sustainability of genetic resources, regulate access to genetic resources.
15. The National Focal Point shall promote proper documentation of genetic resources which are wild, domesticated, and cultivated including in *ex situ* collections and conditions.

Providers of Genetic Resources

16. For the purpose of this Act, the providers of genetic resources shall be:
 - (1) Department of Forests and Park Services, if the genetic resources is from government reserved forests or protected area system;
 - (2) Communities managing the forests, if the genetic resources is from community forests;
 - (3) National Focal Point in consultation with the relevant community custodians or individuals, for *in situ* genetic resources for food and agriculture and genetic resources from private forestry;
 - (4) National Focal Point, if the genetic resources are from *ex situ* collections.
17. If no determination is made under section 16, the National Focal Point shall be deemed to be the provider of genetic resources.

Restricted Genetic Resources

18. All genetic resources declared to be protected under the laws in force in Bhutan shall not be accessed under this Act.

Provided that it may, subject to approval of the Competent National Authority, be accessed for scientific research to promote conservation.

19. The Competent National Authority may, on the recommendation of the National Focal Point, limit or restrict access to genetic resources.

CHAPTER 4 ACCESS TO GENETIC RESOURCES

Access to Genetic Resources

20. Access to genetic resources may be obtained through:
- (1) Scoping Agreement followed by an Access and Benefit Sharing Agreement;
 - (2) Access and Benefit Sharing Agreement;
 - (3) Material Transfer Agreement; or
 - (4) Standard Material Transfer Agreement.

Access Proposal

21. A User shall submit to the National Focal Point an application for access to genetic resources in the format prescribed in the Regulations.
22. The National Focal Point shall assess the access proposal against the criteria set out in the Regulation.
23. The National Focal Point shall determine the conditions of access based on the application and intended use of the genetic resources.
24. An access proposal shall form the basis for negotiation of either a Scoping Agreement or an Access and Benefit Sharing Agreement.
25. The Competent National Authority shall have the final authority to approve or refuse access to genetic resources based on the recommendation of National Focal Point.

Prior Informed Consent

26. Access to genetic resources for commercial purpose including commercial research is subject to Prior Informed Consent of the Competent National Authority.

Provided that the Competent National Authority may seek Prior Informed Consent of the providers of genetic resources where it considers appropriate.

27. The Competent National Authority may grant or refuse Prior Informed Consent based on the recommendations of the National Focal Point.
28. Prior informed consent to access genetic resources shall not imply permission to use associated traditional knowledge and vice versa.

Relationship to Other Permits

29. A Scoping Agreement, Access and Benefit Sharing Agreement, Material Transfer Agreement, or Standard Material Transfer Agreement is not a substitute for other permits required for collection of genetic resources under other laws in force in the country.
30. If a User requires a permit from other agencies, the National Focal Point may assist the User to obtain such permit before execution of a contract.
31. The National Focal Point shall, at any stage of access, determine whether there is a need to carry out an Impact Assessment of access to genetic resources.
32. The cost incurred in conducting the impact assessment under section 31 is to be borne by the User concerned.

Scoping Agreement and Access and Benefit Sharing Agreement

33. A User obtaining access to genetic resources for commercial purpose including commercial research shall enter into Access and Benefit Sharing Agreement or Scoping Agreement followed by Access and Benefit Sharing Agreement.
34. The National Focal Point on behalf of the providers of genetic resources shall, subject to approval of the access proposal by the Competent National Authority, negotiate a Scoping Agreement or Access and Benefit Sharing Agreement with the User.
35. The National Focal Point shall, upon completion of the negotiation, submit the outcome to the Competent National Authority for approval.

36. The Competent National Authority may recommend changes to a Scoping Agreement or Access and Benefit Sharing Agreement before its approval.
37. If the User does not agree to the changes recommended by the Competent National Authority under section 36, the National Focal Point may enter into further negotiation with the User.
38. On behalf of the providers of genetic resources, the National Focal Point shall, subject to the approval of the negotiated terms by the Competent National Authority, execute a Scoping Agreement or Access and Benefit Sharing Agreement with the User.

Scoping Agreement

39. A User may obtain a Scoping Agreement for initial exploratory phase of research, and development with the aim of establishing market or research potential.
40. A Scoping Agreement shall either be a standard contract, or a negotiated contract.
41. The existence of a Scoping Agreement does not bind the National Focal Point to enter into an Access and Benefit Sharing Agreement.
42. A Scoping Agreement shall be conditional on the payment of a processing fee and a commitment fee which is non-refundable.
43. A User is not permitted to transfer research results or accessed genetic resources to a third party without the prior written approval of the National Focal Point.
44. If a User transfers research results or accessed genetic resources to a third party for product development and commercial utilization, the third party shall put forward an access proposal for negotiating an Access and Benefit Sharing Agreement.
45. A User not intending to enter into Access and Benefit Sharing Agreement shall surrender accessed genetic resources, research results, and related information to the National Focal Point.

46. The National Focal Point shall have ownership over the research results, accessed genetic resources, and relevant information surrendered under section 45.

Access and Benefit Sharing Agreement

47. Access and Benefit Sharing Agreement is based on mutually agreed terms and include fair and equitable sharing of benefits as per the conditions set in Chapter 6.
48. Notwithstanding anything contained in section 39, a User may directly enter into an Access and Benefit Sharing Agreement without entering into Scoping Agreement, where the National Focal Point and the User considers it appropriate.

Certificate of Compliance

49. The Competent National Authority shall issue certificate of compliance to the User upon execution of a Scoping Agreement or Access and Benefit Sharing Agreement.
50. A certificate of compliance serves as evidence that the genetic resources or associated traditional knowledge have been accessed in accordance with the provisions of this Act.

Material Transfer Agreement

51. A Material Transfer Agreement is a contract to ensure facilitated access to genetic resources.
52. A User may, subject to the approval of the Competent National Authority, obtain Material Transfer Agreement for any of the following purposes:
 - (1) specific academic research by a student without commercial intent and with the objective of obtaining an academic degree;
 - (2) exchange of samples between national institutions, and between national and international institutions for research without commercial intent;
 - (3) sample testing for specific purposes as may be determined by the National Focal Point and approved by the Competent National Authority; or

- (4) such other cases as may be determined by the Competent National Authority.
53. The National Focal Point shall determine whether a User qualifies for a Material Transfer Agreement.
54. The National Focal Point shall, subject to approval of the Competent National Authority, execute a Material Transfer Agreement.

Access to Plant Genetic Resources for Food and Agriculture

55. Access to duly registered *ex situ* collections of Plant Genetic Resources for Food and Agriculture under Annex-1 of the International Treaty on Plant Genetic Resources for Food and Agriculture shall be in accordance with the terms and conditions of the Multilateral System of Access and Benefit Sharing of the Treaty.

Provided that the Competent National Authority has declared the Plant Genetic Resources for Food and Agriculture to be in the public domain and under the management and control of the Government.

56. The Competent National Authority shall categorize Plant Genetic Resources for Food and Agriculture that are in the public domain and under the management and control of the Government.
57. If there is suspicion that a sample will be used for non-food or non-feed purposes, the National Focal Point may determine access to such plant genetic resources to be subject to Access and Benefit Sharing requirements.
58. Plant Genetic Resources for Food and Agriculture that are held by a public collection in Bhutan or outside and are not explicitly declared to be in the public domain are not covered by the Multilateral System of Access and Benefit-sharing and is to be dealt in accordance with Access and Benefit Sharing requirements.

Sample Transfer Certificate

59. A sample transfer certificate shall be issued by the National Focal Point to facilitate transfer of samples of genetic material under a Scoping

Agreement, Access and Benefit Sharing Agreement or Material Transfer Agreement or Standard Material Transfer Agreement.

CHAPTER 5 ACCESS TO TRADITIONAL KNOWLEDGE

Documentation and Protection

60. The National Focal Point shall, to conserve and protect the rights of Traditional Knowledge holders and to promote utilisation and benefit sharing with the right holders, be the central coordinating agency for inventory, documentation and regulation of traditional knowledge associated with genetic resources.

Provided that non-documentation of Traditional Knowledge associated with genetic resources shall not deprive the National Focal Point, local communities, or individuals holding the knowledge from entering into Access and Benefit Sharing Agreement.

61. The National Focal Point shall maintain a national traditional knowledge database for documenting the information on traditional knowledge associated with genetic resources.
62. The documentation of traditional knowledge associated with genetic resources shall be based on prior informed consent of local communities and individuals holding the knowledge.
63. Access to traditional knowledge associated with genetic resources for research and commercial purpose is to be regulated to promote fair and equitable sharing of benefits from its use.

Community Protocol

64. The National Focal Point shall support and promote communities to develop Community Protocols on traditional knowledge associated with genetic resources.

Providers of Traditional Knowledge associated with genetic resources

65. A community shall be the provider of traditional knowledge associated with genetic resources held within a community, unless an individual is recognised as the holder of the knowledge by that community.
66. If traditional knowledge associated with genetic resources is held by more than one community, where appropriate the communities shall

be jointly considered as the providers of traditional knowledge in accordance with the community protocol.

67. If no determination is made under sections 65 and 66, the National Focal Point shall be deemed to be the provider of traditional knowledge.

Access to Traditional Knowledge

68. A person seeking access to traditional knowledge shall submit an access proposal to the National Focal Point as per the format prescribed in the Regulations.
69. Sections 21 to 25 on submission of access proposal shall apply *mutatis mutandis* for traditional knowledge associated with genetic resources.
70. Sections 26 to 28 on prior informed consent shall apply *mutatis mutandis* for traditional knowledge associated with genetic resources.

Scoping Agreement

71. Sections 33 to 38 and Sections 39 to 46 on Scoping Agreement shall apply *mutatis mutandis* to traditional knowledge associated with genetic resources.

Access and Benefit Sharing Agreement

72. Sections 33 to 38 and sections 47 and 48 on Access Benefit Sharing Contract shall apply *mutatis mutandis* to traditional knowledge associated with genetic resources.

CHAPTER 6
FAIR AND EQUITABLE SHARING OF BENEFITS

73. Fair and equitable sharing of benefits from commercial use of genetic resources and associated traditional knowledge shall be the key component of Scoping Agreement or Access and Benefit Sharing Agreement.
74. The National Focal Point shall negotiate and provide oversight to ensure fair and equitable sharing of benefits arising from research and commercial utilization of genetic resources from Bhutan and associated traditional knowledge.
75. For the purpose of this Act, benefits comprise monetary or non-monetary benefits or both as may be specified in the Regulations.
76. Monetary benefits arising out of research and commercial utilization of genetic resources from government-reserved forests, protected area system and *ex situ* collections is channeled into Access and Benefit Sharing Fund.
77. A portion of monetary benefits arising from research and commercial utilization of genetic resources from community forestry including genetic resources related to food and agriculture developed and sustained by communities is channeled into the Access and Benefit Sharing Fund.
78. A portion of monetary benefits arising from research and commercial utilization of traditional knowledge associated with genetic resources is channeled into the Access and Benefit Sharing Fund.
79. Where the National Focal Point is the provider of traditional knowledge associated with genetic resources under section 67, all monetary benefits arising from research and commercial utilization is channelled into Access and Benefit Sharing Fund.

CHAPTER 7

BHUTAN ACCESS AND BENEFIT SHARING FUND

Bhutan Access and Benefit Sharing Fund

80. The Bhutan Access and Benefit Sharing Fund is hereby established.
81. The National Focal Point is vested with the administration and management of the Bhutan Access and Benefit Sharing Fund under the supervision of the Competent National Authority.

Purpose of the Fund

82. The Bhutan Access and Benefit Sharing Fund shall be used towards:
- (1) conservation and sustainable use of Bhutan's biodiversity; and
 - (2) enhancement of rural livelihoods.

Contributions to the Fund

83. The Bhutan Access and Benefit Sharing Fund is comprised of:
- (1) monetary benefits arising out of research and commercial utilization of genetic resources from government-reserved forests, protected area system and *ex situ* collections;
 - (2) a portion of the 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;
 - (3) a portion of the monetary benefits arising from the research and commercial utilization of traditional knowledge associated with genetic resources;
 - (4) processing fee and commitment fee payable at the Scoping phase;
 - (5) Returns from investments;
 - (6) Grants, donations or financial assistance from domestic or external sources; and
 - (7) such other sources as may be determined by the Competent National Authority.

Investment

84. The National Focal Point may, subject to the approval of the Competent National Authority, invest a portion of the funds as are not immediately required for the purposes of this Act in shares or securities.
85. Returns from investments under section 84 are to be credited to the Bhutan Access and Benefit Sharing Fund account.

Accounts and Audit

86. The Royal Audit Authority shall be the auditor for the Bhutan Access and Benefit Sharing Fund.

CHAPTER 8 REGISTER, RECORDS AND DISPOSAL

Register

87. The National Focal Point shall maintain one or more register containing details on access and utilization of genetic resources as may be specified in the Regulations.

Records

88. A User of genetic resource or associated traditional knowledge shall maintain records of genetic resources or associated traditional knowledge accessed as may be specified in the Regulations.
89. A copy of the records under section 88 shall be furnished to the National Focal Point within such period as specified in the Regulations.

Disposal of a genetic resource

90. If a User of genetic resources intends to dispose genetic resources which are accessed under this Act, the User shall dispose off the genetic resources in accordance with the provisions of the contract.
91. Pursuant to section 90, a User shall, if so required, forthwith furnish evidence of the disposal of the genetic resource to the National Focal Point.

CHAPTER 9 ENFORCEMENT POWER

Enforcement officers

92. The Officials of the National Focal Point shall be the enforcement officers for the purpose of this Act.
93. The Competent National Authority may designate any agency of the Royal Government of Bhutan as enforcement officers to assist the National Focal Point in the enforcement of this Act.

Power of investigation

94. An enforcement officer shall have all the powers necessary to carry out an investigation under this Act.
95. An enforcement officer may summon person who appears to be acquainted with the facts of the case for the purposes of interrogation, testimony, witnessing, presentation of documents, books and records and objects necessary.

Power of arrest

96. An enforcement officer may arrest without warrant any person:
- (1) found committing or attempting to commit or abetting the commission of an offence under this Act; or
 - (2) whom the enforcement officer reasonably suspects of being engaged in committing or attempting to commit or abetting an offence under this Act.
97. An enforcement officer making an arrest under section 96 shall, without unnecessary delay, hand over the person arrested to the nearest police station.
98. A person under section 97 shall be dealt in accordance with Civil and Criminal Procedure Code of Bhutan.

Power to enter, search and seize

99. Where an enforcement officer reasonably suspects that any premises is being used for commission of an offence under this Act, the Officer may apply to a Court of competent jurisdiction for a warrant authorizing the enforcement officer to enter and search such premises.
100. An enforcement officer authorized under section 99 may enter the said premises and seize genetic resources including articles found therein which are being used, or are likely to be used, in connection with the offence in accordance with the Civil and Criminal Procedure Code of Bhutan.
101. A warrant issued under section 99 may authorize an enforcement officer to:
- (1) search the premises for, and seize or remove from the premises any genetic resource, equipment, record, or other article that is reasonably believed to furnish evidence of the commission of an offence;
 - (2) take any genetic resource or relevant articles found in the premises for the purposes of ascertaining, by testing, or otherwise, whether the offence has been committed; and
 - (3) make copies of or take extracts from any book, other article found in the premises.

Access to digital data

102. An enforcement officer with a search warrant may at any time have access to digital data and for such purpose be provided with the necessary password, code, software, or hardware and any other means required for comprehension of the data.

Power to stop, search and seize conveyances

103. If an enforcement officer has reasonable cause to suspect that a conveyance is carrying any genetic resource, equipment, record, document, or other article in respect of which an offence under this Act is being or has been committed, an officer may stop and examine the conveyance.

104. If on examination under section 103, an officer has reasonable cause to believe that such conveyance is or has been used for the commission of such offence, seize such conveyance and any genetic resource, equipment, record, or other article found in the conveyance that is reasonably believed to furnish evidence of the commission of such offence.

Search and seizure without warrant

105. If an Enforcement Officer has reasonable cause to believe that by reason of delay in obtaining a search warrant, the investigation would be adversely affected or evidence of the commission of an offence is likely to be tampered with, removed, damaged, or destroyed, the officer may enter the premises and exercise all the powers referred to in section 101, as if authorized to do so by a warrant issued under that section.

CHAPTER 10 OFFENCES AND PENALTIES

Accessing genetic resources or associated traditional knowledge

106. A person who accesses genetic resources, or associated traditional knowledge in contravention to the provisions of this Act commits an offence and shall, on conviction, be liable to a sentence for misdemeanor or a fine as may be prescribed in the Regulations or both.

Giving false information

107. If a person knowingly provides false, or misleading information to the National Focal Point under this Act commits an offence and shall, on conviction, be liable to a sentence for misdemeanor or a fine as may be prescribed in the Regulations or both.

Providing unlawful Access

108. Except as may be permitted as per customary practice, a person who knowingly provides access to traditional knowledge associated with genetic resources to a person in contravention with the provisions of this Act commits an offence and shall, on conviction, be liable to a sentence for misdemeanor or a fine as may be prescribed in the Regulations or both.

Obstruction of lawful authority

109. A person who purposely obstructs an enforcement officer in the discharge of duties under this Act commits an offence of obstruction of lawful authority and penalized in accordance with the Penal Code of Bhutan, 2004.

Unauthorized transfer of research results

110. A User who transfers research results or accessed genetic resources to a third party for product development and commercial utilization in contravention to section 44 shall be liable for fines as may be prescribed in the Regulations.

CHAPTER 11 MISCELLANEOUS

Confidentiality

111. Enforcement Officers under this Act shall protect all information considered confidential.
112. Access to national traditional knowledge database shall be restricted to prevent any unauthorised person from having access to traditional knowledge information considered confidential by the right holders.
113. Notwithstanding section 112, the National Focal Point may periodically publish information from the national traditional knowledge database with the objective to benefit the traditional knowledge holders.

Monitoring and Tracking

114. The Competent National Authority shall, on the recommendation of the National Focal Point, designate check points for the purpose of monitoring and tracking genetic resource or associated traditional knowledge.
115. The National Focal Point shall ensure that genetic resources or associated traditional knowledge accessed from other countries and utilized in Bhutan have been accessed in accordance with the laws of that Country.

Issuance of Certificate of Origin

116. The Competent National Authority shall, as may be considered necessary, authorize National Focal Point for issuance of Certificate of Origin.

Foreign Direct Investment

117. Activities under this Act eligible for Foreign Direct Investment shall be dealt in accordance with the Foreign Direct Investment laws in force in Bhutan.

Protection from liability

118. A person performing a duty under the provisions of this Act shall not be liable for anything done or omitted to be done in good faith and in the due course of duty.

Power to make rules and regulations

119. The Competent National Authority may, with the approval of the Minister, Ministry of Agriculture and Forests, frame rules and regulations from time to time to carry out the provisions of this Act.

Amendment

120. The amendment of this Act by way of addition, variation or repeal may be effected only by Parliament.

Authoritative text

121. The Dzongkha text is the authoritative text in case of any difference in meaning between the Dzongkha and the English text.

Definitions

122. For the purpose of this Act, the following definitions apply:

“Access and Benefit Sharing Agreement” means a contract between the user and providers of genetic resources or associated traditional knowledge or both consisting of Prior Informed Consent and Mutually Agreed Terms;

“Access to genetic resources” means the collection or transfer of genetic resources from Bhutan for research or commercial purposes or both irrespective of whether they are found *in situ* or *ex situ*;

“Access Proposal” means an application seeking access to genetic resources or associated Traditional Knowledge or both;

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

“Access and Benefit Sharing Agreement” means an agreement between the User and providers of genetic resources or associated traditional knowledge or both consisting of Prior Informed Consent and Mutually Agreed Terms;

“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;

“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;

“Community protocols” means protocols developed by local custodians of Bhutan’s genetic resources or associated traditional knowledge through a participatory process based on customary laws and values and detailing at the minimum a clear process for acquiring their free and prior informed consent and establishing mutually agreed terms and benefit sharing with respect to utilization of their resources and knowledge;

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

“Commercial research” means research aimed towards discovering and developing marketable products;

“Derivatives” means biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, regardless of it occurring naturally, synthesized or otherwise produced, even if it does not contain functional units of heredity;

“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;

“Genetic resources from Bhutan” means genetic resources found within the territory of Bhutan, and genetic resources found outside Bhutan with its origins in Bhutan;

“Sample Transfer Certificate” means a certificate issued to facilitate transfer samples of genetic materials under section 59;

“Scoping Agreement” means a contract executed at an initial exploratory phase of research and development with the aim of establishing market or research potential between the user and providers of genetic resources or associated traditional knowledge or both;

“Traditional knowledge associated with genetic resources” means the knowledge, innovation and practice of communities or individuals relating to the use, properties, values and processes of any biological and genetic resources or any part thereof;

“Utilization of genetic resources” means conducting any research or commercial utilization or both on the genetic resources.