

Draft Biodiversity Rules

PREAMBLE

In exercise of the powers conferred under Section 49 of the Biodiversity Act of Bhutan, 2003, the Ministry of Agriculture, Royal Government of Bhutan hereby frames and adopts the Biodiversity Rules and Regulations of Bhutan, 2008 for effective implementation of the provisions contained therein.

Within the purview of the Act, these Rules shall among other things ensure the National Sovereignty over biological and biochemical resources of Bhutan, regulate and facilitate the process by which collectors may legally access these resources and recognize the rights of local communities over associated Traditional Knowledge. It also establishes mechanisms for sharing benefits resulting from research, use and/or commercialization of the biological and biochemical resources including associated Traditional Knowledge.

CHAPTER 1

PRELIMINARY

Short Title and Commencement

1. These Rules and Regulations shall:
 - a) be called The Biodiversity Rules (Part I) of Bhutan, 2008.
 - b) come into force from the date specified in the notification of enforcement issued by the Ministry of Agriculture.
 - c) apply to the whole of the Kingdom of Bhutan.

Scope

2. These Rules shall apply to:
 - a) all biological and biochemical resources including wild, domesticated and cultivated species of flora and fauna, both *in situ* and *ex situ* conditions found within the territory of the Kingdom of Bhutan including protected areas and/or government reserved forests.
 - b) the Traditional Knowledge, innovation and practices associated with biodiversity.

Exemptions

3. Pursuant to section 4 of the Act these Rules shall not apply to:
 - a) The commodities of direct use and consumption based on the processes and end use of genetic resources as determined by the Competent Authority. Such commodities are listed under Annexure 1 (DOF, AMS & NBC to develop the list – fruits, timber, NTFP, etc. used direct consumption which may be amended and notified, as and when deemed necessary by the Competent Authority.
 - b) Access, use and exchange of biological and biochemical resources among local communities resulting from their traditional and customary practices.
 - c) Access to human genetic resources.
 - d) Access to crop genetic resources provided under Annexure 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and listed in Annexure 2 of these Rules. The access and benefit sharing of these crop

genetic resources shall be in accordance with the procedure outlined in the ITPGRFA.

- e) To plant varieties for which patent or any other Intellectual Property Rights protection is available.
- f) To the biological resources notified by Competent Authority through periodic notification for the prevention of the commercial exploitation, which may be necessary to protect public order or morality including prejudice to the environment and the general interest or traditional rights of farmers.

Repeal

- 4. These Rules shall supersede all by-laws and executive orders including notifications and circulars that are inconsistent with the provisions of these Rules.

Amendments

- 5. These Rules may be amended by the Ministry of Agriculture from time to time as and when deemed necessary.

Language and Legibility

- 6. The following requirements shall apply to all the Application Forms, project and/or research proposals, contract/user agreement and any other documents required to be submitted as required under these Rules:
 - a) must be in Dzongkha or English language and legibly written, typed or printed.
 - b) any interlineations, erasure, cancellation, or other alteration must be made in permanent ink before signing and shall be clearly initialed and dated by the applicant to indicate knowledge of such fact at the time of signing.

Definitions

- 7. In these Rules, unless the context clearly requires otherwise:
 - a) **Access** shall mean obtaining, collecting, utilizing and/or exporting genetic or biochemical resources including associated TK covered by this Act for purposes of conservation, research, bio-prospecting or commercial use.
 - b) **Act** shall mean the Biodiversity Act of Bhutan, 2003.
 - c) **Applicant** shall mean a natural or legal person seeking access to biological or biochemical resources and/or associated Traditional Knowledge.

- d) **Authorized Agency** shall mean the National Biodiversity Center or any other agency in the future that shall be responsible to carry out the functions of the authorized agency pursuant to the Biodiversity Act designated by the Competent Authority.
- e) **Benefit Sharing** shall mean fair and equitable sharing of benefits, on agreed terms, arising from access and the use of biological/biochemical resources and associated TK with the providers.
- f) **Biochemical Resources** shall mean any material derived from plants, fungi, animals or micro-organism, which contains specific characteristics and special molecules.
- g) **Biodiversity (or Biological Diversity)** shall mean the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems.
- h) **Biological Resources/Material** shall mean genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity excluding human genetic resources.
- i) **Bio-prospecting** shall mean the systematic search, classification and research of new sources of chemical compounds, genes, proteins and microorganism for commercial purposes with real or potential economic value, which are found in biodiversity.
- j) **Biotechnology** shall mean any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
- k) **Collectors** shall mean any natural or legal person, entity or agent obtaining access to genetic and biochemical resources or associated traditional knowledge under authority given by the Competent Authority.
- l) **Commercial use** shall include any use of biological resources and their products or derivatives for monetary gains such as in drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts, genetic improvement and modifications.
- m) **Competent Authority** shall mean the Head of the Ministry of Agriculture who shall be the Secretary, Ministry of Agriculture of the RGOB.
- n) **Contract/User Agreement** shall mean a legal document with set of terms and conditions agreed by the contracting parties for access, use and benefit sharing of biological/biochemical resources and/or associated TK.
- o) **Direct Use and Consumption** shall mean any biological material that is used as a commodity for direct consumption but not as a genetic resource for research, development and other purposes.

- p) **Ex situ** shall mean the components of biological resources outside their natural habitats
- q) **Genetic resources** shall mean any material derived from plants, animals, fungi or microorganisms which contains functional unit of heredity.
- r) **In situ** shall mean components of biological resources within natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
- s) **Intellectual Property Rights:** shall mean legal protection given to individual or group of individuals over their creation, invention and innovation under the applicable laws.
- t) **ITPGRFA** means the International Treaty on Plant Genetic Resources for Food and Agriculture ratified by the 83rd session of the National Assembly in 2003.
- u) **Local community** shall mean and include an individual or individuals living together in a defined area such as chiwog/chiwogs, gewog/gewogs or any other political boundary, or having lived as an organized community sharing common bonds of language, customs, traditions and other distinctive cultural traits.
- v) **Material** shall mean vegetative and reproductive material for the purpose of commercial use, conservation, research and bio-prospecting.
- w) **Material Transfer Agreements** shall mean an agreement between the provider and the recipient covering specific terms and conditions for transfer, use as well as benefit sharing of biological/biochemical resources and/or associated traditional knowledge in accordance with these Rules.
- x) **Ministry** shall mean the Ministry of Agriculture or any other Ministry that may become responsible for biodiversity in the future.
- y) **Notification** shall mean the notice issued by the ministry pursuant to these rules by means of publishing in at least one of the national newspapers, radio and television broadcast.
- z) **Prior Informed Consent** shall mean the procedure through which the RGOB and other stakeholders, as the case may be, properly supplied with all the relevant information, give consent to an applicant to initiate application for access to genetic and biochemical resources or associated Traditional Knowledge, under mutually agreed terms.
- aa) **RGOB** shall mean the Royal Government of Bhutan.
- bb) **Rights owners** are owners of TK pursuant to these Rules.
- cc) **Rules** shall mean the rules and regulations of the Biodiversity Act of Bhutan 2003 and shall include annexure and forms under these Rules.

- dd) **TK Registry** means the record of TK owners and associated TK registered with the Authorized Agency.
- ee) **Traditional and Customary use/practices** shall mean the manner of utilization of biological/genetic resources including associated traditional knowledge which is in accordance with established practices and customs of the local communities.
- ff) **Traditional Knowledge** shall mean the knowledge, innovation and practices of local communities relating to the use, properties, values and processes of any biological and genetic resources or any part thereof.

CHAPTER 2 Institutional Arrangement

Biodiversity Management Board

8. There shall be a Biodiversity Management Board (BMB) chaired by the head of the Ministry.
9. The BMB shall consist of members that crosscut various Ministries and organizations that have relevance to the biodiversity conservation and utilization. The BMB shall consist of the following *ex-officio* members:
 - (a) Secretary, MoA as the Chairperson.
 - (b) Director, Department of Forest
 - (c) Director, Department of Agriculture
 - (d) Director, Department of Livestock
 - (e) Director, CoRRB
 - (f) Director, ITMS, MoH
 - (g) Director, IPD, MoEA
 - (h) Executive Director, BAFRA
 - (i) CPO, PPD, MoA
 - (j) CPO, PPD, NEC
 - (k) Farmer Representative
 - (l) Program Director, NBC as member Secretary.
10. The BMB shall meet at least twice a year, and as and when deemed necessary by the Competent Authority.
11. At a meeting the presence of two third members shall constitute the quorum.

Functions of Biodiversity Management Board

12. The Biodiversity Management Board shall:
 - (a) Oversee and ensure the proper enforcement of the Biodiversity Act and its rules.
 - (b) Advise the Competent Authority on matters relating to access and equitable sharing of benefits arising out of the utilization of biological resources and associated traditional knowledge;
 - (c) develop national policy frameworks including creating favorable conditions and incentive that foster the sustainable use and the maintenance of biological resources
 - (d) in order to aid in their decision makings, recommend relevant studies, investigation and research to the institutions involved in biodiversity management.
 - (e) perform such other functions as may be necessary to carry out the provisions of the Act and these rules.

Competent Authority

13. The Competent authority shall be the Secretary of Ministry of Agriculture.

Functions of CA

14. The Competent Authority shall:

- a) appoint members to the Scientific Review Committee (SRC)
- b) grant or refuse prior informed consent (PIC)
- c) approve or refuse the access proposal based on the recommendation of the SRC.
- d) where deemed necessary the CA may consult the BMB on issues pertaining to PIC and access applications.
- e) Issue Certificate of Origin as required under section 10.1 of the Act.
- f) approve or refuse transfer of accessed biological resources to a third party based on the review and recommendations from SRC and Authorized Agency (AA) and endorse Material Transfer Agreements.
- g) endorse contract/user agreements for access and benefit sharing.
- h) revoke access permits in the event the permittee violates any of the provisions of the contract/user agreement and/or these rules.
- i) approve transfer of biological materials pursuant to section 21(h) of these rules.
- j) issue notifications as and when deemed necessary pursuant to section 3(f) of these rules.

Authorized Agency

15. The National Biodiversity Center shall be the AA for the implementation of these rules.

Functions of Authorized Agency

16. The Authorized Agency shall:

- (a) function as a secretariat for implementation of the Biodiversity Act
- (b) receive and facilitate/process PIC and access to biological/biochemical resources and/or associated TK applications
- (c) facilitate PIC approval from Rights Owners of TK
- (d) coordinate BMB and SRC meetings
- (e) maintain Biodiversity and TK Registry
- (f) process all fees and penalties related to this rules
- (g) negotiate, draw and monitor contract/user agreements for access and benefit sharing
- (i) create awareness and education on Biodiversity Act to the stakeholders and public

Scientific Review Committee

17. Scientific Review Committee shall be appointed by the Competent Authority. Members to the SRC shall be technically competent and recommended from the following disciplines by the Authorized Agency:
 - a) Biodiversity
 - b) Agriculture
 - c) Forestry
 - d) Livestock
 - e) Research
 - f) Biotechnology
 - g) Health
 - h) Environment
 - i) Intellectual Property
 - j) Agriculture Marketing Services
 - k) Regulatory services
 - l) Chief Scientific Officer, NBC as the member Secretary.

Functions of Scientific Review Committee

18. The scientific review committee (SRC) shall:
 - a) Conduct scientific assessment of the access applications and proposals on biological resources and TK considering the effects on national policies environment, health and culture, and consider potential benefits
 - b) Provide expert views on possible benefit-sharing mechanisms
 - c) Provide technical recommendations on any matters referred to the committee by the Competent Authority and Authorized Agency.
19. The SRC shall meet quarterly and as and when deemed necessary by the Competent Authority. Chairperson will be elected from among the SRC members by a vote of simple majority during its first meeting. The term will be for one year.
20. At a meeting the presence of two third members shall constitute quorum.

CHAPTER 3

Access to Biological and Biochemical Resources, and Associated Traditional Knowledge

Conditions on Access to Biological and Biochemical Resources, and associated Traditional Knowledge (TK)

21. The following conditions shall apply to access Biological/Biochemical Resources, and/or associated Traditional Knowledge:
- a) Access to totally protected species listed under schedule I of the Forest and Nature Conservation Act 1995 and provided as [Annexure 3](#), and/or biological resources notified pursuant to section 3(f) of this Rules shall be prohibited.
 - b) Except for biological resources for direct use and consumption as listed under Annexure 1 and/or crop genetic resources listed under the FAO multilateral system as Annexure 2 of these Rules, access and use of other biological or biochemical resources existing in Bhutan shall not be permitted without fulfilling the requirements on access and benefit sharing provided under these Rules.
 - c) Use of biological resources listed under Annexure 1 for purposes other than direct use and consumption without PIC and fulfilling the requirements on benefit-sharing is prohibited.
 - d) In the event a biological or biochemical resource is notified pursuant to section 3(f) and it is also listed under Annexure 1 of these Rules; such a biological or biochemical resource shall be automatically de-listed from Annexure 1 unless it is reinstated by the Competent Authority.
 - e) Except for biological resources specified pursuant to Section 3(a) and 3 (d) of these Rules, access to other biological resources shall be regulated in a manner to permit export of only the biochemical resources derived from the biological resource.
 - f) Any applicant seeking access to biological/biochemical resources and associated Traditional Knowledge shall be required to fulfill the additional requirements of access to TK as provided in these Rules.
 - g) Each application for access shall be limited to only one biological (species level) or biochemical resource and/or associated Traditional Knowledge at a time.
 - h) Notwithstanding section 21(e), if a specific approval is accorded by the Competent Authority based on the recommendation of the SRC, a biological resource may be transferred out of the country for research, education and conservation.

Procedure to access biological/biochemical resources and/or associated Traditional Knowledge

Application and grant of PIC

22. Any person seeking access to biological/biochemical resources and/or associated TK shall be subject to Prior Informed Consent (PIC). The applicant shall submit an application for PIC as prescribed in **Form 1**. In case of TK, consent from the rights owners shall be obtained.
23. Every application under section 22 shall be accompanied by a fee of one thousand ngultrum in the form of a cheque or demand draft drawn in favor of the designated Authorized Agency.
24. The Authorized Agency shall upon review submit the PIC application to the Competent Authority. The Competent Authority shall within 45 days of the date of receipt of the application, approve or reject the PIC application.
25. The PIC shall be valid only for 6 months from the date of approval. The applicant shall submit the application for access within the stipulated period of six months.

Application and grant of access to biological/biochemical resources and associated Traditional Knowledge

26. Any person with a valid PIC certificate shall submit to the Authorized Agency a proposal for access as outlined in **Form 2**.
27. Every application under section 26 shall be accompanied by a fee of ten thousand ngultrum in the form of a cheque or demand draft drawn in favor of the Authorized Agency.
28. Upon submission of the Access Application Form, the Authorized Agency shall verify and ensure that all the requirements are fulfilled.
29. Upon fulfillment of Section 28, the Authorized Agency in consultation with the applicant and/or local communities concerned where necessary in case of associated Traditional Knowledge, shall formulate a draft contract/user agreement including benefit sharing as outlined in **Form 3** within 90 days.
30. Any person who intends to apply for an Intellectual Property Rights (IPR) originating from the accessed biological/biochemical resource and/or associated traditional knowledge shall obtain prior approval of the Competent Authority and must include benefit sharing mechanisms.
31. The Authorized Agency shall forward the access application and draft contract/user agreement to the SRC for scientific review. The SRC shall complete the review within 45 days from the date of submission.
32. The SRC while doing the review shall consider the following among other things:

- a) National Policies and laws.
 - b) Conservation and sustainable use
 - c) Public health;
 - d) Environmental and aesthetic values and social harmony.
 - e) Socio-economic, cultural and ethical values; (Bio-cultural heritage)
 - f) State of National Scientific research and development, and capacity to collaborate.
 - g) Allocation for use of resources to the local communities
 - h) Proposed benefit sharing mechanism; and
 - i) Technical and financial capability of the applicant.
33. The Authorized Agency shall submit the draft contract/user agreement and access application with findings from SRC to the Competent Authority for decision.

Grant of Access

34. The Competent Authority may refer the access proposal to BMB for further review and advice where deemed necessary.
35. The Competent Authority may recommend necessary changes on the proposal and the contract/user agreement.
36. On being satisfied with the merit of the application, the Competent Authority may refuse or approve the access to biological/biochemical resources and/or associated TK within 30 days.
37. In the event of grant of access, the Authorized Agency shall issue access/collection permit as specified in **Form 4**. The permittee shall produce the permit whenever being inspected or required by the Forestry officials within the country.

Revocation

38. The Competent Authority may *suo moto* or on the basis of any complaint revoke the access/collection permit and Contract/user agreement under any of the following circumstances:
- a) When the permittee has violated any of the provisions of the Act and these Rules.
 - b) When the permit was obtained by providing false or misleading information.
 - c) When the permittee has failed to comply with the conditions of the Access/collection Permit and/or Contract/user Agreement.
 - d) For reasons of public interest, including the protection of the environment and biological diversity.
39. The Competent Authority shall send a copy of every order of revocation issued by it to the Authorized Agency and agencies/public concerned for prohibiting access to the applicant and to also assess the damage, if any caused and take steps to recover the damage.

Transfer of Biological/biochemical Resources out of the country

40. Transfer of biological resources out of Bhutan shall be prohibited except under section 21(h).
41. BAFRA shall regulate the export of biological/biochemical resources to permit only those biological/biochemical resources for which Material Transfer Agreement has been executed in accordance with sections 42-44 of these Rules.
42. Any transfer of biological/biochemical resources out of Bhutan shall be subject to a Material Transfer Agreement (MTA) entered into with the Competent Authority as outlined in **Form 5** of these Rules.
43. A person intending to transfer biological/biochemical resources shall apply to the Authorized Agency. The Authorized Agency shall facilitate the MTA between the Competent Authority and applicant.
44. The MTA shall serve as a permit for transfer of biological/biochemical resources out of the country. Upon request of the applicant, the Competent Authority may issue a Certificate of Origin.
45. For the purpose of these rules, the official exit points for transfer/export shall be the following:
 - a. Exit by land:
 - i. Phuentsholing;
 - ii. Gelephu;
 - iii. Samdrupjongkhar; and
 - iv. Samtse
 - b. Exit by air:
 - i. Paro International Airport.
46. The Authorized Agency may designate additional exit points as and when deemed necessary.

Third Party Transfer

47. Any person who has been granted approval for access to biological/biochemical resources and/or associated TK, and intends to transfer the accessed biological/biochemical resource and/or associated TK to any other person or organization shall make an application to the Authorized Agency as prescribed in **Form 6**.
48. Every application under section 47 shall be accompanied by a fee of ten thousand ngultrum in the form of cheque or demand draft in favor of the Authorized Agency
49. The Authorized Agency shall after collecting any additional information and on being satisfied that the applicant has fulfilled all the necessary requirements, put up the application to the Competent Authority for final decision.

50. The Competent Authority may decide upon the application within a period of 90 days of the receipt of the same subject to such terms and conditions it may deem fit to impose in each case.

51. The approval may be granted in written form duly signed by the Competent Authority.

Confidentiality

52. The Authorized Agency, applicant/s and any other agencies concerned shall protect all the information deemed confidential, such as trade secrets or other forms of intellectual property rights.

Penalty

53. If any applicant sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without MTA and/or third party transfer approval, and in violation of the Contract/user agreement the applicant shall be liable to pay the Authorized Agency a royalty rate of fifty percent (50%) of the gross income received by the applicant from such sales or other revenues.

54. In the event of breach of confidentiality the permittee shall be liable to pay damages as determined by the Court and revocation of access permit.

55. The Authorized Agency may also seek other damages to which the RGOB may be entitled to including but not limited to injunctive relief against the applicant.

CHAPTER 4

Inventory and Documentation of Traditional Knowledge associated with Biological Resources

56. The Authorized Agency shall in consultation with the local communities document Traditional Knowledge associated with biodiversity in Bhutan.
57. Non-documentation of associated Traditional Knowledge shall not deprive in any way the Authorized Agency, applicant and rights owners from entering into negotiation and user agreements in the event access to such a Traditional Knowledge is sought in accordance with the procedure provided in Chapter 3 of these Rules.

PIC for documentation of associated Traditional Knowledge

58. The Authorized Agency shall obtain a PIC prescribed in **Form 7** from the rights owners prior to documentation of Traditional Knowledge.

Registration/Documentation

59. The Authorized Agency shall maintain a national Traditional Knowledge registry to record the Traditional Knowledge through establishment of an appropriate data base.

Confidentiality

60. Access to Traditional Knowledge registry shall be restricted in a manner to prevent any third person from having access to Traditional Knowledge information deemed confidential by the rights owners.
61. The Authorized Agency may without breach of confidentiality periodically publish information from the Traditional Knowledge registry with the objective to benefit the Traditional Knowledge owners.