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## **THE BIODIVERSITY ACT OF BHUTAN, WATER SHEEP YEAR 2003**

**Royal Government of Bhutan**  
**Ministry of Agriculture**

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## **PREAMBLE**

Noting the provisions of the Convention on Biological Diversity on the sovereignty of the States over their genetic resources and the need to promote the conservation and sustainable use of these resources as well as the fair and equitable sharing of benefits arising from its utilization;

Recalling the numerous decisions of the Conferences of the Parties and other Bodies of the Convention on Biological Diversity promoting and encouraging the Parties to implement legal, administrative and policy measures to regulate access to genetic resources and benefit sharing;

Recognizing that access to genetic resources is currently unregulated in the Kingdom of Bhutan;

Realizing the value of biological and genetic resources in the development of products, compounds and substances that have medicinal, industrial and agricultural and related applications;

Whereas it is necessary to protect and encourage cultural diversity giving due value to the knowledge, innovations and practices of local communities in Bhutan;

Aware of the fundamental principle that prior informed consent and mutually agreed terms for benefit sharing shall be secured before access can take place;

The National Assembly of Bhutan hereby adopts this Act.

## CHAPTER 1

### TITLE, ENACTMENT, COMMENCEMENT, EXTENT, PURPOSE & OBJECTIVES, SCOPE AND EXEMPTIONS

#### 1. Title, Enactment, Commencement and Extent.

- a. This Act shall be called the Biodiversity Act of Bhutan, 2003.
- b. Be it enacted by the National Assembly at it's 81<sup>st</sup> session on the .... day of the .... month of the Water Sheep Year corresponding to ....day of the .... month of 2003.
- c. It shall come into force in the year of the Water Sheep Year, the .... month, the .... day, corresponding to the .... day of .... month, 2003.
- d. It shall extend to the whole of the Kingdom of Bhutan.

#### 2. Purpose and objectives

This Act shall have the following purposes and objectives:

- a. To ensure national sovereignty of the RGOB over genetic resources in accordance with relevant National and International Law.
- b. To ensure the conservation and sustainable use of the biochemical and genetic resources.
- c. To promote the equitable sharing of benefits derived from the use of genetic resources.
- d. To promote technology transfer and capacity building at the national and local levels, including the building of scientific and technological capacity relevant to the conservation and sustainable use of biological diversity.
- e. To recognize and protect Traditional Knowledge, innovation and practices of local communities associated with biodiversity.
- f. To regulate and facilitate the process by which collectors may legally obtain genetic resources.

- g. To prevent illegal access to genetic and biochemical resources and associated Traditional Knowledge.
- h. To recognize and protect the farmers' and breeder's rights.
- i. To make plant varieties subject to property rights.
- j. Ensure that plant breeders are able to recover the cost from useful improvements and innovations, and continue to do so.
- k. Provide legal recognition of varieties which are not protectable under the internationally existing patent and/or plant breeders rights laws and thereby recognize farmers' plant variety improvements and innovations and provide a means of sharing benefits derived from the use of farmers' or traditional varieties as breeding material for commercial purposes.
- l. To promote access to foreign sources of improved plant varieties to Bhutanese farmers.

### **3. Scope**

- a. This Act shall apply to all the genetic 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 Kingdom of Bhutan.
- b. The procedure and conditions provided by this Act shall apply even if the genetic resources for which access is sought are located in protected areas or government reserved forests.
- c. The provision of this Act shall apply to the Traditional Knowledge, innovation and practices associated with biodiversity.
- d. The Traditional Knowledge includes any knowledge that generally fulfills one or more of the following conditions:
  - i) Is or has been transmitted from generation to generation.
  - ii) Is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan.
  - iii) Is collectively originated and held.



#### **4. Exemptions.**

This Act shall not apply:

- a. Where the biological material is used as a commodity for the purpose of direct use or consumption as determined by the Competent Authority, based on the processes and end use of genetic resources, in accordance with the provisions of the Act.
- b. To access, use and exchange of biological and genetic resources among local communities resulting from their traditional and customary practices.
- c. To access of human genetic resources.
- d. Where the Competent Authority may determine plant and animal genetic resources access, which will be governed by Special Rules and Regulations or Conditions such as those established by multilateral systems for access and benefit sharing, especially in the case of plant genetic resources for food and agriculture, in accordance with the international law.
- e. To varieties for which patent protection is available.
- f. 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.

## CHAPTER 2

### ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING CONDITIONS OF ACCESS

#### 5. **Prior Informed Consent.**

Access covered by this Act shall be subject to the prior informed consent of the Competent Authority of Bhutan, representing national interests and the interests of the local communities harbouring, cultivating, developing and maintaining the biological diversity concerned.

In case of access to Traditional Knowledge, innovation and practices of local communities, the procedure and conditions set out in Chapter 4 and Chapter 1, Section 3 of this Act shall also apply.

In both cases, the Authorized Agency is responsible for processing the applications and monitoring the Permits granted.

#### 6. **Authorization Procedure: Application**

The applicant shall submit an application for access to the Authorized Agency in accordance with Section 7. In the event the Authorized Agency is satisfied that the application for access complies with the requirement under Section 7, such an application may be submitted to the Competent Authority to arrive at a decision to grant or refuse a permit in accordance with Sections 7 and 9.

For duly registered *ex-situ* collections the Regulations of this Act may set special procedures for access authorization.

Likewise, the requirements of this Act will be determined in a different way for commercial and for non-commercial applications.

#### 7. **Application for Access Permit**

To enable the Competent Authority to arrive at a decision to grant or refuse a permit, the applicant shall include the following information, when submitting an application for access to genetic and/or biochemical resources or associated Traditional Knowledge covered by this Act:

- a. Provide a description of the applicant including their legal status, place of residence and a list of all entities and individuals,

which will be involved in the access activities and their respective responsibilities.

- b. Describe the applicant's technical and financial capability to conduct the access activity and previous biological resource collection activities within Bhutan and elsewhere.
- c. Identify the kind of genetic and biological resources it is seeking.
- d. Identify the purpose and fields of the access activity and the purpose for which access is requested including the type and extent of research, teaching or commercial intention and use expected to be derived from it. For a different purpose, the applicant shall submit a separate application.
- e. State the potential use and anticipated benefits of the accessed material and how the results will be shared.
- f. Identify the nature of the legal rights the applicant may seek over the collected resources, derivatives of the collected resources, and innovations that are derived from those resources, including any intellectual property rights.
- g. Indicate agreement to abide by the conditions set out by the Competent Authority for collection activities. This includes appropriate arrangements with the Authorized Agency to facilitate the collection mission, including establishing provisional routes, estimated timing, types of material collected and quantities and identification of methods of collection (sampling, harvest and storage methods).
- h. The identification of the national institution or institutions, which will participate in the research
- i. Indicate agreement to bear all costs involved in collection, including participation of at least one government official of the RGOB in the collection mission.
- j. Provide information about existing or proposed contracts between the applicant and any third party relating to the use of any information and products resulting from the access activity.

- k. Provide information on the primary destination of the resources and any expected subsequent destinations of the resources.
  - l. Provide information on the arrangements made within Bhutan to facilitate the collection mission.
  - m. Indicate plans, if any, for cooperation with national institutions, scholars, scientists, students, farmers and farmer groups in Bhutan in the field mission and/or its follow-up activities.
  - n. Provide information on intended distribution of the germplasm collected and list actual or potential beneficiaries.
  - o. Demonstrate that the collection/access activity will have no negative environmental impact.
  - p. Provide information on the prior informed consent of the relevant stakeholders when necessary
  - q. The economic, social, technical, scientific, environmental or any other benefits that are intended or may be likely to be accrued to the country and an indication of the types of short, medium and long term benefits to be shared with the RGOB and other relevant stakeholders as well as the proposed mechanisms and arrangements for benefit sharing.
  - r. All information provided shall be supplied in English or Dzongkha.
  - s. An application shall be affixed with an affidavit.
- 7.1.** The applicant shall be informed in writing of the decision taken within 30 days of receipt of the application by the Competent Authority.

## **8. Confidentiality.**

The Authorized Agency shall protect all the information deemed confidential as per the Act, such as trade secrets or other forms of intellectual property rights.

## **9. Conditions for the Grant of Access.**

Competent Authority, through the Authorized Agency, may grant access if in addition to Section 10, the following minimum requirements are satisfied:

- a. The applicant agrees to bear all costs relevant to the collection, including costs of participating staff identified by the Competent Authority.
- b. The applicant agrees to deposit with the Authorized Agency duplicates of each sample collected and the associated information on collection sites of collected materials gathered from farmers' field or government forest.
- c. The applicant agrees to inform the Competent Authority, through the Authorized Agency, of all findings from subsequent research and development on the collected samples in accordance with the terms of the Material Transfer Agreement or Contract signed between both.
- d. The applicant shall not transfer the resources accessed or associated Traditional Knowledge to any third party without the authorization of the Competent Authority.
- e. The applicant shall notify the Competent Authority prior to applying for intellectual property rights relating to the collected material or intellectual property rights relating to an invention, which is based on associated Traditional Knowledge obtained in Bhutan.
- f. The applicant agrees to benefit sharing conditions negotiated in accordance with Section 10 below. These conditions shall be contained in an appropriate Material Transfer Agreement or Contract Agreement signed between the applicant and the Competent Authority.
- g. The applicant agrees to submit a full report to Authorized Agency on completion of the collection activity, including sites of collection, number of samples collected and associated information gathered.

- h. During collection, the collector should systematically record common passport data and describe plant populations, its diversity, habitat and ecology in detail.
- i. The applicant agrees that, the acquisition of germplasm must not deplete populations or farmers' seed stocks, in order to avoid genetic erosion.
- j. If appropriate, the applicant agrees to bear the cost of environmental impact assessment and abide by the Environmental Assessment Act, 2000 of Bhutan.
- k. The applicant shall abide by the relevant laws of the country, local customs, traditions and values.
- l. In addition to the requirements laid down in Section 9(a) to Section 9(k), the competent authority and the local community or person may where it is deemed necessary or appropriate require the collector to comply with additional requirements.

## **10. Conditions for benefit sharing**

Upon fulfilment of all the conditions described above, the Competent Authority may grant access if one or more, when relevant, of the following minimum conditions for benefit sharing, which are to be included in the Material Transfer Agreement or Contract Agreement to be signed between the Competent Authority and the Applicant. These conditions may also be considered in any Material Transfer Agreement or Contract Agreement to be signed between the applicant and any other relevant stakeholder.

- a. A flat fee and upfront payments.
- b. The sharing of the research results and relevant information.
- c. Royalties
- d. Milestones payments.
- e. Recognition as a partner in intellectual property ownership of products derived from the supplied material.

- f. Joint research activities.
- g. Concessionary rates or free supply of commercial products derived from the resources provided.
- h. Transfer of technologies.
- i. Training and capacity building.
- j. The acknowledgment of the origin of the genetic resources in any publication resulting from the research activities.
- k. Donation of equipment to national institutions.
- l. Other benefits, monetary or non-monetary.

10.1. The Competent Authority shall issue a Certificate of Origin, which states that, the procedures and conditions for granting access to the applicant have been met.

## CHAPTER 3

### A SUI GENERIS SYSTEM FOR THE PROTECTION OF PLANT VARIETIES

#### Part I: CONDITIONS FOR PROTECTION

#### 11. Conditions of Protection.

Plant variety protection shall be granted for plant varieties that are novel, distinct, identifiable, uniform and stable.

#### 12. Novelty.

The variety is novel if at the date of filing of the application, the material of the variety has not been sold with the consent of the applicant or her/his successor in title, for purpose of exploitation of the variety:

- a. For longer than one year for commercial varieties.
- b. In case of varieties bred and developed by farmers and only cultivated within limited areas of the country for longer than 10 years.

#### 13. Distinctness.

The plant variety is 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.

#### 14. Uniformity/ Stability/ Identifiability.

- a. Uniformity;

The variety is 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.

- b. Stability;

The variety is stable if its relevant characteristics remain sufficiently unchanged after repeated propagation.



c. Identifiability;

The variety is identifiable if it can be identified by a person skilled in the art of such identification, recognized by the Competent Authority.

**15. Certificate of Origin.**

A Certificate of Origin of the plant variety under this chapter may be required at the discretion of the Competent Authority.

**Part II: RIGHTS CONFERRED**

**16. Rights conferred.**

- a. Entitlement to the right conferred under this Chapter shall vest in the person(s) who (jointly) bred and developed the plant variety or in her/ his or their successor(s) in title.
- b. Where the person who bred and developed the plant variety is an employee, entitlement to the Right conferred under this Chapter shall be vested in the employer, unless otherwise agreed.
- c. Where an application has been filed by a person who is not entitled, the person entitled may submit a request to the Competent Authority for assignment of the application. Where the right has already been granted to the person not entitled, the person entitled may file an objection for the restitution of the title.

**17. Acts requiring the rights holder's authorization.**

The following acts in respect of material of varieties shall require the rights holder's authorization:

- a. Producing or reproducing (multiplication) for commercial marketing.
- b. Offering for sale, selling or other marketing.
- c. Exporting.
- d. Importing.
- e. Stocking for the purpose of a – d.

## **18. Exceptions to the rights conferred.**

### **a. Farming (farmers' rights)**

The Competent Authority may restrict breeder's rights in relation to plant varieties protected by these provisions in order to permit small farmers, as defined in the regulations of this Chapter or at the discretion of the Competent Authority, to propagate seed which they have harvested on their holding and to exchange that seed with others on a non-commercial basis.

### **b. Breeding (breeder's exemptions).**

The rights conferred on right holders in Section 16, shall not apply to acts done 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.

## **19. Duration of the rights**

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

## **20. Exhaustion of the rights**

The right conferred in Section 16 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/ his consent, unless such activities:

a. Involve further propagation of the variety in question.

b. 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.

## **21. Compulsory Licenses.**

Any person may, by means of an application filed to the Competent Authority, seek the grant of a Compulsory License in respect with the Rights conferred under this Act. A Compulsory License shall not be granted unless one or more of the following conditions are fulfilled:

- a. It is necessary to safeguard public interest.
- b. It is necessary due to insufficient supply by the rights holder of the subject variety.
- c. It is necessary since to high a proportion of the plant variety offered for sale by the right holder in Bhutan is being imported and not produced in the country.
- d. That the right holder is not prepared to grant a license on reasonable commercial terms.

## **22. Other requirements for granting compulsory license.**

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

- a. Offer opportunity to the right holder to be heard and to respond to all assertions of the applicant of the compulsory license.
- b. Hear interest groups and national professional organizations in the field concerned before granting or refusing a compulsory license.

**22.1.** Any decision of the Competent Authority to grant or refuse a compulsory license, or on the amount of equitable remuneration thereof, shall be subject to appeal to a court of law.

## **23. Derogation from exceptions.**

Private contracts, to the extent that they impose restrictions on the use of the material of the variety, or parts thereof, in conflict with the exceptions set out in Section 18 shall be unenforceable.

### **Part III: MISCELLANEOUS**

#### **24. Persons entitled to file applications.**

Any natural or legal person may file an application for a right considered under this Chapter.

The regulation shall set the information and requirement the application form must contain including the procedures of application.

#### **25. Examination of application.**

The variety shall undergo, under the supervision of the Competent Authority, an examination based on the results obtained by the applicant.

#### **26. Denomination.**

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.

#### **27. Interface with seed certification system.**

The Rights conferred under this Chapter shall be separate from the measures taken by the RGOB to regulate the production, certification and marketing of material of plant varieties or the importing or exporting of such material.

#### **28. Interface with patent law.**

Notwithstanding any patent rights restricting the use of material of the variety or parts thereof, the exceptions as set out in Section 18 shall apply.

#### **29. Nullity of breeder's right**

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

- a. The conditions laid down in Sections 11, 12, 13 and 14 were not complied with at the time of the grant of the breeder's right,

- b. The breeder's right has been granted to a person who is not entitled to it.

### **30. Cancellation of breeder's right**

The Competent Authority may cancel a breeder's right if the conditions laid down in Sections 11, 12, 13 and 14 are no longer fulfilled.

Furthermore, the Competent Authority may cancel a breeder's right granted by it if, after being requested to do so and within a prescribed period:

- a. The breeder fails to provide the Competent Authority with the information, documents or material deemed necessary for verifying the maintenance of the variety.
- b. The breeder fails to pay such fees as may be payable to keep his right in force.
- c. The breeder fails to propose, where the denomination of the variety is cancelled after the grant of the rights, another suitable denomination.

## CHAPTER 4

### PROTECTION OF TRADITIONAL KNOWLEDGE

#### Part I: CONDITIONS FOR PROTECTION

**31. Applicability.**

This Chapter applies to Traditional Knowledge that was in existence before the commencement of this Act or is created on or after the commencement of this Act.

**32. Customary uses.**

The customary use of Traditional Knowledge among the local communities does not give rise to any criminal or civil action for liability under this Act.

**33. Rights owners.**

The owners of Traditional Knowledge are the holders of the rights in the Traditional Knowledge.

**34. Material form not required.**

The rights exist in Traditional Knowledge whether or not the Traditional Knowledge is in material form.

**35. Duration.**

Rights conferred by this Chapter continue in force in perpetuity and are inalienable.

**36. Additional rights.**

The Rights in Traditional Knowledge are in addition to and do not affect, any rights that may subsist under any intellectual property laws.

## **Part II: PROCEDURES**

### **37. Application.**

The applicant shall obtain the prior informed consent of the traditional owners of the Traditional Knowledge for use of Traditional Knowledge for a non-customary use.

The Regulations shall set the information and requirements the application form must contain.

### **38. Appraisal of application.**

The owners of the Traditional Knowledge must decide whether:

- a. To reject the application.
- b. To accept the application and enter into negotiations for a written authorized user agreement in relation with the application containing the appropriate benefit sharing arrangements.

### **39. Proposed agreement.**

Before entering into an authorized user agreement the owners of the Traditional Knowledge must submit the proposed agreement for comments to the Competent Authority.

The Competent Authority has the final right to approve or deny the proposed user agreement based on the national interest of the country.

### **40. User agreement and prior informed consent**

If the applicant and the traditional owners enter into an authorized agreement, the owners of the Traditional Knowledge are deemed to have given their prior informed consent to the proposed use. A final copy of the agreement must be forwarded to the Competent Authority. If a copy is not provided the user agreement is null and void.

### **41. Advice of Competent Authority**

The Competent Authority, upon request, may provide advice to the owners of the Traditional Knowledge during the negotiations of the user agreement or during the processing of the access application.

#### **42. Inventory of Traditional Knowledge.**

The Authorized Agency in collaboration with the owners of the Traditional Knowledge will carry out an inventory and documentation of Traditional Knowledge. The Regulations shall set the terms and conditions for applicants for the access of the information inventoried.



## CHAPTER 5

### OFFENCES AND PENALTIES

#### 43. Offences.

The following acts shall constitute an offense under this Act.

- a. In-situ or ex-situ collection of genetic resources without access Permit.
- b. Non-compliance of conditions for grant of access as provided in Section 9.
- c. Non-compliance of the conditions for benefit sharing as provided in Section 10.
- d. Breach of confidentiality as provided in Section 8.
- e. Non-compliance with the traditional knowledge rights as provided in Chapter 4.
- f. Failure to comply with any other provisions of this Act or Regulations.

#### 43.1 Civil liability

Beside the offences mentioned in the Section 43, any violation of material terms and agreement in respect to this Act shall be treated as a breach of contract.

#### 44. Penalties

- a. Whoever,
  - i) Conducts *in-situ* or *ex-situ* collection of genetic resources without access Permit, or
  - ii) Fails to comply with or contravenes the provisions of Section 10 or Section 11, or
  - iii) Fails to comply with or contravenes with Chapter 4 of the Act, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to 3 years or with fine which shall not be less than 2 years

equivalent of the minimum daily wage rate but which may extend to 6 years equivalent of minimum daily wage rate provided in the Chathrim for wage rate and recruitment agencies and workman's compensation, 1994 or with both.

- b. The Authorized Agency shall take appropriate measures to provide for confiscation of such genetic resources collected in contravention of the provisions of this Act and impose liability on the person deemed guilty to pay damages.
- c. Where the Authorized Agency contravenes the provisions of Section 8, the Authorized Agency shall be liable to compensate for the damage caused by the contravention with a fine equivalent to the compensation paid for the damage.
- d. Whoever contravenes any of the provisions of this Act or rules and regulations issued there under, for which no penalty has been elsewhere provided under this Act, shall be punishable with imprisonment for a term which may extend to 3 months or with fine which may extend to 6 months equivalent of minimum daily wage rate as provided in Chathrim for wage rate, recruitment agencies and workman compensation, 1994.

#### **45. Revocation of access permit**

Access permits may be withdrawn by the Competent Authority under any of the following circumstances:

- a. When the collector has violated any of the provisions of this law.
- b. When the permit was obtained by providing false or misleading information under Section 8.
- c. When the collector has failed to comply with the conditions of the access permit and the Material Transfer Agreement or Contract Agreement.
- d. For reasons of public interest, including the protection of the environment and biological diversity.

**46. Determination of liability.**

The determination of liability for offences committed under this Act shall take the following factors.

- a. Magnitude of the offence.
- b. Frequency of the offence.
- c. Actual or potential impact on the plant genetic resources.
- d. Culpability of the offender.
- e. The extent of the achieved or intended economic advantage from the offence.

**47. Protection of action taken in good faith.**

No suit, prosecution or other legal proceeding shall be against the Competent Authority or the Authorized Agency or any member or employee thereof in respect of anything which is done or intended to be done in good faith in pursuance of this Act or the rules and regulations made there under.

**48. Jurisdiction.**

- a. A court of law or any specialized court or tribunal, which may be established by the RGOB having original jurisdiction shall hear the disputes under this Act.
- b. When any other law also covers the penalties for offences committed under this Act, the penalty shall be determined as per this Act.

## CHAPTER 6

### RULES AND REGULATIONS, AMENDMENTS, INTERPRETATION AND DEFINITIONS.

#### 49. Rules and regulations.

In accordance with the provisions of this Act, the Competent Authority shall have the power to formulate and adopt rules and regulations for the implementation of the Act.

#### 50. Amendments.

When necessary the National Assembly of Bhutan shall amend the Act.

#### 51. Interpretation

In case of differences, in interpretation of this Act between Dzongkha and English, the interpretation in Dzongkha text shall be final and binding.

#### 52. Definitions

In this Act, unless the context requires otherwise;

- a. Access: means obtaining, collecting, utilizing and/or exporting genetic or biochemical resources covered by this Act for purposes of conservation, research, bioprospecting or commercial use.
- b. Applicant: means a natural or legal person seeking access to genetic or biochemical resources.
- c. Authorized Agency: means the body designated as Authorized Agency by the Competent Authority under this Act.
- d. Biochemical Resources: means any material derived from plants, fungi, animals or micro-organism, which contains specific characteristics and special molecules.
- e. Bioprospecting: means 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.

- f. **Competent Authority:** means the Head of the Ministry of Agriculture of RGOB.
- g. **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
- h. **Collectors:** means 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.
- i. **Essentially derived varieties:** means varieties that are genetically similar to an existing variety, except for one or a few characters. Such a variety can, for instance, be obtained through natural or induced mutation, or a soma-clonal variant, the selection of a variant individual from plants of the original variety, resulting from back -crossing or from transformation by genetic engineering.
- j. **Genetic resources:** means any material derived from plants, animals, fungi or microorganisms which contains functional unit of heredity.
- k. **Material:** means vegetative and reproductive material for the purpose of commercial exploitation.
- l. **Plant variety:** means any variety of all the plant species found in Bhutan.
- m. **Prior informed consent:** means the procedure through which the RGOB and other stakeholders, as the case may be, properly supplied with all the relevant information, allow access to their genetic and biochemical resources or associated Traditional Knowledge, under mutually agreed terms.
- n. **RGOB:** means Royal Government of Bhutan.
- o. **Right holder:** means natural or legal person who owns the intellectual property rights on a plant variety.

- p. *Sui Generis System*: means a system of its own kind for the protection of plant varieties.
- q. Traditional Knowledge: means 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.