

Table of Contents

Preamble	1
CHAPTER 1	2
PRELIMINARY	2
Title	2
Commencement	2
Extent	2
Repeal	2
Application	2
Objects.....	4
CHAPTER 2	5
INSTITUTIONAL ARRANGEMENT	5
Competent National Authority	5
Functions of Competent National Authority	5
Session	6
National Focal Point	6
Functions of the National Focal Point	6
CHAPTER 3	8
CONSERVATION AND SUSTAINABLE USE	8
Conservation and Sustainable Use	8
Providers of Genetic Resources	10
Restricted Genetic Resources	11
CHAPTER 4	11
A SUI GENERIS SYSTEM FOR THE PROTECTION OF PLANT VARIETIES	11
Conditions for Protection	11
Novelty	12
Distinctness	12
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Biodiversity Act of Bhutan 2022	1

Uniformity	12
Stability	12
Identifiability	13
Certificate of Origin	13
Rights Conferred	13
Acts requiring the Rights Holder’s Authorization	14
Exceptions to the Rights Conferred	14
Farmers’ Rights	14
Breeder’s Exemptions	14
Duration of the Rights	15
Exhaustion of the Rights	15
Compulsory Licenses	15
Other requirements for Granting Compulsory License	16
Derogation from Exceptions	16
Application for Protection	17
Examination	17
Denomination	17
Interface with Seed Certification System	17
Interface with Patent Law	18
Nullity of Breeder’s Right	18
Cancellation of Breeder’s Right	18
CHAPTER 5	19
ACCESS TO GENETIC RESOURCES	19
Access to Genetic Resources	19
Access Proposal	19

Prior Informed Consent	20
Relationship to Other Permits	21
Scoping Agreement and Access and Benefit Sharing Agreement	21
General Procedure	21
Scoping Agreement	22
Access and Benefit Sharing Agreement	23
Certificate of Compliance	24
Material Transfer Agreement	24
Access to Plant Genetic Resources for Food and Agriculture	25
Standard Material Transfer Agreement	26
Sample Transfer Certificate	26
CHAPTER 6	27
ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES	27
Documentation, Preservation and Protection	27
Community Protocol	28
Providers of Traditional Knowledge Associated with Genetic Resources	28
Access to Traditional Knowledge Associated with Genetic Resources	29
CHAPTER 7	29
FAIR AND EQUITABLE SHARING OF BENEFITS	29
Intellectual Property Rights	30
CHAPTER 8	31
BHUTAN ACCESS AND BENEFIT SHARING FUND	31
Bhutan Access and Benefit Sharing Fund	31
Purpose of the Fund	32
Contributions to the Fund	32
Accounts and Audit	33

CHAPTER 9	33
REGISTRY, RECORDS AND DISPOSAL	33
Registry	33
Records	33
Disposal of a Genetic Resources	34
CHAPTER 10	34
MONITORING AND ENFORCEMENT	34
Enforcement Officers	34
Confidentiality	35
Monitoring and Tracking	35
Power of Investigation	35
Access to Digital Data	36
Power to Stop, Search and Seize Conveyances	36
Power to enter, search and seize	37
CHAPTER 11	37
OFFENCES AND PENALTIES	37
Illegal Access to Genetic Resources or Associated Traditional Knowledge...	37
Unauthorized Transfer of Research Results	38
Non deposition of sample and specimen of biological resources	38
CHAPTER 12	39
MISCELLANEOUS	39
Foreign Direct Investment	39
Protection from Liability	39
Power to Make Rules	39
Amendment	39
Authoritative Text	40
Definitions	40

Preamble

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

Whereas, recognizing the importance of rich biological diversity which has been protected by the wise and far-sighted leaderships, Bhutanese traditional beliefs, socio-cultural outlook, and the overarching development philosophy of Gross National Happiness;

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

Whereas, recognizing the importance of regulating access to and utilization of genetic resources and traditional knowledge associated with biological resources;

Whereas, being the party to the Convention on Biological Diversity (CBD), the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the International Treaty on the Plant Genetic Resources for Food and Agriculture (ITPGRFA).

The Parliament of the Kingdom of Bhutan hereby enacts as follows:

CHAPTER 1

PRELIMINARY

Title

1. This Act is the Biodiversity Act of Bhutan 2022.

Commencement

2. This Act comes into force on the 17th Day of the 5th Month of the Water Male Tiger Year of the Bhutanese Calendar corresponding to the 15th Day of July 2022.

Extent

3. This Act extends to the whole of the kingdom of Bhutan.

Repeal

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

Application

5. This Act shall promote conservation and sustainable use of biological resources and applies to access to or utilization of genetic resources or its derivatives from Bhutan, whether they are accessed in-situ or ex-situ.
6. This Act applies to access to, and utilization of traditional knowledge associated with biological resources of Bhutan.

Provided that the Act does not apply to the use, sharing, and exchange of traditional knowledge within and between local communities as part of its customary practices.

7. This Act provides for protection of varieties, breed, and rights of breeders to encourage the development of new varieties and rights of farmers in respect of their contributions made in conserving, improving, and making available of the genetic resources.
8. This Act does not apply to biological resources which are traded, shared, exchanged, and used as commodities for direct use and consumption.

Provided that a biological resource traded, shared, exchanged, and used as commodities which are later utilized as genetic resources for research or commercial purposes, shall be governed by this Act.

9. Human genetic resources are not covered by this Act.
10. This Act does not apply to varieties for which patent protection is available.
11. This Act does not apply to the prevention of the commercial exploitation, which is necessary to protect public order or morality including prejudice to the environment, the general interest or traditional rights of farmers.

Objects

12. The objects of this Act are to:

- (1) ensure national sovereignty and secure trusteeship of the Bhutanese people over its biological resources;
- (2) promote conservation and sustainable use of biological resources, and secure the value of Bhutan's biological resources and associated traditional knowledge;
- (3) recognize and protect knowledge, innovation, and practice associated with genetic resources;
- (4) regulate access to genetic resources and associated traditional knowledge for research and commercial utilization;
- (5) ensure fair and equitable sharing of benefits derived from the use of genetic resources and associated traditional knowledge for research and development;
- (6) recognize and protect the farmer's and breeder's rights; and
- (7) Provide legal recognition of varieties which are not protectable under the internationally existing laws on patent or plant breeder's rights, and thereby recognize farmer's plant variety improvements and innovations and provide a means of sharing benefits derived from the use of farmer's or traditional varieties as breeding material for commercial purposes.

CHAPTER 2

INSTITUTIONAL ARRANGEMENT

Competent National Authority

13. The Competent National Authority shall be established with the following members:
- (1) Minister, the Ministry of Agriculture and Forests as Chairperson;
 - (2) A member, the National Environment Commission;
 - (3) Four members from other relevant agencies identified by Ministry of Agriculture and Forest; and
 - (4) Head, the National Biodiversity Centre as the Member Secretary.

Functions of Competent National Authority

14. The Competent National Authority shall:
- (1) ensure enforcement of this Act;
 - (2) create favourable conditions and incentives that foster the conservation and sustainable use of biological resources and associated traditional knowledge;
 - (3) approve or reject access proposal based on recommendation of the National Focal Point;
 - (4) issue directives to the National Focal Point;

- (5) ensure protection of plant variety and the rights of farmer's and breeder's;
- (6) ensure the timely revision of the National Biodiversity Strategies and Action Plans; and
- (7) perform such other functions, as may be necessary, to carry out under the provisions of this Act.

Session

15. The Competent National Authority shall conduct sessions as prescribed in the Rules.

National Focal Point

16. The National Biodiversity Centre under the Ministry of Agriculture and Forests, is the National Focal Point.

Functions of the National Focal Point

17. The National Focal Point shall:
 - (1) administer the implementation of this Act;
 - (2) The National Focal Point shall be the National clearing house publishing authority for information related to access and benefit sharing for Bhutan.
 - (3) function as national repository for genetic resources and biological collections.

- (4) receive and process access proposal for genetic resources or associated traditional knowledge or both;
- (5) negotiate 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;
- (6) 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;
- (7) recommend the approval or rejection of access proposal to the Competent National Authority;
- (8) review and publish information in the Access and Benefit Sharing clearing house;
- (9) establish measures with the aim of monitoring and tracking of genetic resources and associated traditional knowledge;
- (10) represent Bhutan under any treaty, agreement, convention, or protocol relating to access and benefit sharing;
- (11) create awareness and promote education to the stakeholders and public on conservation, sustainable utilization, and access and benefit sharing of genetic resources;
- (12) conduct and facilitate taxonomic and systematic studies on biodiversity of the country;

- (13) inform the Competent National Authority within a reasonable period of any offence committed under this Act;
- (14) prepare annual reports on access proposals and its decisions;
- (15) coordinate the implementation of the National Biodiversity Strategies and Action Plan; and
- (16) perform such other functions as may be required to implement the provisions of this Act.

CHAPTER 3

CONSERVATION AND SUSTAINABLE USE

Conservation and Sustainable Use

18. The State has sovereign rights over its biological resources. The sovereign rights under this section shall include the right to overrule the community rights recognized under this Act for national importance.
19. The Competent National Authority shall promote:
 - (1) biodiversity conservation and sustainable use of biological resources;
 - (2) conservation and sustainable use of agro-biodiversity for food and agriculture including crop wild relatives; and
 - (3) informal seed systems under which farmers save, use, share, exchange and sell farm-saved seeds or propagating material

including rights to save, use, sell, share and exchange protected varieties.

20. The National Focal Point in order to promote conservation and sustainability of biological resources shall:
 - (1) regulate access to and utilization of genetic resources;
 - (2) strengthen national gene banks;
 - (3) enhance plant taxonomic and systematic research;
 - (4) enhance and manage living plant collections for long term ex-situ conservation;
 - (5) strengthen on-farm conservation of animal genetic resources, traditional crops and varieties including crop wild relatives;
 - (6) strengthen national repository of biodiversity information and bio-discovery research; and
 - (7) engage general public on biodiversity conservation and sustainable utilization;
21. The National Focal Point shall promote and maintain proper documentation of genetic resources which are wild, domesticated and cultivated, including in ex-situ conditions and collections.
22. The National Focal Point shall prioritize species for ex-situ conservation in consultation with relevant agencies.

23. The National Focal Point in consultation with the relevant agencies shall coordinate, develop national management strategies, and furnish invasive alien species list to the regulatory authorities for import regulation.

Providers of Genetic Resources

24. For the purpose of this Act, the providers of genetic resources shall be the:

- (1) Department of Forests and Park Services, if the genetic resources is from the state reserved forests;
- (2) Communities managing the forests, if the genetic resources are accessed 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 forest;
- (4) National Focal Point, if the genetic resources are from ex-situ collections;
- (5) Department of livestock if the genetic resources is from the livestock; and
- (6) Department of Agriculture if the genetic resources are from food and agriculture resources.

25. If no determination is made under section 24 of this Act, the National Focal Point shall be deemed to be the provider of genetic resources.

Restricted Genetic Resources

26. 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 or such other purposes.

27. Access to genetic resources shall be done in compliance with the existing customary practices prevailing in the communities.

Provided that the Competent National Authority may, on the recommendation of the National Focal Point, grant access to genetic resource for the purpose of national importance.

28. The Competent National Authority may, on the recommendation of the National Focal Point, limit or restrict access to genetic resources or overrule restrictions specified under sections 26 and 27 of this Act for national importance.

CHAPTER 4

A SUI GENERIS SYSTEM FOR THE PROTECTION OF PLANT VARIETIES

Conditions for Protection

29. The Competent National Authority shall grant protection for plant varieties that are novel, distinct, uniform, stable, and identifiable.

Novelty

30. The variety shall be considered as novel if at the date of filing of the application, material of the variety has not been sold with the consent of the applicants or their successor in title, for purpose of exploitation of the variety within the following period:
- (1) for longer than one year in case of commercial varieties; and
 - (2) for longer than 10 years in case of varieties bred and developed by farmers and only cultivated within limited areas of the country.

Distinctness

31. The plant variety shall be considered as distinct, if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of filing of the application.

Uniformity

32. A plant variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation and reproduction, it is sufficiently uniform in relevant characteristics.

Stability

33. The plant variety shall be considered as stable, if its relevant characteristics remain sufficiently unchanged after repeated propagation.

Identifiability

34. The plant variety shall be considered as identifiable, if it can be identified by a person skilled in the art of such identification and so recognized by the Competent National Authority.

Certificate of Origin

35. A certificate of origin of the plant variety under this Act may be required at the discretion of the Competent National Authority.

Rights Conferred

36. Entitlement to the right conferred under this Act shall vest in the person or persons who bred and developed the plant variety or its successor in title.
37. Where the person who bred and developed the plant variety is an employee, entitlement to the right conferred under this Act shall be vested in the employer, unless otherwise agreed.
38. Where an application has been filed by a person who is not entitled, the person entitled may submit a request to the Competent National Authority for reassignment of the application in its name.
39. Where the right has already been granted to the person not entitled, the person entitled may file an application for restitution of the title.

Acts requiring the Rights Holder's Authorization

40. The following in respect of material of varieties requires the authorization of the rights holder:
- (1) producing, reproducing or multiplication for commercial marketing;
 - (2) offering for sale, selling or other marketing;
 - (3) exporting;
 - (4) importing;
 - (5) stocking for the purpose of subsection (1) to (4).

Exceptions to the Rights Conferred

Farmers' Rights

41. The Competent National Authority may restrict breeder's rights in relation to plant varieties protected under this Act in order to permit farmers to save, use, exchange, share, and sell farm-saved seed or propagating material on a non-commercial basis as determined by the Competent National Authority.

Breeder's Exemptions

42. The rights conferred on right holders in sections 36 to 39 of this Act shall not apply to acts framed for the purpose of breeding other varieties and shall not apply to any acts in respect of such other varieties provided these other varieties have not been essentially derived from a protected variety.

Duration of the Rights

43. The plant variety protection shall last 20 years from date of grant of the right and 25 years for trees and vines.

Exhaustion of the Rights

44. The rights conferred in sections 36 to 39 of this Act shall not extend to acts concerning any material of the protected variety or any material derived from such protected variety, which has been sold or otherwise marketed by the holder with her or his consent, unless such activities:
- (1) involve further propagation of the variety in question; or
 - (2) involve an export of material, for the purpose of propagation, into a country that does not protect varieties of the plant genus or species to which the variety belongs.

Compulsory Licenses

45. A person may file an application to the Competent National Authority, for grant of a compulsory license in respect of the rights conferred under this Act.
46. A compulsory license shall not be granted unless one or more of the following conditions are fulfilled, if:
- (1) it is necessary to safeguard public interest;

- (2) it is necessary due to insufficient supply of the subject variety by the rights holder;
- (3) a high proportion of the plant variety offered for sale by the right holder in Bhutan is being imported and not produced in the country; or
- (4) the right holder is not prepared to grant a license on reasonable commercial terms.

Other requirements for Granting Compulsory License

47. The Competent National Authority shall act in compliance with the general laws and regulations in granting or refusing a compulsory license. In particular, the Competent National Authority shall:

- (1) provide opportunity to the right holder to be heard and to respond to all assertions of the applicant of the compulsory license;
- (2) consult the interest groups and national professional organizations in the field concerned before granting or refusing a compulsory license.

48. Any appeal against the decision of the Competent National Authority to grant or refuse a compulsory license, or on the amount of equitable remuneration thereof, shall be brought before a court of law.

Derogation from Exceptions

49. Any private contracts that impose restrictions on the use of the material of the variety, or parts thereof, in contravention to the exceptions set out in sections 41 and 42 of this Act shall be unenforceable.

Application for Protection

50. A person may file an application for a plant variety right under this Act and the procedures of application shall be prescribed in the Rules.

Examination

51. Under the supervision of the Competent National Authority, the variety shall be examined based on the results obtained by the applicant as prescribed in the Rules.

Denomination

52. The denomination of a protected variety shall be its generic designation in a way that the variety may be identified. The denomination may consist of any suitable word, combination of words, combination of words and figures or combination of letters and figures, provided that the denomination allows the variety to be identified.

Interface with Seed Certification System

53. The rights conferred under this Act shall be separate from the measures taken by the Royal Government of Bhutan to regulate the production, certification and marketing of material of plant varieties or the importing or exporting of such material.

Interface with Patent Law

54. Notwithstanding any patent rights restricting the use of material of the variety or parts thereof, the exceptions as set out in sections 41 and 42 of this Act shall apply.

Nullity of Breeder's Right

55. The Competent National Authority shall declare a breeder's right null and void when it is established that:

- (1) the conditions laid down in sections 29 to 34 of this Act are not complied with at the time of the grant of the breeder's right; or
- (2) the breeder's right has been granted to a person who is not entitled to it.

Cancellation of Breeder's Right

56. The Competent National Authority may cancel a breeder's right, if the conditions laid down in sections 29 to 34 of this Act are no longer fulfilled.

57. The Competent National Authority may cancel a breeder's right granted, if the breeder within a prescribed period fails to:

- (1) provide the Competent National Authority with the information, documents or material deemed necessary for verifying the maintenance of the variety;
- (2) pay such fees as may be payable to keep the right in force; or

- (3) propose another suitable denomination, where the denomination of the variety is cancelled after the grant of the rights.

CHAPTER 5

ACCESS TO GENETIC RESOURCES

Access to Genetic Resources

58. Access to genetic resources shall be obtained through one of the following procedures:
 - (1) Scoping Agreement;
 - (2) Access and Benefit Sharing Agreement;
 - (3) Material Transfer Agreement; or
 - (4) Standard Material Transfer Agreement.

Access Proposal

59. A user shall submit to the National Focal Point an access proposal for access to genetic resources in the format prescribed in the Rules along with a processing fee wherever applicable.
60. The National Focal Point shall assess the access proposal against the criteria set out in the Rules and inform the user in writing of the decision taken as per the time stipulated in the Rules.

61. The National Focal Point shall determine the conditions of access based on the access proposal and intended use of the genetic resources as prescribed in the Rules.
62. An access proposal is the basis for negotiation of either a Scoping Agreement or an Access and Benefit Sharing Agreement.
63. The Competent National Authority shall have the final authority to approve or reject an access proposal to genetic resources based on the recommendation of National Focal Point.
64. The National Focal Point may submit request for exemptions from procedural requirements or a fee waiver under this Act to the Competent National Authority where the access to genetic resources is driven by national priorities and programmes.
65. The Competent National Authority shall, for the purpose of section 64 of this Act, render its decision based on the degree of benefit that may accrue to the nation in general and a community in particular.

Prior Informed Consent

66. The National Focal Point shall before entering into Scoping Agreement or Access and Benefit Sharing Agreement seek prior informed consent of the providers of genetic resources or holders of associated traditional knowledge as prescribed in the Rules.

Relationship to Other Permits

67. A Scoping Agreement, Access and Benefit Sharing Agreement, Material Transfer Agreement, or Standard Material Transfer Agreement is not a substitute for other permits or clearance required for collection of genetic resources under the relevant laws in force.
68. If a user requires a permit or clearance from other agencies, the National Focal Point may assist the user to obtain such permit before execution of a contract.
69. The National Focal Point shall, at any stage of access, determine whether there is a need to carry out resource sustainability assessment for access to genetic resources.
70. The concerned user shall bear the cost for conducting resource sustainability assessment under section 69 of this Act.

Scoping Agreement and Access and Benefit Sharing Agreement

General Procedure

71. A user obtaining access to genetic resources for commercial utilization including commercial research shall enter either directly into Access and Benefit Sharing Agreement or a Scoping Agreement followed by Access and Benefit Sharing Agreement.
72. 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.

73. The National Focal Point shall, upon completion of the negotiation, submit the outcome to the Competent National Authority for approval.
74. The Competent National Authority may recommend changes to a Scoping Agreement or Access and Benefit Sharing Agreement before its approval.
75. If the user does not agree to the changes recommended by the Competent National Authority under section 74 of this Act, the National Focal Point may further negotiate with the user.
76. The provider of genetic resources 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 in the presence of the National Focal Point.

Scoping Agreement

77. A user may obtain a Scoping Agreement for initial exploratory phase of research, and development with the aim of establishing commercial research potential.
78. A Scoping Agreement shall either be a standard contract as may be prescribed in the Rules, or a negotiated contract.
79. The existence of a Scoping Agreement shall not bind the National Focal Point to enter into an Access and Benefit Sharing Agreement.
80. A Scoping Agreement shall be conditional on the payment of a processing fee and a commitment fee as prescribed in the Rules which is non-refundable.

81. A user shall not transfer research results or accessed genetic resources to a third party without the prior written approval of the Competent National Authority.
82. 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.
83. 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 as determined in the Scoping Agreement.
84. The National Focal Point shall have ownership over the research results, accessed genetic resources, and relevant information surrendered under section 83 of this Act.

Access and Benefit Sharing Agreement

85. 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 7 of this Act.
86. Notwithstanding anything contained in section 77 of this Act, 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.

87. An Access and Benefit sharing Agreement sets out the terms and conditions for access to and utilization of genetic resources or access to and utilization of associated traditional knowledge for research or commercial purposes.
88. An Access and Benefit Sharing Agreement shall be conditional on the payment of a processing fee and a commitment fee as prescribed in the Rules which is non-refundable.
- Provided that the commitment fee shall not be payable, if the payment has been made at the scoping phase.

Certificate of Compliance

89. The Competent National Authority shall issue certificate of compliance to the user upon execution of a Scoping Agreement or Access and Benefit Sharing Agreement.
90. 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

91. A Material Transfer Agreement is a contract to ensure facilitated transfer of genetic resources.
92. 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 for the purpose of obtaining academic degree;

- (2) exchange of samples between national and international institutions for research without commercial intent;
- (3) sample testing for specific purposes as 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.

93. The National Focal Point shall determine whether a user qualifies for a Material Transfer Agreement under section 92 of this Act.

Access to Plant Genetic Resources for Food and Agriculture

94. 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 specifically for food and feed purposes 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.

95. 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.
96. If there is a reasonable ground to believe 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 subject to Access and Benefit Sharing requirements provided in this Act.
97. Plant genetic resources for food and agriculture that are held by a public collection in Bhutan or outside and not explicitly declared to be in the public domain are not covered by the Multilateral System of Access and Benefit-sharing and shall be dealt in accordance with Access and Benefit Sharing requirements.

Standard Material Transfer Agreement

98. A Standard Material Transfer Agreement is a standard contract to ensure access to plant genetic resources for food and agriculture under Multilateral System of Access and Benefit Sharing of the Treaty.

Sample Transfer Certificate

99. A sample transfer certificate as provided in the Rules 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.

100. The sample transfer certificate shall indicate the place from where the sample is collected and the destination of the sample.

CHAPTER 6

ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Documentation, Preservation, and Protection

101. The National Focal Point in order to ensure the continuity of the rich traditional knowledge associated with genetic resources shall, promote its documentation, preservation, and protection.
102. The National Focal Point shall, be the central coordinating agency for inventory, documentation and regulation of traditional knowledge associated with genetic resources.
- Provided that non-documentation of associated traditional knowledge shall not deprive the National Focal Point, local communities, or individuals holding the knowledge from entering into Access and Benefit Sharing Agreement.
103. The National Focal Point shall maintain a national database on traditional knowledge for documenting the information on traditional knowledge associated with genetic resources.
104. Any other national entity intending to inventory and document traditional knowledge associated with genetic resources shall require prior approval of the Competent National Authority on recommendation of the National focal Point.

105. The documentation of traditional knowledge associated with genetic resources shall be based on prior informed consent of the providers.
106. The National Focal Point shall ensure the protection of the rights of traditional knowledge holders and promote the utilisation and benefit sharing with the right holders.
107. Access to traditional knowledge associated with genetic resources for research and commercial utilization shall be regulated to promote fair and equitable sharing of benefits from its use.

Community Protocol

108. The National Focal Point shall support and promote communities to develop community protocols on traditional knowledge associated with genetic resources, if necessary.

Providers of Traditional Knowledge Associated with Genetic Resources

109. 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.
110. If traditional knowledge associated with genetic resources is held by more than one community, the Competent National Authority upon the recommendation of the National Focal Point shall have the right to engage any of the communities as the providers of traditional knowledge.

111. If no determination is made under sections 109 and 110 of this Act, the National Focal Point shall be deemed to be the provider of traditional knowledge.

Access to Traditional Knowledge Associated with Genetic Resources

112. A person seeking access to traditional knowledge shall submit an access proposal to the National Focal Point as per the format prescribed in the Rules.

113. Submission of access proposal for traditional knowledge associated with genetic resources shall comply with the procedures laid down under sections 59 to 65 of this Act.

Access and Benefit Sharing Agreement for Traditional Knowledge Associated with Genetic Resources

114. Access and Benefit Sharing Agreement for traditional Knowledge associated with genetic resources shall comply with procedures laid down under sections 71 to 76 and sections 85 to 88 of this Act.

CHAPTER 7

FAIR AND EQUITABLE SHARING OF BENEFITS

115. Fair and equitable sharing of benefits from commercial use of genetic resources shall be the key component of a Scoping Agreement or Access and Benefit Sharing Agreement.

116. Fair and equitable sharing of benefits from commercial use of traditional knowledge associated with genetic resources shall be the key component of an Access and Benefit Sharing Agreement.

117. 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 and associated traditional knowledge.
118. For the purpose of this Act, benefit-sharing arrangement shall comprise monetary or non-monetary benefits; or both, as may be specified in the Rules.
119. Monetary benefits arising out of research and commercial utilization of genetic resources from the state reserved forests and ex-situ collections shall be channeled into Bhutan Access and Benefit Sharing Fund.
120. A mutually agreed portion of monetary benefits arising from research and commercial utilization of genetic resources from community forest including genetic resources related to food and agriculture developed and sustained by communities shall be channelled into the Bhutan Access and Benefit Sharing Fund.
121. A mutually agreed portion of monetary benefits arising from research and commercial utilization of traditional knowledge associated with genetic resources shall be channelled into the Bhutan Access and Benefit Sharing Fund.
122. Where the National Focal Point is the provider of traditional knowledge associated with genetic resources under section 111 of this Act, monetary benefits arising from research and commercial utilization shall be channelled into Bhutan Access and Benefit Sharing Fund.

Intellectual Property Rights

123. The Access and Benefit Sharing Agreement shall stipulate the legal consequences of applying for any intellectual property rights.

124. Where there is no Access and Benefit Sharing Agreement, the application for an intellectual property right shall require the negotiation of an Access and Benefit Sharing Agreement.
125. Where no agreement is reached under section 124 of this Act, the access to genetic resources or associated traditional knowledge shall be illegal and fined as per section 157 of this Act.
126. A negotiation under section 124 of this Act shall be initiated immediately after the submission of the application for the intellectual property right.
127. A negotiation shall be finalized as soon as possible but no later than the deadline for raising objection to the grant of such right.

CHAPTER 8

BHUTAN ACCESS AND BENEFIT SHARING FUND

Bhutan Access and Benefit Sharing Fund

128. The Bhutan Access and Benefit Sharing Fund is hereby regularized into a statutory fund.
129. The National Focal Point shall administer and manage the Bhutan Access and Benefit Sharing Fund under the supervision of the Competent National Authority.

Purpose of the Fund

130. The Bhutan Access and Benefit Sharing Fund shall be used towards:

- (1) conservation and sustainable use of Bhutan's biodiversity and, or associate Traditional Knowledge; and
- (2) enhancement of rural livelihoods.

Contributions to the Fund

131. The Bhutan Access and Benefit Sharing Fund shall be from:

- (1) monetary benefits arising out of research and commercial utilization of genetic resources from the state reserved forests, and ex-situ collections;
- (2) monetary benefits arising from the research and commercial utilization of genetic resources from community forest including genetic resources related to food and agriculture developed and sustained by the communities;
- (3) 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 or during the execution of an Access and Benefit Sharing Agreement;
- (5) grants, donations or financial assistance from domestic or external sources; and
- (6) such other sources as may be determined by the Competent National Authority.

Accounts and Audit

132. Bhutan Access and Benefit Sharing Fund shall be auditable as per existing laws.

CHAPTER 9

REGISTRY, RECORDS, AND DISPOSAL

Registry

133. As per the sections 17 (2) and 17 (3) of this Act, National Focal Point shall archive genetic and biological resources information and national biodiversity database.
134. The National Focal Point shall maintain a registry containing details on access and utilization of genetic resources and associated traditional knowledge as specified in the Rules.

Records

135. A user of genetic resources or associated traditional knowledge shall maintain records of genetic resources or associated traditional knowledge accessed as specified in the Rules.
136. A copy of the records under section 135 of this Act shall be furnished to the National Focal Point within such period as specified in the Rules.
137. A person or an agency discovering a species new to the country or new to science shall register and deposit the voucher type specimens at the national repositories of the National Focal Point.

138. A person or an agency releasing a new crop variety or de-notification of the variety shall register and deposit the samples to the National Focal Point.
139. A person or an agency collecting germplasms and genetic materials of genetic resources shall deposit a sample to the national focal point.

Disposal of a Genetic Resources

140. If a user of genetic resources intends to dispose genetic resources which are accessed under this Act, the user shall unless otherwise agreed, return the accessed genetic resources to the National Focal Point.
141. Pursuant to section 140 of this Act, a user shall, if so requires, forthwith furnish evidence of the appropriate disposal of the genetic resource to the National Focal Point.

Chapter 10

MONITORING AND ENFORCEMENT

Enforcement Officers

142. The National Focal Point after the approval from the Competent National Authority shall designate relevant officials as enforcement officers for the purpose of this Act.
143. The Competent National Authority may coordinate with other relevant agencies of the Government to support the National Focal Point in the enforcement of this Act.

Confidentiality

144. An enforcement officer under this Act shall protect all information considered confidential.
145. Access to national database on traditional knowledge shall be restricted to prevent any unauthorized person from having access to traditional knowledge information considered confidential by the right holders.
146. Notwithstanding anything contained under Section 145 of this Act, the National Focal Point may periodically publish information from the national database on traditional knowledge with the objective to benefit the traditional knowledge holders.

Monitoring and Tracking

147. The Competent National Authority shall, on the recommendation of the National Focal Point, designate checkpoints for the purpose of monitoring and tracking access and utilization of genetic resource or associated traditional knowledge.
148. The National Focal Point shall cooperate with member states to ensure compliance with respective legislation of member countries relating to access to genetic resources or associated traditional knowledge.

Power of Investigation

149. An enforcement officer shall have all the powers necessary to carry out an investigation under this Act.

150. 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.
151. The National Focal Point may seek the assistance of any law enforcement agency in exercising its powers under this Act.

Access to Digital Data

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

Power to Stop, Search and Seize Conveyances

153. 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, such officer may stop and examine the conveyance at the designated check post and point of entry and exit.
154. Subject to section 152 of this Act, if an enforcement officer has reasonable grounds 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.

Power to enter, search, and seize

155. Where an enforcement officer has reasonable grounds to believe that a premise 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.
156. A warrant issued under section 155 of this Act may authorize an enforcement officer to:
- (1) search the premises 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 audio visual recording, make copies of or take extracts from any book, other article found in the premises.

CHAPTER 11

OFFENCES AND PENALTIES

Illegal Access to Genetic Resources or Associated Traditional Knowledge

157. A person who accesses or utilises genetic resources or associated traditional knowledge without executing a scoping agreement, access and benefit sharing agreement, material transfer agreement or standard material transfer agreement in accordance with the provisions of this

Act shall be liable for payment of fines and compensations as prescribed in the Rules, which shall be determined according to particular facts and circumstances.

158. Except as may be permitted under customary practice, a person who knowingly provides access to traditional knowledge associated with genetic resources to a person in contravention to the provisions of this Act shall be liable for payment of fine as prescribed in the Rules, which shall be determined according to particular facts and circumstances.

Unauthorized Transfer of Research Results

159. A user who transfers research results or accessed genetic resources to a third party for product development and commercial utilization in contravention to section 81 of this Act shall be liable for payment of fine and compensation as prescribed in the Rules, which shall be determined according to particular facts and circumstances.
160. Notwithstanding to sections 81 and 159 of this Act, research results and accessed genetic resources for academic research within the country and publication purposes shall be permitted.

Non deposition of sample and specimen of biological resources

161. Any person or an agency failing to deposit sample and specimen of biological and genetic resources as per sections 137, 138, and 139 of this Act shall be liable for payment of fine as prescribed in the Rules.

162. Pursuant to above section 161 of this Act, the sample and specimen of biological and genetic resources concerned may be surrendered to the National Focal Point.

CHAPTER 12

MISCELLANEOUS

Foreign Direct Investment

163. Activities under this Act eligible for foreign direct investment shall be dealt in accordance with the foreign direct investment laws and other relevant laws in force in Bhutan.

Protection from Liability

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

Provided that, such immunity shall not cover corrupt acts committed by the person in connection with the discharge of the official duties.

Power to Make Rules

165. The Competent National Authority shall frame Rules, consistent with the provision of this Act within 6 months from the date of coming into force.

Amendment

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

Authoritative Text

167. In any instance of a difference in meaning between the Dzongkha and the English texts of this Act, Dzongkha text shall be regarded as the authoritative.

Definitions

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

- (1) “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;
- (2) “Animal Genetic Resources” means all species, breeds, and strains that are of economic, scientific, and cultural interest, now and in the future.
- (3) “Access to genetic resources” means access to and 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;
- (4) “Access proposal” means an application seeking access to genetic resources or associated Traditional Knowledge or both;
- (5) “Access to traditional knowledge” means access to and utilization of traditional knowledge associated with biological resources for the purpose of conducting any research and commercial utilization;

- (6) “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;
- (7) “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 to support biodiversity conservation and enhancement of rural livelihood;
- (8) “Compulsory license” means the mechanism through which the Royal Government of Bhutan or any Third Party, without the consent of the owner of the intellectual property rights, and after compliance with due process is entitled to use the protected plant variety for reasons of public interest;
- (9) “Community protocol” means protocol developed by local custodians of traditional knowledge associated with biological resources through a participatory process based on customary practices 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 traditional knowledge;
- (10) “Commercial research” means research aimed towards discovering and developing marketable products;

- (11) “Commercial utilization” 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;
- (12) “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;
- (13) “Enforcement officer” includes police officer, customs officer, Bhutan Agriculture and Food Regulatory Authority officer, forest officer, and any other law enforcement officials designated by National Focal Point;
- (14) “Ex-situ conditions” means conditions where genetic resources exist outside its natural habitat;
- (15) “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;
- (16) “Genetic resources from Bhutan” means genetic resources found within the territory of Bhutan, and genetic resources taken outside Bhutan with its origin in Bhutan;

- (17) “In-situ conditions” means conditions where genetic resources exist in its natural habitat;
- (18) “National clearing house publishing authority for biodiversity information” means a platform for collecting, collating, validating, verifying, sharing, integrating and exchanging data and information on biodiversity of the country. It includes databases such as Biodiversity Portal, Bhutan Biodiversity Specimen Portal, plant and animal genetic resources and traditional knowledge.
- (19) “Plant variety” means any variety of all the plant species from Bhutan;
- (20) “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;
- (21) “Right holder” means natural or legal person who owns the intellectual property rights on a plant variety;
- (22) “Rules” means rules and regulations for the purpose of this Act;
- (23) “Sample transfer certificate” means a certificate issued to facilitate transfer of genetic resources samples under section 99 of this Act;

- (24) “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;
- (25) “Sui generis system” means a system of its own kind for the protection of plant varieties;
- (26) “Sustainable use” means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations;
- (27) “Traditional knowledge associated with biological 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;
- (28) “User” means a natural or legal person seeking access to or utilization of genetic resources or associated traditional knowledge or both;
- (29) “Utilization of genetic resources” means conducting any research or commercial utilization or both on the genetic resources.

