

तत्रुग'मी'भ्रे' श्वर रेग्राय स्वरं पठत'धिया' ५८ स्त्रुग'मानि

Biodiversity Rules and Regulations 2023

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Royal Government of Bhutan Ministry of Agriculture and Livestock

तत्रुग'मी'क्के''त्र्व'र्भगश्रुत्रेत'चठत'धिग'न्द्रिग्ग'मिले'

Biodiversity Rules and Regulations 2023



र्शे वया न्दार्श्चे र्वे न खुवावणा

ROYAL GOVERNMENT OF BHUTAN Ministry of Agriculture & Livestock Thimphu: Bhutan



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(ખે.ખેશ-રનળ વર્ફેર)

बु.यहूर्या भिजालूरकाक्ट्राक्रियानेचरायहूर्या



श्रीवयाद्यार्श्वीर्वेत्राध्यवापा

ROYAL GOVERNMENT OF BHUTAN Ministry of Agriculture & Livestock Thimphu: Bhutan



MoAL/MISC/2023/ 594

February 16, 2023

Executive Order for Implementation of Biodiversity Rules & Regulations 2023

In exercise of the power conferred under sections 14 and 165 of the Biodiversity Act of Bhutan, 2022; the Competent National Authority is pleased to issue the Biodiversity Rules and Regulations, 2023 to facilitate the effective implementation of the Biodiversity Act of Bhutan, 2022.

The Biodiversity Rules and Regulations, 2023 has been endorsed and adopted by the Competent National Authority on 13th February 2023 after thorough consultations conducted with relevant stakeholders. This Rules and Regulations will come into force from 16th February 2023 and it shall supersede all the executive orders and circulars which are inconsistent with the Act and the Rules and Regulations.

All concerned Ministries and Agencies identified by the Biodiversity Rules and Regulations 2023 shall be responsible for the implementation of these Rules and Regulations. Further, we solicit the kind support and cooperation of other Ministries, Agencies and general public for the smooth implementation of the Biodiversity Act of Bhutan, 2022 and its Rules and Regulations, 2023.

(Yeshey Penjor) Chairperson

Competent National Authority

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Definition	89

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७. पठतःभिगातिः तत्रुगागीःक्षेुःयुद्दान्देग्रसःसूतिःपठतःभिगान्दनःक्षेगाःगिद्धेः ४०४३ ठदःसःचेनः महेदःदर्गि।

यम्.चर्थ्याश्च म्राष्ट्रिया

४. परुतः ह्या १ पतः हेसः १८ समात्रम् स्वाद्यां स्वत्यां स्वाद्यां स्वाद्यां स्वाद्यां स्वाद्यां स्वाद्यां स्वाद्यां

দ্রব্দর্ভব

द. चडतः भेषा तद्भैषीया तद्भुषा भी सार्चित र्भेट्या सु खुना र्कर र्भेट्या स्थिता

न्श्रेग्रह्मःसुव्य

८. चरुतःधेमा'त्देते:द्रश्चेम्राख्यायदेः त्युमामो क्षेः ध्वतःदेम्राश्च द्रते:चरुतः विस्रसः १०११ रत्

CHAPTER 1

PRELIMINARY

Title

1. This Rules is called the Biodiversity Rules and Regulations of Bhutan, 2023.

Commencement

2. This Rules shall come into force on the 26th Day of the 12th Month of the Bhutanese Calendar corresponding to the 16th Day of the 2nd Month of 2023.

Extent

3. The Rules extend to the whole of the Kingdom of Bhutan.

Objectives

4. The objectives of this Rules is to implement the provisions of the Biodiversity Act of Bhutan, 2022.

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क्चिताःल्ट्रा क्र्यं स्वरं निरायह्में बी

- - (1) र्शेवस ५८ से वें राष्ट्रवायमा मी र्सेवर्ये हैं। है। विषदिवा
 - (४) र्शेवस'न्दर्भे र्वेर'झ्रुन'यग'गे'र्न्ट्र्टेबा द्ये'वहें सर्वेषा
 - (४) मैजालूरमायवयायात्राच्यावयास्याच्यास्यास्यास्या
 - (८) तुषःभुग्रथः नुःरम्प्तित्वे त्र्ये त्र्युक्षः भ्रीतः व्याप्यः विष्यः विषयः विषयः
 - (u) र्कें त्रवार् न र्क्कें र्वे न त्यूवायमार्विमानी र्कें त्रवायमार्थिमानी र्कें त्रवायमार्थिमानी स्वाप्तिमानी स्वापितिमानी स्वाप्तिमानी स्वापितिमानी स्वाप्तिमानी स्वापितिम
 - (७) र्श्वसाद्वास्त्री र्वेन स्वापादिनानी स्वीर्वेन त्यस्यात्व स्वीर विद्या विद्या विद्या विद्या विद्या विद्या

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- ৴ বহর দ্রীশ।
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CHAPTER 2

INSTITUTIONAL ARRANGEMENT

Competent National Authority

- 5. The Competent National Authority shall consist of the following members as per section 13 of the Act:
 - (1) Minister, the Ministry of Agriculture and Livestock, Chairperson;
 - (2) Secretary, Ministry of Agriculture and Livestock, Vice Chairperson;
 - (3) National Environment Commission, Member;
 - (4) Head, Department of Forests and Park Services, Ministry of Energy and Natural Resources, Member;
 - (5) Head, Department of Agriculture, Ministry of Agriculture and Livestock, Member;
 - (6) Head, Department of Livestock, Ministry of Agriculture and Livestock, Member; and
 - (7) Head, the National Biodiversity Centre, Member Secretary.
- 6. The concerned member specified under section 5 of this Rules shall nominate an alternate member to the Competent National Authority and the alternate member shall exercise the rights to represent the Competent National Authority.

Rules of Procedures of the Competent National Authority

- 7. The Competent National Authority shall exercise all the functions prescribed under section 14 of the Act.
- 8. In accordance with section 15 of the Act, the Competent National Authority shall:

- (1) विं ने वर्षं माने अने वर्षं अने प्रति अने
- (४) विषाप्रहें स्था की के प्राचित्र प्राचित्र
- (३) कुल र्लेट्स र्वं न्यू त्र प्रतास्त्र की के स्वीत्र में की माने के त्र की स्वीत्र स्वीत्र में स्वीत्र स्वत्
- ८. ଏଓ ଓଡ଼ିଶ୍ୟ ହୁର୍ଥ ବ୍ୟ ଅଧିକ । ଏହି । ଏହି ବ୍ୟ ଅଧିକ । ଏହି । ଏହି
- २०. तद्युक्षःश्रेतः दुन्छेदः द्युक्षःश्रेः वावद्यक्षुः त्युः स्वेकाः वर्षः त्यां प्रत्ये । वर्षः वर्षः वर्षः व प्रसुदः तप्तप्तः ने तद्युक्षःश्रेः वावद्यक्षः त्युः स्वेकाः वर्षः प्रवेषः वर्षः वर्षः वर्षः वर्षः प्रवाद्यः व न्या
- १७१. विषायहूं श्रमायदे. क्रुमां चरमान्यां रि.शु. रेटायह्मिताः हे.शू. म्यू. व्याप्त स्वाप्त स्
- ୨૧. તક્ષુષાશ્રેતે કુંન્દ્રેત શુંષા લાગ તર્દેશમાં શું કેષા શું કું શાન્ય સ્ટેર વર્ષે તાન ના સ્ટેર્યોના વિધાન કે માના માના માના કું તક્ષ્યા સામા કર્યો છે. તેમ સામાન સામાન સામાન સામાન સ્ટેર્યોના સામાન સ્ટેર્યોના સામાન સ્ટેર્ય કું માના સામાન સામાન
- ७५. તદ્યુષાઐતૈઃકું ન છે વાયા વહેં અથા ભૂ નું માં જે વાયા ભૂ નું માં તાલું નું ના તાલું ના તા
- ગત પટ્ટી. પટ્ટી. પ્રજ્ઞાનમાં મુંબા. ભૂપત્રા. મુંચા. મુંચા. મુંચા. મુંચા. પ્રજ્ઞા. પ્રજ્યા. પ્રજ્યા. પ્રજ્ઞા. પ્રજ્ઞા. પ્રજ્ઞા.

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१८. चरुतः ह्येशः क्वियः पेट्(८) यतः दर्षे न्याः देवः दरः व्यव्यः क्वियः क्वियः व्यवः विवाधः क्वियः विवाधः व्यवः विवाधः व

- (1) Meet biannually and as and when required.
- (2) The meeting shall require a minimum quorum of two-third members.
- (3) The decision of the Competent National Authority shall be based on simple majority.
- 9. The Chairperson may authorize the Vice Chairperson to conduct the meeting, if the Chairperson is not available for meeting on the scheduled date.
- 10. The Member Secretary shall prepare an annual schedule of meeting in consultation with the Chairperson and share it with the members at the beginning of the financial year.
- 11. The meeting shall be conducted as per the schedule except in inevitable circumstances where the Chairperson has altered the meeting date.
- 12. The Member Secretary shall provide prior information within five working days to the members for any change in the meeting schedule.
- 13. The Member Secretary shall circulate the agenda and related documents for the meeting prior to five working days from the date of meeting.
- 14. The Member Secretary shall keep record of all the proceedings of the meeting and maintain proper documentation including signed copy of resolution.
- 15. The Member Secretary may propose for an ad-hoc meeting to the Competent National Authority when it has received an access proposal that requires immediate intervention.

Directives to the National Focal Point

16. In accordance with section 14 (4) of the Act, the Competent National Authority shall provide policy directives to the National Focal Point on the implementation of the Act and its Rules.

क्वुवार्धेरशर्रेक्याम्र्डे उदा

 7^{10} . 18 માં મુંભાર્ષે માર્જે ક્રાં મુંજ માર્જે ક્રાં મુંજ માર્જે માર્જ

क्विताल्ट्याम्बर्यासून्द्रियान्तर्मे वार्षा

१५. चडतः विस्त्र श्री दें तं क्वर ११० (१) धति द्वी द्रश् दें द्र द्र द्रविशः क्वर विस्त्र श्री दें तं क्वर श्री द्रश् विस्त्र श्री द्रश् विस्त्र हें तं द्रियः क्षेत्र स्त्र विस्त्र हें तं विस्त्र हें तं विद्रश् क्षेत्र स्त्र विस्त्र हें तं विद्रश हैं ते विद्रश हैं तं विद्रश हैं ते विद्रश हैं तं विद्रश हैं ते विद्रश हैं ते

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- (४) क्विलार्लेट्सार्कन्य्वरन्यन्यदेवर्न्नः क्विलार्लेट्सार्ट्स्वनाम्वर्षः ठवार्सुः मीपन्यन्ते व
- (व) कृ.मूर्ट-प्रसूर्यम्बर्ट-प्रसूर्यम्बर्ट-प्रमुख्यम्बर्धः स्वर्यम्बर्धः स्वर्यम्
- (८) यदेवार्श्वेराप्तायनेवाप्त्रीयाः क्ष्याः श्वेपार्श्वेपायन्यवाप्त्रीयम् विष्
- (प) तत्तुगागी क्षेष्ट्रे स्वाया स्वेती प्रत्या तत्त्रेया या क्षेष्ट्र स्वाया स्वेती प्रत्या स्वाया स्वया स्वाया स्
- (७) र्यायाक्षियार्म्यत्यार्थित्यार्थित्यार्थित्यार्थित्यार्थित्या
- (व) वाम्ववसायदेग्वहार्देवा

National Focal Point

17. The National Biodiversity Centre shall be the National Focal Point and carry out the functions specified in section 17 of the Act.

National Clearing House Publishing Authority

- 18. In accordance with section 17 (2) of the Act, the National Focal Point as a clearing house publishing authority shall publish the information related to access and benefit sharing at the Access and Benefit Sharing Clearing House through online platforms.
- 19. The National Focal Point shall share the information upon approval of the Competent National Authority.
- 20. The National Focal Point under section 19 of this Rules shall share the following information on:
 - (1) Legislative, administrative and policy measures on access and benefit sharing;
 - (2) Information on the Competent National Authority and National Focal Point;
 - (3) Details on compliance document including Prior Informed Consent, Mutually Agreed Terms, Convention on International Trade in Endangered Species permit, Standard Material Transfer Agreement, subject matter of genetic resources, utilization and conditions on third-party transfer;
 - (4) Information on access and benefit sharing checkpoints;
 - (5) Information on Bhutan Biodiversity Portal and Clearing House Mechanism;
 - (6) Methods and tools developed to monitor genetic resources; and
 - (7) Non-compliance information

मुवार्धेरशयर्डेवायर्हेगा

- २१. चरुतः ह्येश्वरः क्ष्यः प्रदेशः वाल्यः श्रीः भ्रवः भ्रवः प्रदेशः पर्देशः प्रदेशः व्यव्याः स्वायः स्वायः स्व स्यः स्वायः प्रवेशः स्वायः स्वयः स्वयः
- 44. मुलिर्ल्स्स्रेन्स्य न्यू क्षित्र हुँ निक्ष्य हुँ स्वर्ष्ट्र स्वर्ण्य स्वर्ण स्वर्ण्य स्वर्ण स्वर्ण्य स्वर्ण्य स्वर्ण स्वर्ण्य स्वर्ण स्

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- ४३. चरुतः विस्रशः भुः देव र्क्षतः १००(१४) धतः द्वे छो दर्ग द्वे द्वाद्य द्वाद्य द्वाद्य विष्यः क्षुः व्यव्य द्वे व्यव्य द्वे व्यव्य विष्यः क्षुः व्यव्य द्वे व्यव्य द्वे व्यव्य विष्यः क्षुः व्यव्य विष्यः विषयः वि
- ५८. ब्रिस्माश्वरक्की स्त्रः स्वर्धान्य स्वर्धान्य स्वर्धान्य स्वर्धान्य स्वर्धः स्वरं स्वर्धः स्वरं स

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National Repository

- 21. In accordance with section 17 (3) of the Act, the National Focal Point shall be the repository for plant and animal gene bank, traditional knowledge associated with biological resources, national herbarium, ex-situ living plant collection, fungi, microbial and invertebrate genetic resources and other biological resources.
- 22. The National Focal Point shall identify relevant agencies dealing with the traditional knowledge associated with biological resources for documentation, preservation and the identified relevant agency shall share a copy of the documentation to National Focal Point for maintaining record in the national repository.

Taxonomy and systematic study of biodiversity

- 23. In accordance with section 17 (12) of the Act, the National Focal Point shall conduct and facilitate taxonomic and systematic studies on biodiversity in collaboration with relevant stakeholders.
- 24. Any legal or natural person conducting taxonomic and systematic studies on biodiversity shall submit the information and specimens thereof to the National Focal Point to be maintained in the National Repository.

Reporting of offense

25. The National Focal Point shall compile an offense record received from the enforcement officers designated under section 127 of this Rules and submit the report to the Competent National Authority annually.

२७. चरुतः विस्रसं मुः देवः क्व. १०(१५) यदैः दर्गे दसं देवः दर्गविषः मुषः र्षेदः स्वः वर्षेः रुवः वर्षे वर्षः मुषः र्षेदः स्वः वर्षेः वर्षः वर्षे वर्षः स्वः वर्षे वर्षः वर्षे वर्षे

National Biodiversity Strategies and Action Plan

26. In accordance with section 17 (15) of the Act, the National Focal Point shall coordinate implementation of the National Biodiversity Strategies and Action Plan.

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७बबःशुर्द्ररम्युवःचहवःर्षेगःशुःर्श्वेरःदी

रत्यत्वेद्वासार्वेदसायसास्रेदासीक्षसासुत्

- (1) यम्रेयः १ अवसः श्रुप्तान द्वेतः देवः वान्यान्य वान्यः वान्यः
 - (ग) मुत्राश्चे. लट.व. मैल.लूटम.मु.१४ शका.सैट.मवका.प्रथा.पट. रचका.कट.पुतरे.१४ पा.२४.
 - (म) र्केटप्रचेयां विपायर्केया दर्गेटप्रसेया मुःर्ने दायुः र्वस्थाय स्वाप्त स्त
- (१) रेग्यामुन्यार्ह्नायरार्ने वास्य
 - (ग) वंबदादधुराद्दावसावदुरादेवासूरा
 - (प) र्ष्ट्र-ख़्रिंग.जू.सूचा.२८. श्रुशश.२४.कु.५४४४.थेंट.
 - (म) प्रन्यासेन्द्रस्यार्स्युन्यतः रेग्यास्यूतः कुस्रसः सुन्
 - (८) अःग्रवसःग्रीःदेग्रसःस्रुतःकुस्रसःसुदा
 - (७) सःस्पःर्श्वेषाःकषायः ५८ः ५वः यदः देषायः ५वयः शुरा

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- - (१) ख्रनःक्रेब्रःक्ष्मः ख्रेतः रेग्रमः स्रूं र्द्धः धेगाः र्वेगः पर्गितः वितः तर्गे। तर्देवः तर्वाः पर्वा

CHAPTER 3

CONSERVATION AND SUSTAINABLE USE

Ex-situ conservation

- 27. In accordance with section 22 of the Act, the National Focal Point shall prioritize species for:
 - (1) Live ex-situ conservation in consultation with relevant agencies based on the following criteria:
 - (a) Global or national conservation status of threatened species; or
 - (b) Species potential for research and development at commercial scale.
 - (2) Gene bank for:
 - (a) Food and nutrition security;
 - (b) Conservation of traditional varieties of crops and local breeds of animal;
 - (c) Conservation of neglected and under-utilized species;
 - (d) Conservation of native species; or
 - (e) Conservation of microbes and fungi.

Invasive alien species

- 28. In accordance with section 23 of the Act, the National Focal Point shall in consultation with relevant stakeholders:
 - (1) Coordinate documentation of invasive alien species;

- (४) ख्रिनःक्रेब्र-इब्र-क्रीःक्षेत्रेन्द्रम्बरःक्षुःबीःर्न्बर्त्तः क्रुतःवर्षःव्यव्यव्यव्यव्यक्षेत्रः र्नोयः र्
- (4) ख्रिंच हेर् च्रे के क्रिंच के क्रिंच के क्रिंच क्रिंच
- વહું ન ને ક્ષેત્ર ક્ષેત્ર ને ક્ષેત્ર હો કર્યા કરા કર્યા કર્યા કર્યા કર્યા કર્યા કર્યા કર

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- - (१) व्यायार्थ्यः न्यायात्र्वे त्रायुः क्षेत्रः क्षेत्रः क्षेत्रः क्षेत्रः व्यायात्रः व्यायायः व्यायायः व्यायायः व्यायायः व्यायायः व्यायः व्यायायः व्यायायः व्यायः व्यायः
- कृति प्रत्यः क्रियं क्ष्यः व्यापा न्यापा न्यापा न्यापा न्यापा न्यापा क्ष्यः विद्याप्त क्ष्यः क्ष्यः विद्याप्त विद्याप्त क्ष्यः विद्याप्त विद्यापत विद्याप्त विद्यापत विद्य विद्यापत विद्यापत विद्यापत विद्यापत विद्यापत विद्य विद्यापत विद्य विद्यापत व

- (2) Develop national management strategies for invasive alien species; and
- (3) Publish and share a list of invasive alien species with pictorial guide and identification description to regulatory authorities for prohibition from import annually or as and when required.
- 29. The enforcement officers at the first point of entry shall upon detection of invasive alien species, forward to the relevant regulatory authority as per the guideline and standard operating procedure. In the event, the regulatory authority or enforcement officer is not able to identify the species, it shall seek the support of the National Focal Point for accurate identification.

Restricted genetic resources

- 30. In accordance with section 26 of the Act, genetic resources of the species:
 - (1) Listed under Schedule I of the Forest and Nature conservation laws shall not be accessed except for scientific research to promote conservation; and
 - (2) Listed under Schedule II and III of the Forest and Nature Conservation laws shall be accessed for scientific research to promote conservation; or commercial utilization with exception to wild fauna.
- 31. In accordance with section 27 and 28 of the Act, notwithstanding the prevailing customary practice, the Competent National Authority may, on the recommendation of the National Focal Point, grant or limit or restrict access to genetic resources for national importance to:

- (१) रनमः कर्त्वेदेः क्षेत्रायः उत् क्षेत्रे रीषामञ्चादे रीषामञ्चाद्वेत्र वित्रावित्रमः क्ष्यमः श्रुरः यन रात्वी
- गलव'गरऱ्रा

- (1) Conserve genetic resources of threatened species;
- (2) Utilize genetic resources of high economic value; or
- (3) Any other situation considered as necessary by the Competent National Authority.

जेतु ६ म

ર્ક્સન્સ ક્રિયાના શે. શેન્સ્સેન્સ ફ્રિયાના સર્થેન્સ ક્રિયાના લેવાના ક્રિયાના સ્થિત ક્રિયાના ક્રિયા

नहगाः दिना

- ત્ર્ય. મુખ્ય ખેત્ર મેં ત્રંત્ર માર્જે સ્વરમું માર્જે ત્ર સ્વર્થ માર્જે ત્ર સ્વર્થ માર્જે મ
- द्र. र्क्ट्रियः दर्मे त्रियः श्री प्रमुवा त्रियः प्रमुवः वाम्ययः वाम्ययः प्रमुवः प्रमुवः व्यवसः व्यवसः विद्यसः विद
 - (१) धेमार्झमानर्गेत्त्री
 - (४) अ'र्विरअ'द्यर'यहण'त्वेय'त्यर'द्दी
 - (३) र्बे:विरःक्षेत्र्यः कर्पः प्रदानुष्यः विदान्ते । विदान्ते ।
 - (८) यहमालेया भी देवास प्राप्त प्रमुख प्रमुख

क्चित्रातम्या की र्ने वासुर्ग में अ

CHAPTER 4

A SUI GENERIS SYSTEM FOR THE PROTECTION OF PLANT VARIETIES

Application Procedure for Plant Variety Protection

32. Any applicant may file an application for plant variety right protection to the National Focal Point as per the format prescribed in Form I of this Rules.

Examination

- 33. The National Focal Point shall assess the application to examine the variety through conduct of examination for the criteria specified under section 30 to 34 of the Act in collaboration with relevant agencies.
- 34. The examination of the plant variety shall be conducted based on the following methods:
 - 1) Documentation;
 - 2) On-site inspection;
 - 3) Growing test; or
 - 4) Any other methods relevant for examination.
- 35. The National Focal Point shall develop standards and technical guidelines for the examination methods prescribed under section 33 and 34 of this Rules

Publication for Opposition

36. The National Focal Point shall publish the results of the test carried out under section 33 and 34 of this Rules in the public domain for validation of the variety protection for 90 days as per the format prescribed in Form II of this Rules.

- ४७. म्या स्त्रीतः द्रो सुर्वायन प्येत्यति स्तरि सुनाय स्त्रीत् स्

र्के.चैरन्त्राक्र्यांत्राक्री.क्र्यंत्राचित्राचे

- ઋત. મુત્ય પ્લૅન્સ મેં ઇન નાર્કે ક્રિયા મું જેવાલું ૧૮ તાલી ભાગે મુત્ય પ્લૅન્સ ઇન વિદ્યાન કે ક્રિયા મું સ્થિત પ્લેન્સ મું સ્થિત પ્લેન પ્લેન્સ મું સ્થિત પ્લે
- ८०. क्चुत्यः पॅर्ट्स क्ष्यः क्षयः क्ष्यः क्ष्यः क्षयः क्ष्यः क्षयः क्ष्यः क्षः क्ष्यः क्ष्यः क्ष्यः क्ष्यः क्ष्यः क्ष्यः क्ष्यः क्ष्यः
- र्यर्यहूष्यंति, अष्ट्र.यर्थियान्त्रात्यर्य्यूय्या ययर्त्यूर्त्रत्युःखे.यःग्रीरः जै.र्थेशःश्चेषःग्राच्यः ३० क्वी.षरःयपूर्यःजी क्वीयःलूर्यःक्ट्राज्ञेषः ९७. क्र्रंत्वेरःब्रे.क्र्यावान्त्रीःखे.ल्यान्त्रियःश्चाच्यः क्वीयःलूर्यःस्यान्त्र्यःक्ष्यःचक्चिरःदेः क्वीयःयर्ट्षयः

श्रीत्मक्षूत्रावर्ष्ट्रभाग्नीः लु प्याप्ता यात्रप्ता श्रीत्मात्र्व्यानी स्वाप्ता स्वापता स्वाप्ता स्वापता स्वापत

- ૯૧. શે દેશ માર સુર કે મા મા મહત લે અશ છે દેવ હતા વર્ષ ધારા કર્યા હતા હતા. કે દેશ માર સુર કે મા મા મહત લે હતા હતા હતા. કે દેશ માર સુર કે મા માર કે સ્ટાર્ગ હતા હતા. કે દેશ માર કે મા કે માર કે મા કે માર કે મ
- ८३. मुल्यं र्स्यन्यार्डे उत्युक्तः तुः धेवा सुल्यं प्रति कुत्रसं त्या सुल्यं प्रति सुल्यं क्ष्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्षयं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्षयं सुल्यं क्ष्यं सुल्यं क्ष्यं सुल्यं क्षयं सुल्यं सुल्यं
- च्याया त्राप्त्र त्राप्त्र क्षेत्र च्या त्राप्त्र क्षेत्र च्या क्षेत्र क्षेत्र च्या क्षेत्र क्षेत्र च्या क्षेत्र क्षेत्र च्या क्षेत्र क्षेत

- 37. In the event of any opposition to the published results, the National Focal Point shall carry out the reassessment on the assignment of the right.
- 38. The National Focal Point shall submit the assessment results to the Competent National Authority for grant of the variety right if no opposition is made on the result.

Grant or Rejection of Plant Variety Right

- 39. The Competent National Authority shall grant certificate of registration of plant variety right based on the report of the National Focal Point and inform the applicant accordingly.
- 40. The Competent National Authority may reject protection for plant variety based on the assessment report of the National Focal Point and inform the applicant accordingly.
- 41. The applicant may appeal to the Competent National Authority through National Focal Point in the event of rejection within 10 working days of the issuance of the decision.

Assignment of Application or Restitution of the Title

- 42. Any person intending to file for reassignment or restitution of the title of variety rights under section 38 and 39 of the Act, respectively, shall be filed to the National Focal Point as per the format prescribed in Form II of this Rules.
- 43. The National Focal Point shall submit the report of assessment on the reassignment or restitution of title within 30 working days from the date of receipt of the application to the Competent National Authority.
- 44. The Competent National Authority shall conduct a meeting within five working days from the date of submission of the report by National Focal Point to reassign or restitute the title of variety right based on the assessment report of the National Focal Point.

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६५. तुं प्रेमांस्याक्षेत्रीयः रेम्याक्षेत्रेविनंद्वरम्भैराम्बेर्टात्वर्मे प्रित्रात्वर् व्यान्ति । विद्यान्ति । विद्यानिक । विद्

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८७. पठतं धेर्मे में ने दें ब र्क्ष के प्रते दें प्रते प

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- - (१) लॅ.नक्षेत्रःबिर्ह्मयं.ज्ञ्.ह्मगी ल्. ४ लका ५ थर. क्र्यामञ्जारी
 - (४) सुत्र गत्र अ है नि न र्थे । यथ ११५ वर कर गडिगा
- ५०. देन्य श्रेया श्रे क्या क्या या क्या प्रत्य क्षेत्र क्षेत्र क्षेत्र प्रत्य क्षेत्र क्

Variety Rights Registration Certificate Renewal

45. The applicant shall be required to renew the variety rights certificate after five years of the grant of the certificate with payment of Nu. 500 as renewal fee except for farmers.

Lapse of rights protection

46. In the event the applicant fails to renew the variety rights certificate as per section 45 of this Rules, the rights protection will lapse automatically.

Cancellation of Breeders Right

- 47. The National Focal Point shall monitor the variety protection granted as per the purity maintenance and breeding standards. In the event of non-compliance to the standards, the Competent National Authority shall cancel the breeders right based on the recommendation of the National Focal Point.
- 48. The National Focal Point shall carry out the monitoring of the protected plant variety based on the following prescription:
 - (1) Biannual crops: Once in three to five years; and
 - (2) Perennial crops: Once in five to 15 years.
- 49. The Competent National Authority shall notify the breeder on the decision of the cancellation along with the monitoring report within two working days from the date of the meeting, if there is cancellation in accordance with section 47 of this Rules
- 50. The breeder may appeal to the Competent National Authority within 10 working days from the date of issue or cancellation of the breeders rights by the Competent National Authority.

पर्चैट.पिटश्र.ग्री.जबी.प्रीरी

- - (१) श्रॅब रेग्नश ग्री त्युर तिरुष रेश गृहत पर्वे प्पेर्या
 - (४) क्वित्यः पॅरसः र्रें क्वं या स्रें रुद्धा क्वें स्वरं क्वें या स्रों स्वरं स्वरं
 - (4) मुलर्लेन्सर्ज्यम् वर्षः क्वान्त्रे क्वान्त्रे स्वान्त्र स्वान

Certificate of Origin

- 51. The National Focal Point may issue the certificate of origin of the plant variety on the instruction of Competent National Authority upon fulfillment of the following:
 - (1) Determination of the source of seed variety;
 - (2) Documentation of the variety by the National Focal Point; and
 - (3) Validation of information on the variety by the National Focal Point from the relevant agencies.

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५३. वंडतः ब्रिस्मा ग्रीं देवा क्ष्या प्राप्त वित्या क्ष्या प्राप्त क्ष्या प्राप्त क्ष्या क्ष

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- ५८. चरुतः विश्वश्रः शुः र्नेत्रः र्कतः प्रतः प्रतः प्रतः प्रतः प्रतः प्रवेतः प्रतः प्रवेतः प्रतः प्रवेतः प्रवेतः प्रवेतः प्रतः प्रवेतः प्रवेत
 - (१) मायाश्चेतः लुःधिमासुत्यासीयदिः सुत्याश्चेतिः दें पंजी समास्त्रीतः स्वा

 - ्व) मुलावनःर्ष्,मुन्दर्व, बुट्सुंग्रथःर्षुर्वः व्यव्यानः ५००.०० द्व्मा

CHAPTER 5

ACCESS TO GENETIC RESOURCES

Application for access to genetic resources

52. Access to genetic resources shall be obtained through one of the procedures specified in section 58 of the Act.

Access Proposal

53. In accordance with section 59 of the Act, an applicant shall submit an access proposal to the National Focal Point in the format prescribed in Form III of this Rules.

Processing fees

- 54. In accordance with sections 59 and 88 of the Act, the applicant shall make non-refundable payment as application processing fee during the submission of access proposal to grant access to genetic resources and actualization phase to the National Focal Point as follows:
 - (1) 500.00 US Dollars, if an applicant is an international entity; or
 - (2) Equivalent fee in Ngultrum calculated at prevailing US Dollar exchange rate on the day of application by Bhutanese entity; or
 - (3) Any currency agreed in bilateral trade agreements between countries at the equivalent fee of 500.00 US Dollar.
- 55. The applicant intending to access genetic resources through Material Transfer Agreement and Standard Material Transfer Agreement shall be exempted from payment of the processing fee.

- चुःन्रेअःचुःतद्युअःर्श्वेन्त्रेन्यः ५० यतःनूर्वेन्यःर्न्वान्यः कुषःर्थः कुषःर्थः कुषःर्थः विन्यः कुषः विन्यः कुषः विन्यः कुष्यः विन्यः कुषः विन्यः कुष्यः विन्यः कुष्यः विन्यः कुष्यः विन्यः विन्यः कुष्यः विन्यः व
- (१) र्वेतःश्चेंर्-१८-१ते स्वर् नर्गे न्यवर तर्रे मुव्यः व्यर्भन्य मुद्द्यः मुद्द्यः
- (4) ब्रन्यास्य प्राणा विषय त्या क्षेत्र क्षेत्र क्षेत्र क्षेत्र त्या क्षेत्र त्या

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- ५७. कुलार्लेन्सार्ट्रक्वामुई उत्राम्चीसा विचार्सुद्वाम्य विचार्म्य विचार्म विचार्म्य विचार्म विचार्म्य विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचारम्य विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्य विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्म विचार्य विचार्म विचार्य विचार्म विचार्म विचार विचार्म विचार्म विचार्य विचार विचार्य विचार्म व
- स्यः चरुतः विस्रक्षः भी देव क्षेतः त्यन् द्वी न्यायन द्वी न्याय क्षेत्रः कष्टेतः कष्
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- 56. In accordance with section 64 of the Act, the National Focal Point may recommend exemption from payment of processing fee to the Competent National Authority for access to genetic resources in a situation:
 - (1) Where Access and Benefit Sharing is only option for economic revival at national level; or
 - (2) Where genetic resources are used for countering pandemic.

Review of Access Proposal

- 57. The National Focal Point shall conduct preliminary resource assessment of particular genetic resources in consultation with the relevant stakeholders upon receipt of application for grant of access.
- 58. In accordance with section 60 of the Act, the National Focal Point shall review access proposals to ensure completeness of an access application and make an assessment of the access proposal as per the guidelines for assessment.
- 59. The National Focal Point shall submit the assessment report to the Competent National Authority for approval or rejection.
- 60. In accordance with section 60 and 61 of the Act, the National Focal Point upon assessment of access proposal and based on the intended use of genetic resources provide recommendation to the user on suitable access procedures from the options specified under section 58 of the Act within five working days from the date of receipt of an application.
- 61. In accordance with section 63 of the Act, the Competent National Authority based on the recommendation of the National Focal Point may approve or reject the access to genetic resources, and the National Focal Point shall communicate the decision within five working days of the Competent National Authority meeting.

শূর্ণীনমন্ব দেইবিশারনমা

८१. चडतः विश्वश्रः श्रें देवं क्वतः ५८ यदि दर्गे दशदे द्वाद्वर दिवा क्वारे क्वरः विश्वश्यः विश्वरं वि

(१) मुलावस्य ग्रै खुरर्भे त्वाया क्या के वाया के वाया क्या के वाया क

(४) क्रु-२र्देशर्श्वे पशुर्वित्वर्वे त्रित्वे त्रिते त्रित्वे त्रिते त्रिते त्रित्वे त्रित्वे त्रित्वे त्रित्वे त्रित्वे त्रित्व

(4) क्रुं'न्द्रं स्थार्श्वे प्यत्न द्वेतिः द्वेत् त्यः त्वुषा प्यव्यः स्थान्यः स्थानः स्थान्यः स्थानः स्थानः स्थान्यः स्यान्यः स्थान्यः स्थानः स्थान्यः स्थानः स्यानः स्थानः स्थान

(८) ब्रिस्मान्ध्र क्री नर्ग्सास स्वार्य प्रमुद्ध प्राप्त क्ष्य प्रमुद्ध क्षेत्र क्षेत

र्वेद'तुरस'सुद'नहद'र्न्चे'लेग

- ८० चरुतः विश्वश्रः श्री देवा क्षवः । ५० चरिः द्र्ये द्रश्यः द्रवः द्रवः व्यवश्रः व
 - (१) र्वेत्रः सुरुषः स्पूर्यः सेर्या
 - (४) यशस्त्रते के कुरद्र र वरत्र (य.स. विरश्ची के कुर्
 - (३) श्वे खुर रेग्य श्वर धुर धुर व न व रे

Prior Informed Consent

62. In accordance with section 66 of the Act, the National Focal Point shall seek Prior Informed Consent of the providers of genetic resources or holders of associated traditional knowledge in the format prescribed in Form IV of this Rules.

Relationship with other Permits

- 63. In accordance with sections 67 and 68 of the Act, the National Focal Point may assist the User to obtain the following permits or clearance, where applicable:
 - (1) Clearance or permit from the Department of Forests and Park Services for collection of genetic resources from the State Reserved Forest Land;
 - (2) Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permit for transfer of materials;
 - (3) Phytosanitary or Zoosanitary certificate from the Bhutan Food and Drug Authority for transfer of materials;
 - (4) Any other clearance or permit as may be required with change in legal requirement.

Resource Sustainability Assessment

- 64. In accordance with section 69 of the Act, the National Focal Point shall carry out resource sustainability assessment in consultation with the relevant stakeholders if there is a need to carry out such assessment, interalia on the following:
 - (1) Availability of the resource;
 - (2) Magnitude of the activity and size of the intervention area;
 - (3) Impacts on biological diversity;

- (८) अञ्चतःतर्वेदःग्वदशःश्रूदशःशुः सदःगर्वेद।
- ७५. चरुतः ब्रिस्स ग्रीः र्ने त्र क्व. २० मदिः नुर्वे न्सः र्ने तः नृष्टः व्यविषः क्वें न्से क्वें व्यविषः नुर्वे व्यविषः निष्टे व्यविषः निष्टे व्यविषः निष्टे व्यविषः निष्टे व्यविषः निष्टे व्यविष्टे व्यविष्टः विष्टे व्यविष्टः विष्टे व्यविष्टः विष्टे व्यविष्टः विष्टे विष्टे व्यविष्टः विष्टे विष्ट

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હેહ. ફ્રેંડ્ર-સે-ર્સ્ જેને સ્ટ્રિક્ડ્ર-જે-માત્ર માત્ર માત્ય

क्र्य-रन्तरः वायः क्रा

- ८४. चङ्क्षः चिश्रश्रः चुन्द्रक्ष्यः भूरं सदीन् में स्थान्त्रे स्थान्त्रः स्थान्तः स्थान्त्रः स्थान्तः स्थान्तः स्थान्तः स्थान्त्रः स्थान्त्रः स्थान्त्रः स्यान्तः स्थान्तः स्थान्यः स्थान्तः स
- ८०. र्बेर, नेन्नेन प्रमुख्य के पानी र्वेष प्रमुख्य के प्रमुख्य के
- २०. चरुतः त्रिस्त्राः केंद्र्वं क्वं ५१ पत्रे न् व्यन् ने वित्राः केंद्र्यः क्वं व्यन् केंद्र्यः क्वं व्यन् केंद्र्यः केंद्र्

- (4) Environmental impacts;
- (5) Such other matters as the National Focal Point may consider necessary.
- 65. In accordance with section 70 of the Act, the User shall pay the actual cost for the conduct of assessment.

General Procedure

66. The User shall comply with the general procedures prescribed under section 71 to section 76 of the Act to enter into Scoping Agreement or Access and Benefit Sharing Agreement.

Scoping Agreement

- 67. In accordance with sections 17 (5) and 77 of the Act, the National Focal Point on behalf of the providers of genetic resources shall, upon the approval of the negotiated terms by the Competent National Authority, execute a Scoping Agreement with the User for the initial exploratory research.
- 68. In accordance with section 78 of the Act, the National Focal Point and users shall execute Standard Scoping Agreement as prescribed in Form V or negotiated contract.
- 69. The User shall be granted access to a maximum of one genetic resource under one Scoping Agreement. In the event, there is a request for more than one genetic resource, it shall be approved by the Competent National Authority.
- 70. In accordance with section 82 of the Act, a User shall submit a third-party access proposal in the format prescribed in Form VI for negotiating an Access Benefit Sharing Agreement, upon approval from the Competent National Authority; if a third-party intends to undertake product development or commercial activities.

यबाय.जुय.बी.पर्श्वश्री

(१) योजासुर. खे.लुयो.सेजा.सु.पर्ट. मैजा.मुैद्ध्रां सू.स्रम.स.कुर. ली.स्रम.प्र.जर.

(૧) માતાસુર. લે.ભુમાં સંળામું. તર્કા, તર્ચમાં મુંદાશ્રુષ મોંગાસું. પેરંગામાં સંગામ કે. પેરંગામાં સંગામ કે. તર્ચમાં સંગામ કે. તર્યામ કે. તર્ચમાં સંગામ કે. ત

(व) मैलायन र्थ्, मी. पराय. बेट हुँ मेश कूँ र प्रमुल ग्वाय क्रा में १०००.०० स्मा

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क्र्. क्षेत्रः कष्टे कष्टे

यहराष्ट्रियायसः क्रियायस्य द्वाप्त्यसः ह्वाप्तायस्य प्रमान्त्रस्य प्रमा

Commitment fee

- 71. In accordance with section 80 of the Act, a Scoping Agreement shall be conditional on the payment of non-refundable commitment fee to the National Focal Point as follows:
 - (1) 5000.00 US Dollars, if an applicant is an international entity; or
 - (2) Equivalent fee in Ngultrum calculated at prevailing US Dollar exchange rate on the day of application by Bhutanese entity; or
 - (3) Any currency agreed in the bilateral trade agreement between the countries at the equivalent fee of 5000.00 US Dollars.
- 72. In accordance with sections 86 and 88 of the Act, the User shall pay the non-refundable commitment fee prescribed under section 71 of this Rules during the execution of Access and Benefit Sharing Agreement, if the National Focal Point determines that the User may directly enter into Access and Benefit Sharing Agreement without execution of the Scoping Agreement.

Surrender of accessed genetic resources, research results and related information

73. In accordance with section 83 of the Act, a User not intending to enter the Access and Benefit Sharing Agreement or after termination of the Scoping and Access and Benefit Sharing Agreement, shall surrender the accessed genetic resources, research results and related information at their own cost within 30 working days after the termination of the Scoping Agreement to the National Focal Point.

र्वेयःर्श्वेन्द्रनावेष्यव्यवर्गायम्बद्धाः

- - (१) ह्युँन् से नीस स्मिन्यस न्सेन्यस न्सेन्यस नुस्तिस्य मुद्य स्मिन्यस कुर्ने स्थान स्मिन्यस कुर्ने स्थान स्यान स्थान स्यान स्थान स
 - (४) र्रम्भारम्बुद्रार्घेद्रात्तुरस्याम्डेगामी द्रस्यास्य प्रम्था । स्यान्य स्थान्य स्
- चुतःर्घतः त्येन'तदेते देत्रक्तः ५० मते दुर्गेत्र्यद्वापः र्वतः र्श्वेद्वापः र्वतः र्श्वेद्वापः व्यवः स्वाप्ति व चुतःर्घतः त्यतः त्याः त्येदः देवः व्यवः विदः विद्यः विद्यः विद्यः विद्यः विद्यः विद्यः विद्यः देवः विद्यः विद्यः

कःग्रदशः ५८:पश्चरःगर्शे।

- ७७. र्षेत्रप्तुन्यत्वात्रक्तात्र्वात्त्र्वात्त्रः र्वेत्रार्श्वेत्रप्तात्त्र्वेत्रः वित्रक्षेत्रः वित्रक्षेत्र भण्यात्रक्षात्र्वेत्रः वित्रक्षेत्रः वित्रक्षेत्र
- हे.स.तम. खे.च.सैप.ट्यू। यथपु.वाष.मै.चभीर्य.ट्यूच.वार्यू.११व.ली. क.वाषम.जी.वाषम.तीव.म.ह्वाम.तपु.केष.वारम. ७० वी. वण. श्रीट.भु.वाम. मैजा.लूरम.ट्र.क्च.वार्यू.२१व.ली. र्जूब.ट्येट.वाष.मी.चे.टट. सूच.श्रीट.दटावा.तथ.पर्यू.
- न्तः मृतःस्र्रेन्द्राचे स्वराचम् प्रवितः मृताःस्य स्वर्तः मृतः मृतः स्वराचे स
- चि. र्श्वेन्योग्नेयं कुषार्धेन्यः र्ह्यान्यर्श्वेन्यः विषयः विषयः

Access and Benefit Sharing Agreement

- 74. In accordance with section 86 of the Act, the Provider and the Users may enter directly into a Standard Access and Benefit Sharing Agreement as prescribed in Form VII or negotiated contract between Provider and the User and the National Focal Point shall recommend under the following circumstances:
 - (1) there is prior research conducted on the specific genetic resource by the User;
 - (2) the research findings on particular genetic resource are already in public domain; or
 - (3) the User comes with a prototype and product line from or for specific genetic resources.
- 75. The Access and Benefit Sharing Agreement shall be executed for individual genetic resources and products during the actualization phase for the genetic resources accessed under section 69 of this Rules.

Validity and Renewal

- 76. The validity of the Scoping Agreement and Access and Benefit Sharing Agreement shall be mutually agreed between the Provider and User.
- 77. The User shall apply to the National Focal Point for renewal of the Scoping Agreement and Access and Benefit Sharing Agreement, 90 Days before the expiry of the validity.
- 78. The National Focal Point shall seek the approval of the Competent National Authority to renew the Scoping Agreement and Access and Benefit Sharing Agreement.
- 79. The User shall pay non-refundable renewal fee to the National Focal Point upon approval of the renewal of the Scoping Agreement or Access and Benefit Sharing Agreement as follows:

ग्रायाश्चितः लुःणिगासुत्यासीःतदीः क्वाताः श्चितः देन्तः लीतः यः देतः सुःलेखाः देनः व्यवः विष्यः विषयः विष्यः विषयः विष्यः विषयः विष्यः विष्यः विष्यः विष्यः विष्यः विष्यः विष्यः विष्यः विष्यः

વ) લું.તાના સંતા શાળા તે તર્વા તાલું માં જા કું માં મુખ્ય સું ને વેળ ત્યાલા તાલું છે વેલા તાલું તાલું માં ત્યા મું. પેટેળ તાલું સ્ત્રૂપ, કો. મું પ્લર્થના સું સું મામના કુંથે. પેટેળ ત્યાલા તાલું છે થયા ની. તાલું માં સું મા તાલું માં તાલું માં તાલું માં તાલું માં સું મામના સું માં પેટે તાલું માં તાલું માં તાલું માં તાલું માં તાલું મ

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- २०. क्वित्यः स्ट्रिन् स्वर् न्यन्य स्वर् न्यन्य स्वर् न्या स्वरं न्या स्वरं
- २७. हे.अ.जश्चावश्चात्रः क्षेत्रः क्षेत्रः त्यावश्चात्रः ज्ञात्रः व्यक्षः स्त्रं व्यवस्यः स्त्रः व्यक्षः स्त्रः स्त्रः
- २४. मार्याभागत्र में द्वाराय का स्वाराय के प्राप्त का स्वाराय के स्वराय के स्वाराय के स्वराय के स्वाराय के स्वराय के स्वाराय के स्वाराय के स्वाराय के स्वाराय के स्वाराय के स्व
- २३. मुलार्लेट्यार्स्य मर्थे प्रविश्व मुलार्लेट्या क्षेत्र प्रमाविश्व प्रविश्व प्रवि

मार्थकार्यः त्यमाः ख्रीरा

२८. चरुतःब्रिस्रसःश्चैःर्नेत्रःक्षतः २० धतःन्बेन्सःर्नेतःन्दःत्विषः क्वाषःर्धन्सःर्कनःस्तःन्तः वर्द्धतःश्चेसःश्चेन्द्रःत्रः वर्द्धतःश्चेसःश्चेन्द्रःत्रः वर्द्धतःश्चेसःश्चेन्द्रःत्रः वर्द्धतःश्चेसःश्चेन्द्रःत्रः वर्द्धतःश्चेसःश्चेन्द्रः वर्द्धतःश्चेसःश्चेन्द्रः वर्द्धतः। वर्द्धतःश्चेसःश्चेन्द्रः वर्द्धतः। वर्द्वतः। वर्द्दतः। वर्द्धतः। वर्द्वतः। वर्द्धतः। वर्द्वतः। वर्द्दतः। वर्द्वतः। वर्द्वतः। वर्द्वतः। वर्द्वतः। वर्द्वतः। वर्द्दतः। वर्द्वतः। वर्द्वतः।

क्रुं कर्शे प्रभुट् ग्री ग्रावाका

र्ष. चडतः ख्रेंस्यः क्षें चतुरः क्षें प्रतः क्षें प्रतः प्रतः प्रतः प्रतः प्रतः प्रतः व्याप्तः क्षें प्रतः वडतः ख्रें प्रतः व्याप्तः क्षें प्रतः वडतः ख्रें प्रतः व्याप्तः क्षें प्रतः व्याप्तः व्यापतः व्याप्तः व्यापतः व्यापतः

- 1) 250.00 US Dollars, if an applicant is an international entity;
- 2) Equivalent fee in Ngultrum calculated at prevailing US Dollar exchange rate on the day of application for Bhutanese entity; or
- 3) Any currency agreed in the bilateral trade agreement between the countries at the equivalent fee of 250.00 US Dollars.

Amendment

- 80. The Provider and User may mutually consent to amend the terms and conditions of the Scoping Agreement and Access and Benefit Sharing Agreement after seeking approval from the Competent National Authority.
- 81. The Providers and User upon mutual consent to amend the agreement shall negotiate on the amendment of existing or inclusion of new terms and conditions.
- 82. The amendment of agreement shall be effective only upon signing of addendum to the agreement by the parties.
- 83. The National Focal Point shall publish the non-compliance report by the Provider and User in the Access and Benefit Sharing Clearing House upon approval from Competent National Authority.

Certificate of Compliance

84. In accordance with section 89 of the Act, the Competent National Authority shall issue the Certificate of Compliance to the Users as per the format prescribed in Form VIII of this Rules.

Material Transfer Agreement

85. In accordance with section 91 of the Act, a User shall submit a request for Material Transfer Agreement to the National Focal Point in the format prescribed in Form IX of this Rules and the request for Material Transfer Agreement.

- र्ण. क्रीत्रं स्वर्त्त्रं स्वरं त्रम् त्रम् स्वरं त्रम् त्र
- २२. क्विया यग्रहें क्वा क्वी स्वाप्त स्वाप्त

चबतःत्रमुद्दर्द्दर्श्वत्रयःग्रीःर्द्दरायुः र्श्वःभीदगीःदेग्यःश्चृदार्भद्दासुद्दर्शःगीःर्भवःश्चृद्दी

- ल्ट्याक्ष्रं मी में इं स्वाप्त क्ष्याम् प्रत्याक्ष्याम् प्रत्याक्ष्याम् विष्याक्ष्याम् विष्याक्षयाम् विषयाम् व

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- ८१. चरुतः ब्रिस्स क्रैं म्द्रिक्त ८५ सते नुर्वे न्यान्त्र क्रिन्त विषयः क्रिन्स क्रिया क्रया क्रिया क्रया क्रिया क्रया क्रिया क
- ५२. म्यां भेश्यः मुला भेर्यः म्यां भ्रमः म्यां भ्रमः

- 86. In accordance with section 93 of the Act, the National Focal Point shall determine whether the User qualifies for execution of Material Transfer Agreement under the purposes specified in section 92 of the Act.
- 87. The Competent National Authority shall delegate power to approve and execute Material Transfer Agreement to the National Focal Point within five working days from the date of receipt of the application and submit the report to Competent National Authority biannually.
- 88. The National Focal Point shall execute the Letter of Undertaking as per the format prescribed in Form XII for all the genetic resources which are exported for personal consumption and non commercial research.

Access to plant genetic resources for food and agriculture

- 89. In accordance with section 94 of the Act, the National Focal Point shall carry out assessment and determine which genetic resources of released varieties for food and agriculture shall be based on the multilateral system.
- 90. The National Focal Point shall carry out the listing of plant genetic resources for food and agriculture in consultation with relevant agencies and the list shall be approved by the Competent National Authority.

Standard Material Transfer Agreement

- 91. In accordance with section 98 of the Act, a User shall submit a request for Standard Material Transfer Agreement to the National Focal Point in the format prescribed in Form X of this Rules.
- 92. The Competent National Authority shall delegate power to approve and execute Standard Material Transfer Agreement to the National Focal Point and submit the report biannually to the Competent National Authority.

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Sample Transfer Certificate

93. In accordance with section 99 of the Act, the National Focal Point shall issue a sample transfer certificate as per the format prescribed in Form XI of this Rules.

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- ८८. चरुतः विस्रसः श्री द्वार्क्षतः १०० मः ५८ १०० मंत्रे द्वां दस्य द्वां द्वां दस्य विश्वः के स्यार्थे व्याप्ते दस्य विश्वः के स्यार्थे व्याप्ते दस्य विश्वः विद्यार्थे विद्या
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र्मरःख्र्याःमेशर्प्यदामुःमुत्रार्प्यरश्यावश्यस्त्रा

- (१) शें रें ग्राट्यु र डिंग मीश श्रू र श्रें श्
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CHAPTER 6

ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

Documentation, Preservation and Protection

- 94. In accordance with section 101 and 102 of the Act, the National Focal Point shall carry out the inventory and documentation of traditional knowledge associated with genetic resources.
- 95. In accordance with section 104 of the Act, the Competent National Authority shall delegate the authority to National Focal Point to identify the relevant agencies or individual for inventory and documentation of traditional knowledge associated with genetic resources.
- 96. Any individual or Agency documenting traditional knowledge associated with genetic resources under section 105 of the Act shall require a prior informed consent from the provider of the traditional knowledge associated with genetic resources in the format prescribed in Form IV of this Rules in accordance with section 62 of this Rules.

National database on Traditional Knowledge

- 97. Any person intending to access the national database on traditional knowledge shall seek approval from the National Focal Point.
- 98. The person authorized to access the national database by the National Focal Point under section 97 of this Rules shall be required to sign a non-disclosure undertaking to safeguard traditional knowledge associated with genetic resources from misappropriation.

श्र-क्रेंद्र-द्वःद्रश

- त्तः चरुतः विश्वश्यः ग्रुः देवः क्षतः १०५ धतः द्वाद्यः प्रवाद्यः क्षः श्रेतः श्रेतः श्रेतः स्वाद्यः विश्वः विश्व
 - (१) र्ष्ट्राम्ट्रिन्यम् पर्स्ट्रिन्याबन्यः याबन्द्रितः स्था

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- २००. चडतः विश्वश्वः शुः र्देष् क्षतः १२० चतः द्र्येष्ट्रिशः र्द्षद्रप्तः विश्वः व्यव्यः विश्वः विश्वः विश्वः व ऑक् द्रत्यञ्चेषः चः व्यद्यं द्रिश्चः विश्वः विश्वः
 - (१) इस्र्स्थियः विश्वास्त्र मुन्त्र स्वाप्त्र स्वाप्त्र मान्य मान्य स्वाप्त्र स्वाप्त

 - (व) न्रीम्याप्तरामी स्ट्रास्था प्रेस्पार्थे संस्था स्ट्रिस स्
 - (८) श्रेष्ट्रेर्पणायर्चेर्यावयास्रम्या

<u>इन्-र्ख्याभेशर्य्य, र्न्यवेयानर्य्यन्यते स्वायाकृतर्वे त्राव</u>्यस्य क्रुं वीर्व्यनर्खुन्।

- १०१. भ्रीन्स डिन्न निश्च स्ट्र र्श्वियः विश्व र्षेत्र प्रत्ये विश्व र्षेत्र प्रत्ये से निश्चित्र स्ट्र से निश्चित्र से स्ट्र से निश्चित्र से निश्चित्र से से निश्चित्र से निश्चित्य से निश्चित्र से निश्चित
- १०२. শূर-র্প্রথ-প্রথ-অর্থর-বের্র্রথ-ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর-র্ত্তর্ব-র্ত্তর্ব-র্ত্তর-র্ত্তর্ব-র্ত্ব-র্ত্তর্

Community protocol

99. In accordance with section 108 of the Act, the National Focal Point shall support establishment of community-based group and facilitate development of community protocols; if necessary, on the following:

Process of granting Prior Informed Consent;

- (1) Formulation of Mutually Agreed Terms; and
- (2) Fair and equitable sharing of benefits.

Providers of Traditional Knowledge associated with genetic resources

- 100. In accordance with section 110 of the Act, if a traditional knowledge associated with genetic resources is held by more than one community, the National Focal Point shall consider following criteria to engage particular community as the holder:
 - (1) Evidence of traditional knowledge documented in the National Traditional Knowledge Database or any other available evidence of traditional knowledge;
 - (2) Community with no Access and Benefit Sharing project;
 - (3) Community with abundant genetic resources associated with the particular traditional knowledge; and
 - (4) Socio-economic status of the community.

Access to Traditional Knowledge associated with genetic resources

- 101. A person seeking access to traditional knowledge associated with genetic resources shall submit an access proposal to the National Focal Point in the format prescribed in Form III of this Rules.
- 102. The access proposal for traditional knowledge associated with genetic resources shall comply with the requirement prescribed under Chapter 5 of this Rules.

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१०५. पठतः দ্রীয়য়'য়ৢ৾'র্বর'র্কর' १११ ध'র্বং ११९ धति'র র্গিনয়'র্ব্বর'র্বর'র বিশ্বরাধি ক্রিঅ'র্ ক্রিঅ'র্র্জনমার্নি র্কব'শার্ক্ত 'বর'য়ৣ'য়য়য়য়'য়ৢ৾য়য়য়য়য়

- ४. अध्वरःश्चेषाःतयन् र्वरःपत्रेशुत्यः यथः श्रुवःतव्यश्वः स्वर्धेषाःतयन् वेतः र्वेदः र्वेदः श्रुः श्रुवः श्रुवः स्वरः विद्यः स्वरः स
- २००. मुलार्ल्स्स्य प्राप्त पश्चीर पर्स्य मिना स्वाप्त स्वाप्त
- १०५. कुलार्लेन्स्रार्कन्त्र्वे न्वरायद्वे मुक्ता सञ्चत्र श्चेता वितायद्वे स्वर्णे स्व

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- १००७. मुल्यार्थेन्यार्ट्स्वनाम् र्डं उत्राच्चीयः चर्द्रार्ट्वतात्यः क्षेत्राचनाः वित्रयात्यः क्षेत्राच्याः स्व चरुत्राधीमामी र्द्रेवाक्वरः १०० याव्यामी द्रियः वित्रयात्राः उत्रक्षः मान्यास्य क्षेत्राच्याः स्व स्वायाः स्वायाः स्वायाः स्वयाः स्वयाः स्वर्णान्यः क्षेत्राच्याः स्वयः स्वर्णान्यः स्वयः स्वर्णान्यः स्वयः स्वयः

Access and Benefit Sharing Agreement for traditional knowledge associated with genetic resources

- 103. In accordance with section 111 and 114 of the Act, the National Focal Point shall:
 - (1) Negotiate an Access and Benefit Sharing Agreement with a User on behalf of the providers of traditional knowledge associated with genetic resources upon the approval of the access proposal by the Competent National Authority; and
 - (2) Submit the outcome to the Competent National Authority for approval upon completion of the negotiation.
- 104. The Competent National Authority may recommend changes to an Access and Benefit Sharing Agreement at the time of approval.
- 105. The Provider shall, upon the approval of the negotiated terms by the Competent National Authority, execute an Access and Benefit Sharing Agreement with the User in the presence of the National Focal Point.

Third-Party Transfer

- 106. In accordance with sections 81 and 82 of the Act, if a User intends to transfer research results, accessed genetic resources or traditional knowledge associated with genetic resources to a third-party for product development and commercial utilization, the User shall submit the request to the National Focal Point with details prescribed in Form VI of this Rules.
- 107. The National Focal Point shall after reviewing information and on being satisfied that the applicant has fulfilled all the necessary requirements under section 106 of this Rules, submit recommendation to the Competent National Authority for decision within 30 days from the receipt of an application.

- २०२. मुल र्लेट्स र्क् न्यान्य द्वा मुल र्लेट्स स्वा निका त्य क्षेत्र स्व न्या स्व क्षेत्र स्व न्या स्व क्षेत्र स्व न्या स्व क्षेत्र स्व क
- यहार स्त्रीया स्वराध्य स्वराध
- ११०. इ.सर्.चंच्यं व्यव्यां व्यत्त्रे सी.सी.सूर्य स्थान्य स्था
- ११११. इ.सब्.मोवध.मुश. पश्यक. १०४ मःक्ष्य. कुरे.टी.म्मूरे.सूर्य मःक्ष्य. पश्च मःक्ष्य.

- 108. The Competent National Authority based on the recommendation of the National Focal Point shall render its decision within five working days after the conduct of the Competent National Authority meeting.
- 109. The National Focal Point upon approval for third-party transfer shall initiate or facilitate negotiation with the third party for accessed genetic resources or traditional knowledge associated with genetic resources.
- 110. The National Focal Point shall communicate to the User, if the application for third-party transfer is rejected by the Competent National Authority.
- 111. The third-party shall fulfill all the requirements prescribed under section 71 to 93 of the Act and section 52 to 103 of this Rules.

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तदःसकुसः नृरङ्गीःर्स्रुस्रमः ग्रीः विष्यतः नर्गे निम्ता

मिम्बद्

୨୨२. चरुतः बिस्रसः ग्रीः र्ने दार्कतः १९५ यदिः र्नो रस्यः र्ने द्वार्त्तः विष्यः विष्यदः यर्गे यत्वितः व्यारस्यः विष्यदः विषयदः विष्यदः विषयदः विषयदः विषयः विष्यदः विषयदः विषयदः विष्यदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयदः विष्यदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयदः विषयः विषयदः विषयः विषयदः विषयः विषयदः विषयदः विषयदः विषयः विषयः विषयः विषयः विष

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- (४) पश्चिमःग्रस्यः तहुश
- (८) देव अर्धे पर्धे दिशे
- (५) र्वेद'न्रेंसर्वेटं क्षुरातवन भेरायस नरत्वुसर्श्वेन्द्री
- (v) कूर्म्स रायवयः कु. कृताः वताः ग्रीः यद्येश
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 - (१) यस्यारेगार्स्यान्त्र्राचमुर्दार क्षेत्रामान्यानायरादगा
 - (४) मर्डुमास्रेर्सुंगीप्तरादायकुर्यासुनार्दर यकुर्यायसेया

CHAPTER 7

FAIR AND EQUITABLE SHARING OF BENEFITS

Benefits

- 112. In accordance with section 118 of the Act, the benefit sharing shall comprise monetary or non-monetary benefits and the benefit shall be negotiated between the Provider and User.
- 113. The monetary benefit where appropriate may include:
 - (1) Processing fee;
 - (2) Commitment fee;
 - (3) Renewal fee;
 - (4) Payment of premium price;
 - (5) Payment of commission from the sale of product;
 - (6) License fees in case of commercialization;
 - (7) Contribution to be paid into the Bhutan Access and Benefit Sharing Fund;
 - (8) Research funding;
 - (9) Joint ownership of relevant intellectual property rights; or
 - (10) Any other monetary benefits which may be negotiated between the parties.
- 114. The non-monetary benefit where appropriate may include:
 - (1) Technology transfer and capacity building;
 - (2) Institutional collaboration and cooperation;

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- (ॻ) अँसामध्रुत र्झिमायायकमायतः नृहुत्यायञ्चेत्यासेत्रायते वास्तरमान्यतः मानस्तरम्

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- (3) Support in machinery, equipment and tools;
- (4) Infrastructure development;
- (5) Social recognition;
- (6) Admittance to ex-situ facilities of genetic resources and database; or
- (7) Any other mutually agreed non-monetary benefits.

Mutually agreed portion of the fund

115. In accordance with section 24 (3) of the Act, the Provider of the genetic resources cultivated on farmland or any private land by community-based groups may mutually agree to channel a certain portion of the monetary benefits into the Bhutan Access and Benefit Sharing Fund.

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- ११७. चरुतः विस्रसः श्रीः र्वेदाः स्वरः १४० यदः र्वोद्यसः र्वेदः रद्याः श्रीः यत्त्वाः स्वरः विद्यः स्वरः विद्य श्रीः तत्त्वाः वीः विद्यः श्रीः र्वेदः यदः यवेदः यवेदः स्वरः यवेदः सः प्रदेशः स्वरः यवेदः स्वरः यवेदः स्वरः यविदः स्वरः यविदः सः विद्यः स्वरः यविदः सः विद्यः स्वरः यविद्यः स्वरः यविद्यः स्वरः यविद्यः सः विद्यः स्वरः यविद्यः सः विद्यः स्वरः यविद्यः सः विद्यः सः विदः सः विदः
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 - (४) व्रद्यार्थिन् न्द्र्चे 'यञ्चेथा है बाले नाया र्क् 'मीबा सान्द्र्या मुँ। है बाले नायन न्द्री खु । हुवः व्यवसायन न्द्री खु । व्यवसायन न्द्री खु ।
 - (४) चरुतः ह्येस्रमः हुं सर्वेदः १४० मतः द्वेदः द्वेदः स्ट्यः त्वेदः प्रवेदः स्वयः हुः सर्वेदः स्वयः स्ययः स्वयः स
 - (८) ८८'ण.पत्रंज.मैंन.भूँर.पत्रर.लूर.मपु. जम.मैंप्य.मंथ.प्रं.मी.भूंर.जम. मैंज.लूरम. १८) ८८'ज.पत्रंज.मैंन.भूँर.पत्रर.लूर.मपु. जम.मैंप्य.मंथ.प्रं.मी.भूंर.जम. मैंज.लूरम.
- ११७ . चरुतः विस्रसं भी दें तर्कतः १४० पते दें तर्म द्रसः दें तर्दा विषे . मुर्था प्रेंट्स के द्रदा विषे . स्वा प्रेंट्स के त्र के त्र
- ११२२. क्वियः प्रेंट्सः क्व्रंत्वर्त्वर्त्वरः वहात्वर्ध्वरः वहुवाः विश्वरः व्यवः विश्वरः विश्व

CHAPTER 8

BHUTAN ACCESS AND BENEFIT SHARING FUND

Bhutan Access and Benefit Sharing Fund

- 116. In accordance with section 129 of the Act, the National Focal Point as the administrator and manager of the Bhutan Access and Benefit Sharing Fund shall:
 - (1) Submit financial statement to the Competent National Authority annually;
 - (2) Facilitate auditing of the fund by internal as well as external auditors;
 - (3) Invite project proposal to secure funding for implementation of activities allowed under section 130 of the Act; and
 - (4) Report biannually on the progress of the activities funded to the Competent National Authority.
- 117. In accordance with section 129 of the Act, the Competent National Authority as the supervisor of the Bhutan Access and Benefit Sharing Fund shall approve the fund utilization proposal submitted by the National Focal Point.
- 118. The Competent National Authority shall authorize the utilization of the Bhutan Access and Benefit Sharing fund only after the total amount reaches Nu. 20 million.

जश्र त्यायार्ज्य श्रातकर।

११०. त्व्नामि क्षेम् प्रेम् प्रमाणक्ष्म प्रमाणक्षम प्रमाणक्ष्म प्रमाणक्षम प्रमाणक्ष्म प्रमाणक्ष्म प्रमाणक्ष्म प्रमाणक्ष्म प्रमाणक्षम प्रमाणक्म प्रमाणक्षम प्

यश्रात्रग्या शुः भूति गार्र र र शुः विचा

Project proposal

119. Any entity, individual or community-based group interested to implement activities related to conservation and sustainable use of Bhutan's biodiversity and enhancement of rural livelihoods shall be eligible to submit project proposal to the National Focal Point and the assessment shall be carried out as per the Guidelines for administration and management of Bhutan Access and Benefit Sharing Fund.

Project monitoring and evaluation

120. The National Focal Point shall carry out monitoring and evaluation of the project activities and furnish report biannually to the Competent National Authority as per the Guidelines for administration and management of Bhutan Access and Benefit Sharing Fund.

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୨२१. ସङदः ख्रिस्रशः ग्रीः देव क्ष्यः ११६ यदेः दर्भे द्रशः देव द्रश्यक्षियः क्षुत्रः ख्रीयः व्यक्षियः विष्णवेषः विष्णवेषः विष्णवेषः विष्णवेषः विष्णवेषः विषणवेषः विषणवे

(१) द्रैग्नशः क्रुंदः र्घेदः त्यात्रः त्यात्रः त्यात्रः त्यात्रः व्यात्रः व्यात्यः व्यात्रः व्यात्रः

- (४) मार्बरमः च्रिवासदे केंश मार्चर स्टर कामार्वश
- (३) यायकथायतीयात्रकार्क्षण
- (८) र्वेच र्श्वेन प्रतामे प्रवास्त पर्यो प्रवित्त मान स्वास प्रतास स्वास स्वास
- (u) क'तर्हेग'५८' क'तर्हेग'अ'तय५'यते'लु'भेग'५८' तर्नेते'कु'अर्वत्र
- (v) वर्ष्ट्राणेव. लट्य. वर्टट्ल्र्रानायुः द्वायाक्रुवा क्वाया क्रुं वी अर्ह्ट्रा वा क्याया विकास क्रिं वी अर्ह्
- (४) त्रें श्रेण पर्णे दार्थे प्रमान देवा
- १९९२. कुल प्लॅंट्स टेंक्ट पंचाई रुद्द चीस की कि स्मित्र की प्लंड की प्लंड की प्लंड की स्मित्र की प्लंड की प्लं
 - (१) बु.च.स्याक्षान्दरः ज्येषःश्रादेशवानाम्या
 - (४) ग्रवरायाञ्चेत्रायतिः केषा ग्राम्या
 - (4) रेग्याक्तुवार्घवातुरसार्द्धानी नर्गेयार्नेवा
 - (৫) ঝামাব্রু

CHAPTER 9

REGISTRY AND RECORDS

Registry

- 121. In accordance with section 134 of the Act, the National Focal Point shall maintain a registry containing details on:
 - (1) The name of the entity to whom access to genetic resources or traditional knowledge is granted;
 - (2) The date it was granted and validity;
 - (3) Conditions agreed;
 - (4) Information on the Access and Benefit Sharing Agreement;
 - (5) Information on applications approved or declined and reason thereof;
 - (6) Stock of genetic resources collected or dispatched;
 - (7) Information on research results and genetic resources surrendered; and
 - (8) Such other information as it may deem fit.
- 122. The National Focal Point shall maintain a registry of all the genetic resources dispatched from the country under the Material Transfer Agreement and Standard Material Transfer Agreement.
 - (1) Detail of the applicant and recipient;
 - (2) The date it was granted;
 - (3) Purpose of the genetic resources;
 - (4) Destination;

- (u) विच तर्क्ष्यः शुः युच तत्र्वर्यः सुवा चतिः र्केशः युद्धा
- (७) अधयः रस्चिरः श्रुवः लुदेः यदः रहा
- (ग) प्रातक्षामद्राम्बर्धम्

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- ११४. पंडतः ब्रिस्स ग्री दें तृर्कतः १४५ पते द्वेद्य स्वित् द्वेद्य प्रति वित्र स्वितः वित्र स्वितः वित्र स्वितः वित्र स्वितः वित्र स्वितः वित्र दें त्वेद्य स्वितः क्षेत्र स्वितः वित्र स्वितः स्वतः स्वतः
 - (१) बुन.पक्रूज.बीन.पर्चशःस्री
 - (१) विनायर्केयामुनायम्बर्धानीन्ये सुद्
 - (4) नर्जे भुत्रातन् पेर्प्नायते भेर्त् नर्द्यो है स्वाया न्या ने प्रया है स्व है स्व
 - (८) रेगायःक्वृदःर्घदःस्ट्रियःपत्वगःसदेःसःर्वेरसःग्रीःगःगाययःरह्य
 - (u) र्वेन'र्बेर'प्यनर'र्कर'क्षे:रेगम्शक्तुंब'र्वेब'स्ट्रम्थर्जुः सहगःश्चेत्य'त्यनर'र्वे'र्ना
- ११८ पठतः विश्वसः ग्रीः र्नेब्रः ४१८ पदेः र्नोह्मरः प्रेन्द्रः प्रद्याविषः क्षेत्रः क्षेत्रः स्वापः पठतः ध्रीतः विश्वसः भ्रीतः विश्वसः स्वापः स्वापः विश्वसः स्वापः स्वपः स्वापः स
- ११५५. पडतः विश्वस्य मुँग देव क्व पश्च पार्श्व प्रत्य प्रति प्रति प्रति प्रति प्रति क्व प्रति क्व

- (5) Date of submission of research result;
- (6) Copy of final report; and
- (7) Conditions agreed.

Records

- 123. In accordance with section 135 of the Act, a User of genetic resource or associated traditional knowledge shall, as the case may be, maintain records on:
 - (1) Research results;
 - (2) Publication of research results;
 - (3) Type and number of products developed, and sales record;
 - (4) Details of the location where the genetic resource is kept;
 - (5) Disposal of the accessed genetic resources; and
 - (6) Such other information that may be considered necessary by the National Focal Point.
- 124. In accordance with section 136 of the Act, a User shall furnish a copy of the records maintained under section 123 of this Rules to the National Focal Point annually or as and when required.
- 125. In accordance with sections 137, 138 and 139 of the Act, the person or an agency who discovers new species, releases new crop variety, de-notifies seed variety or collects germplasm and genetic materials shall deposit the sample or specimen to the National Focal Point within 90 days from the date of discovery, release, de-notification or collection.

रेगाशः क्रुवार्षेद्रासुरशः र्कुः सह्याः श्रेवः यान्नारम्

(१) मायास्त्रेन. द्रमायास्त्रव्याप्त्रम्। ११) मायास्त्रेन. द्रमायास्त्रव्याप्त्रम्। स्राम्भेयाद्वेदार्य्यायमायस्त्रम्। द्रमायास्त्रम्।

(४) द्रशायनमः उदाष्ट्री सार्यम् प्रमात्त्रेयः प्रमात्त्रेयः प्रमात्त्रेयः व्याप्तेयः विष्यः विषयः विष्यः विषयः विष्यः विषयः विष्यः विष

(व) सह्याः श्चेतः याहरू न्यां । त्याः श्चेतः प्रतायाः देवायः देवायः श्चेतः व्यव्याः केतः व्यव्याः विद्याः केतः व्यव्याः विद्याः केतः व्यव्याः विद्याः विद्याः

Disposal of genetic resources

- 126. In accordance with section 140 of the Act, the National Focal Point shall adopt following methods to dispose the returned genetic resources by the Users:
 - (1) Store in the gene bank if the genetic resource has potential for regeneration;
 - (2) Safe storage for potential future research and development; or
 - (3) Safely dispose of the genetic resources as per the disposal guidelines.

जेतुः १० म

सॱहेंग'न्नम्सरर्धेन।

नश्रूरःर्श्वेदायमें दियं

- ११५. चरुतः विश्वश्यः ग्रुः र्देब् रह्म १८५ यदिः द्र्येत्र श्रुं द्राद्यः विश्वश्यः क्ष्यः विश्वश्यः विश्य
 - (१) मुलःगलुरःदर्च्याःगःदयागःश्रे।
 - (४) पर्चिमा.चचप.क्रम.रेट.श्रैष.मुम्म.रेचर.प्रहूषी
 - (३) दग्रथःक्षः ५८ स्त्रीत्याः विषयः र्हेगाः ययः सुरयः ५८ ।
 - (८) मुगः पॅरशः रें क्या गर्डें उदा
- १९५. नष्ट्र-र्श्चेन्त्रवीं न्धें त्र्चें अः भू: न्द्र-त्यादः तुः वीं अः नष्ट्र् तर्भे वीं भः नवें अः वाद्यः की इतः की भागा भेतः चः ने अः न्द्र-त्वे भः ने स्ट्र-र्श्चेन्त्र वीं वीं अः नष्ट्र् वीं भः नवें वीं भः वाद्यः की व
- - (१) रे.ट्रम्थ.कु.ट्रम्थ.कें. ४मश्र.क्त. ४मश्र.व्य.ट्रम्बेटम्य.खंटश.सं. क्वेंट्रम्भ्य.कें.
 - (४) चवतःत्रश्चरः प्रस्ति त्रवा श्चीः रेगाया र्षुः त्रव्या प्रवतः स्था प्रस्ति । स्या प्रस्ति । स्था प्रस्ति । स्या प्रस्ति । स्था प्रस्ति । स्या प्रस्ति । स्था प्रस्ति । स्या प्रस्ति । स्या प्रस्ति । स्या प्रस्ति । स्या प्रस्ति ।
 - (4) चडतः धेना में 'र्ने व'क्व' १४३ घ'षशः १४० घते 'र्ने वंद्राह्म के स्वाप्त के स्वाप्त

CHAPTER 10

MONITORING AND ENFORCEMENT

Enforcement Officers

- 127. In accordance with section 142 of the Act, the National Focal Point with an approval from the Competent National Authority designate the following relevant officers as enforcement officers to monitor and regulate genetic resources at entry and exit:
 - (1) Royal Bhutan Police;
 - (2) Bhutan Food and Drug Authority;
 - (3) Department of Forests and Park Services; and
 - (4) National Focal Point.
- 128. The enforcement officer shall carry out the enforcement roles and responsibilities as per the Standard Operating Procedures (SoP) developed consultatively.
- 129. The enforcement officer specified under section 127 of this Rules at the entry and exit point shall forward all the cases apprehended to the following Departments or Agencies for imposition of fines and penalties as per the relevant laws:
 - (1) The Department of Forest and Park Services for any wild genetic resources;
 - (2) The Bhutan Food and Drug Authority for food and agriculture; or
 - (3) The National Focal Point for any violation specified under section 133 to 139 of this Rules.

झॱहेंग'८८सुय'दर्ढेया

- - (१) दग्रथार्क्यान्द्रज्ञीरामाः बन्याः र्नेमाः ययाः सुरस्य
 - (४) तनुषा पञ्च तरक्षा ५८ स्थ्रुव देवा वर्ष दिवा
 - (३) वॅदप्रवव द्र उर् अ थश (बुर श
 - (८) क्वृत्यः पॅरमः र्देः क्वाः नर्देः ठवः दरा
 - (५) वह वर्षु र वर्षे यु ग्वा वर वर्षे द र हीं देवा हु र देश धरा सुर हा
- १६१. तब्रेल'र्लेन्'नेत्रक्ष्र्वर्रन्यनेत्'न्धन्'र्लेन्'रलेन्
- १४२. कुल'र्लेट्स'र्कर्'न्य्र र्वर्प्यद्वेत्र चैसं कुल'र्लेट्स'र्क्य मुल'र्लेट्स'र्ट्स वामार्डं उत् ची में स्वरंदिय न्यार्थं प्रत्येत्र प्रत्ये

Monitoring and tracking

- 130. In accordance with section 147 of the Act, the Competent National Authority shall on the recommendation of the National Focal Point designate the following agency as access and benefit sharing checkpoint:
 - (1) Department of Forests and Park Services;
 - (2) Bhutan Food and Drug Authority;
 - (3) Department of Revenue and Customs;
 - (4) National Focal Point; and
 - (5) Department of Media, Creative Industry and Intellectual Property.
- 131. The concerned checkpoint shall verify the information and document as per the Standard Operating Procedures(SoP) developed consultatively under this Rules.
- 132. The Competent National Authority may, on the recommendation of the National Focal Point, by written notification, designate additional check-points as and when considered necessary.

जिस ११ म

गर्बेन्द्रप्रमेथःन्द्रश्रेशःम

(१) र्श्विर्ध्वरण्चिःम्बर्क्चःवर्देः क्षेत्रःकर्रःद्वियःग्रयः ६५०००.०० र्रूटः सुर्रःवश्वतः र्वेत्रःकर्रःवर्षाः प्रायः ६५००००.०० प्यत्यः क्षेत्रःकर्रःवर्षाः स्वरःवश्वतः व्याप्यः व्यवःक्षेत्रयः सुर्रःवश्वतः र्वेतः (१) र्श्वेत्रः सुर्वः व्यव्यविद्याः वित्रः विद्याः प्रायः १००००.०० र्रूटः सुर्वः वश्वतः र्वेतः विद्याः स्वरः विद्याः विद्याः स्वरः विद्याः विद्याः स्वरः विद्याः विद्याः स्वरः विद्याः विद्याः

(व) र्वेन हुँ न नियम प्रतानमें प्रमित्र मित्र म

(व) क्रिंक्.स्र्रांचर्यत्वे व्यक्तिः स्रेक्षक्तः हे. स्रेक्षःक्ष्रः द्विकः त्यत्वः क्षेत्रः क्ष्रः क्ष्रेकः क्ष्रः क्ष्रेकः क्ष्रः क्ष्रेकः क्ष्रः क्ष्रेकः क्ष्रः क्ष्रेकः क्ष्रः क्ष्रेकः क्ष

(८) म्वर्थःक्ट्रं न्य्युं कुं कर्श्वे न्यत्वि न्यत्वे क्ष्यं कुं स्था कुं

१३६. चरुतः बिस्रसः शुःर्त्वरक्ष्यः १५७ घः तर्रः १५५ घतः प्रवेश्वरः व्यवसः स्वरः स्वरः स्वरः विस्रसः स्वरः स

CHAPTER 11

OFFENSES AND PENALTIES

Unlawful access to genetic resources or associated traditional knowledge

- 133. In accordance with section 157 of the Act, the National Focal Point shall impose fines on any person who accesses or utilizes genetic resources or traditional knowledge associated with genetic resources for research and development, commercial or potential commercial purpose without executing the following agreements:
 - (1) Scoping Agreement shall be liable to a fine of Nu. 45,000.00 and compensation of Nu.450,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.
 - (2) Access and Benefit Sharing Agreement shall be liable for payment of fine of Nu.45,000.00 and compensation of Nu. 900,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.
 - (3) Material Transfer Agreement shall be liable for payment of fine of Nu. 5,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation; and
 - (4) Standard Material Transfer Agreement shall be liable for payment of fine of Nu.5,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.
- 134. In accordance with section 157 and 158 of the Act, any person who knowingly provides access to traditional knowledge associated with genetic resources except as permitted under customary practice shall be liable for payment of fine of Nu. 25000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.

याबरन्य खेर्म्यते खेन्यते खेन्यते खेन्य याच्या व्यवस्य व्यवस्य व्यवस्य खेन्य क्षेत्र स्थानी स्थानी

१३५५. पड़ित्र विश्व क्षिया च निष्ठ क्षित्र क्

क्रुं व्यव वित्रास्त्र स्तु की नियन नियन के वित्र स्तर्भे नियन

१५७.क्वियाधित्सर्म्हिताविष्ठः उत्राधीसः क्वियाधित्सः क्वित्वित्त्वः वित्त्वः त्वितः त्वितः वित्तः वित्वः क्वियाधित्यः क्वियाधित्यः क्वियाधित्यः क्वियाधित्यः क्वियाधित्यः क्वियाधितः वित्वः वित्वः क्वियाधितः वित्वः वित्व

गर्वेद्रत्योवः यद्यमुद्रत्ववःया

१४४. पठतः धेमा पदेते ते देव क्वा १४४ मा धर्मा १४७ मा क्वा मे के प्रत्या में म

यः तर्ज्ञयः प्रतिणः क्ष्यः क्ष्रींद्राद्मात्र प्रत्यां प्रविष्णं क्ष्रात्म प्रति । विष्णं वि

Unauthorized transfer of research result or accessed genetic resources

135. In accordance with section 159 of the Act, any User who transfers research results or accessed genetic resources to a third-party for product development and commercial utilization in contravention to sections 81 and 82 of the Act and section 106 to 111 of this Rules except for academic research not intended for product development and commercial utilization shall be liable for payment of fine of Nu. 45,000.00 and compensation of Nu.900,000.00; or equivalent to US Dollar at the prevailing rate on the day of imposition of fines and compensation.

Non-deposit of sample and specimen of biological resource

- 136. Any person or agency who fails to deposit samples and specimens genetic resources as required under sections 137, 138 and 139 of the Act and section 125 of this Rules shall be liable for payment of fine of Nu. 5,000.00; or US Dollar at the prevailing rate on the day of imposition of fines and compensation.
- 137. The National Focal Point shall publish the report on the failure to deposit samples and specimens of genetic resources in the Access and Benefit Sharing Clearing House upon approval of the Competent National Authority.

Subsequent Offense

- 138. Any person committing subsequent offense under section 133 to 136 of this Rules shall be imposed with double the fine amount of the first offense.
- 139. In the event of failure to pay the fines and compensation, the National Focal Point shall bar the proponent or User from accessing any genetic resources and such non-compliance shall be reported to the Access and Benefit Sharing Clearing House upon approval of the Competent National Authority.

मेतुः १९ म

শ্ব.জুমাপা

यञ्चे:र्मेगा

पह्नु.ह्र्यू

ळॅगॱर्नेद'श्चै'न्नरळंन्।

देशःक्रिया

- - (१) प्रकरः ख्रेस्रमः चेरः से तर्देः तर्चुमः में भ्रे ख्रुतः प्रकरः ख्रेस्रमः ४०४४ ठतः स्थः स्थः में।
 - (४) त्व्रुगःगीः श्रमः भ्रे:बेरःश्रे:पर्ने: त्व्रुगः मुशः विषयः वि
 - (व) यर्ने बर्झे र्रिंट्य प्रिंट्य प्रमान्ति । स्वार्थित स्वार्य स्वार्थित स्वार्य स्व

CHAPTER 12

MISCELLANEOUS

Forms

140. The National Focal Point shall amend the forms under this Rules to accommodate relevant information.

Amendment

141. The amendment of these Rules by way of addition, variation or revision may be affected by the Competent National Authority.

Authoritative text

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

Definition

- 143. In addition to the definitions set out in the Act and for the purpose of this Rules, the following terms shall have the meaning ascribed to them in this section, unless the context otherwise provides:
 - (1) "Act" shall mean the Biodiversity Act of Bhutan, 2022.
 - (2) "Bhutanese entity" shall mean any company or business organization registered in Bhutan.
 - (3) 'Check point' shall mean any designated agency to collect or receive or verify relevant information as appropriate for collection, utilization, trade and transit of genetic resources.

- (૯) શ્રે.ક્રે.ਭ્ર-જ્ઞ.તટ્ટ ફ્રે.ત્યા. ત્યાર્થ. મુટેત્વા.વટ્ટ્રેટ.જ્ય. જ્ઞુત્ર.ક્રે.જ્ય. જ્ઞુત્ર.જ્ય. ત્યાર્થ. મુટેત્વા.વટ્ટ્રેટ.જ્ય. જ્ઞુત્ર.જ્ય. જ્ઞુત્ર.જ્ઞા. જ્ઞુત્ર.જ્ય. જ્ઞુત્ર.જ્ઞા.જ્ય. જ્ઞુત્ર.જ્ય. જ્ઞુત્ર.જ્ય.
- (प) ट्र.म्.जम्प्रप्तः चर्चःश्चैयायचर्भ्यः श्वेतःश्चितः क्ष्यः स्वायः व्यव्यः स्वायः चर्चःश्चेतः क्ष्यः श्वेतःश्चितः क्ष्यः श्वेतःश्चेतः क्ष्यः श्वेतःश्चेतः क्ष्यः श्वेतःश्चेतः क्ष्यः श्वेतः श्वेतः
- (v) ब्रेटमः चेरः शेरादीः तुषः क्रुवः तुः ब्रेटम्यूः यटावः शंरवशः क्रीः यूप्रत्वनः शेषानः सुरः सुः म्री
- (च) ब्रिट्मते भू कें न्या चेर के त्ये के प्रत्ये के त्ये त्ये के त्ये के त्ये के त्ये के त्ये के त्ये
- (४) र्श्वेन्त्रुक्षेत्रं क्रिन्द्र्यं क्रिन्द्र्यं क्षित्रं क्षित्रं क्षेत्रं क्षेत
- ह्रवाच्रकाक्षेटकाद्रुवालीचाकाक्षीली त्याच्रक्षीली चार्च्यक्षीली स्थानिकाक्षीली स्थानिकाक्षिणीली स्थानिकाक्षीली स्थानिकाक्षिणीली स्थानिकाक्षीली स्थानिकाक्षीली स्थानिकाक्षीली स्थानिकाक्षीली स्थानिकाक्षीली स्थानिकाक्षिणीली स्थानिकाक्षीली स्थानिकाक्
- तर्थ्वायाल्यं स्थाः क्ष्रूट्यम् अत्यत्ते स्थाः क्ष्यायाः विष्यायाः क्ष्यायाः कष्यायाः कष्यायः कष्यायः कष्यायाः कष्यायः कष्यायाः कष्यायः कष्यायः कष्यायः कष्यायः कष्यायः कष्यायः कष्यायाः कष्यायः विष्यायः विष्
- (11) क्रिंट्यचेषाक्षेत्रायाचेराक्षेत्रायन् क्रिंट्यचेषाची द्रियम् स्थाप्याया स्थापिता स्यापिता स्थापिता स्थापित

- (4) "Community" shall mean any group of people residing together in one Chiwog or Gewog.
- (5) "Essentially Derived Variety" shall mean a new variety developed using protected variety retaining the essential characteristics of the protected variety.
- (6) "Farmer" shall mean any person who is actively engaged in farming or agricultural activities
- (7) "Farmers' Variety" shall mean a variety which has been traditionally cultivated and evolved by the farmers in their fields.
- (8) "Growing test" shall mean cultivation of candidate variety in the field or greenhouse comparing with similar existing varieties by evaluating morphological and physiological traits.
- (9) "Invasive alien species" shall mean plants, animals, pathogens and other organisms that are non-native to an ecosystem, and which may cause economic or environmental harm or adversely affect human health. In particular, they impact adversely upon biodiversity, including decline or elimination of native species through competition, predation, or transmission of pathogens and the disruption of local ecosystems and ecosystem functions.
- (10) "International entity" shall mean any foreign company or business organization based in foreign land.
- (11) "Non-commercial" shall mean any activity without commercial intent.

- (१४) सूर्वेष्मश्चाश्चरमा चेराश्चेरत्वे त्यार्थ स्थाया स्थाय स्याय स्थाय स्याय स्थाय स्थाय
- - (१८) क्षे नेर क्षे पदी राष्ट्र राष्ट्र विवर पार विवर दिवर के में क्षे क्षे के रें
 - (१५) चरुतः धेना : बेरः से 'तर्रे' त्व्नुना ने 'क्के 'ख्वरं रेन्य स्थूते चरुतः धेना 'त्रक्षेन 'त्रक्षेन 'त्रक्ष रुदः संस्था वि
 - (१७) श्रृंब चेराश्चे पर्ने प्रमानी ने प्यत्न पर्श्वम्यानी स्वित्त श्रृं प्रमान प्रमान स्वत्त स्वत्त

- (12) "New Variety" shall mean a variety developed by a breeder which conforms to the criteria for Novelty, Distinctiveness, Uniformity, Stability and Identifiability.
- (13) "On site inspection" shall mean the conduct of systematic inspection of the site where the seed variety is grown by the applicant or the relevant agency responsible for carrying out the testing in compliance to Novelty, Distinctiveness, Uniqueness, Stability and Identifiability criteria.
- (14) "Person" shall mean any natural or legal person.
- (15) "Rules" shall mean the Biodiversity Rules and Regulations of Bhutan, 2023.
- (16) "Seed" shall mean any unit of reproduction used for sowing or planting and includes seed of food, feed, forages, fruits and vegetable crops. It also includes seedlings and tubers, bulbs, rhizomes, roots, cuttings, all types of grafts and other vegetatively propagated materials.

Form I: Application form for Registration of Plant Variety under the 'Sui Generis System of Protection of Plant Varieties'

[See section 32 of Biodiversity Rules and Regulations 2023]

Instruction to applicant: Wherever a box item appears against queries, please tick the relevant box and provide legibly written/typed response in other queries
Section 1: Identity of the Applicant(s):
Individual Breeder(s)
Successor of Breeder
Farmer/Farming Community
Institutional/Employer
Assignee of Any of Above
Section 2: Name(s) of Applicant(s)
(If natural person): (Insert additional rows, if required)
Name(s):
Complete Address:
Dzongkhag:
If a legal person; for example, a firm or company or institution)
Name:
Complete Address:
Year of Registration:
Section 3: General Information of the Candidate Variety:
Common Name of the Crop:
Scientific Name:
Family:
Denomination (in block letters):
, , , ,
Section 4: Type of Variety (see section 29 of the Sui Generis System of Protection of Plant Varieties and of Biodiversity Act of Bhutan 2022)
New Variety
Farmers' Variety
*If new variety is a tGMO/GMO attach clearance on Biosafety from BAFRA.
Section 5: Names and Addresses of Breeder(s) who has/have bred the Candidate
Variety*:
Name:
Address:
Telephone:
Email:
Nationality:
*In case of more than one breeder, mention all names as (ii), (iii) and so on in the above
format If required invest an extra nage

a. What is (are) the Novelty, Distinctness, Uniformity, Stability and Identifiability feature on the basis of which registration is sought. Explain in detail the group characters.
Has the candidate variety been commercialized or otherwise exploited? Yes No *If yes, please indicate the following: Date of the first sale of the variety: Denomination used: Variation in important trait with Respect to first filing: (attach sheet) b. If the candidate variety is a hybrid, state whether all the parental lines required for the repeated propagation of the hybrid are bred exclusively by the applicant(s):
Yes No
*If no, mention which of the parental line is outsourced, whether letter of agreement is obtained for each of the outsourced protected parental lines in compliance with Section 35 of the Sui Generis System for Protection of the Plant Varieties of the Biodiversity Act of Bhutan 2022 and also provide following information on each of them: Parental line (S): Denominations ⁷ : Source: Authorisation letter obtained: Attached Not attached
*Denomination should not be altered from what was used at the source. Information on source may include name of breeder or institution or farmer or farming community who had bred and maintained the parental line. Repeat above information for additional applicable parental line.
c. State if any Farmers' Variety or Variety of Common Knowledge or variety in public domain is used as parental line for the repeated propagation of the hybrid: Yes
d. The Sui Generis System of Protection of Plant Varieties under the Biodiversity Act of Bhutan 2022 provides access to benefit sharing to farmers who have conserved the genetic resource that has contributed towards variety development. In this particular case what sort of farmer/community recognition the Applicant has planned?

e. In case exotic germplasm was used in the derivation of the variety or hybrid, give details:

Section 6: Declarations

The undersigned hereby apply for the grant of registration of the candidate variety with the above said denomination and I/we am are conversant with the Sui Generis System of Protection of Plant Varieties and Rules thereof related to this application under the aegis of Biodiversity Act of Bhutan 2022.

The undersigned hereby declare that no person other than the person or persons mentioned in this application has been involved in the breeding, or discovery or development of the candidate variety.

The undersigned hereby declare that the candidate variety complies with the section 29 to 34 of Sui Generis System of Protection of Plant Varieties of the Biodiversity Act of Bhutan 2022.

The undersigned hereby declare that I/we have not applied for or received a trademark for the said denomination of the variety.

The undersigned hereby declare that the information given in this application for the registration of the above said candidate variety, including annexure and all supporting documents are complete, true and correct to the best of my/our knowledge, information and belief and no information has been willfully concealed.

The undersigned hereby declare that genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired.

The undersigned hereby declare that the undersigned shall abide by all the provisions and guidelines of Sui Generis System of Protection of Plant Varieties of the Biodiversity Act of Bhutan 2022.

Signature of Applicants

*Wherever the applicants are more than one person each applicant has to sign. In the case of authorized application or application by assignees, such person(s) authorized or assigned shall sign

Annex I: Following are the attachments (duly signed/seal) to be submitted along with application:

- complete application;
- · document of authorisation;
- document of assignment;
- documents in support of (b) and (c) as given above. (If applicable);
- affidavit that the Terminator Technology and the Genetic Use Restriction Technology is not involved:

- technical Questionnaire for the Candidate variety (attached);
- in case of transgenic relevant Genetic Engineering Approval Committee clearances and approvals; and
- Fees as applicable;

^{*}If felt necessary attach colour pictures of specific characteristics used for establishing distinctness. Please sign each page of the application and other documents on the left margin.

Form II: Assignment of Application or Restitution of the Title

Application form for the assignment of application or restitution of the Title of variety rights under section 38 and 39 of the Act				
This application is with regard to the plant variety protection number of the				
The undersigned would like to submit that the grant of plant variety protection to the aforementioned variety may be reassigned/restituted based on the following. (a) The information provided by the applicant is incorrect. (b) The plant variety protection is granted to a person who is not eligible for protection under the Act. (c) The rightful owner of the Title of the variety rights is as follows:				
 Name: Address: Telephone: Email: Nationality: 				
(d) Proof of breeding is submitted				

Form III: Access proposal

Form for Access Proposal (Information included in this Form shall be in sufficient detail
to enable the relevant authorities to make a decision whether to grant or refuse Access)
Section 1. Applicant
Name:
Address:
Address: Home Tel
E-mail address:
Mobile:
Name and address of principal researcher:
Address of the contact person/agent if any in Bhutan:
Section 2. Category
(Tick the relevant box)
Type of Phase
□ Scoping □ Access and Benefit Sharing
Type of Resources
□Genetic Resources □ Associated Traditional Knowledge □ others (specify)
Section 3. Application Checklist
The following list outlines all of the information necessary to provide a timely decision
on your application. All items on the list must be provided with the application. We are
unable to accept applications that do not have all of the required items.
 Profile of the organization including Board of Directors and Shareholders.
□ Company's Article of Incorporation.
 Copy of passport of foreign applicant (if investor is individual).
Power of Attorney for the authorized representative or contact person.
☐ Identity and responsibilities of all entities who will be involved in the activities, if
any.
☐ Annual turnover of the organization in Ngultrum or US dollars (including Tax return

Section 4: Proposal

The proposal shall include:

- a) Identification (scientific name) of genetic resource and its use, description and nature of traditional knowledge (oral/documented).
- b) Purpose for which access is requested including the type and extent of research, mechanism for sharing of results, commercial use being derived and expected to be derived from it and any other benefits anticipated.
- c) Geographical location of proposed collection.
- d) Any identified individual or community for access to traditional knowledge.

or audited accounts of foreign investors for the last 3 years).

Equipment and laboratories relevant to the activity.

- e) Quantity of biological resources to be collected.
- f) Information of collaborating local partners.
- g) Information on the arrangements made within Bhutan to facilitate the collection.

- h) Whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access.
- Nature of legal rights including any intellectual property rights the applicant intends to seek over the accessed genetic resources and ensuing innovations.
- j) Work plan and timeframe within which the project is to be completed.

Section 5. Others

- Information on the primary destination of the resources and any expected subsequent destinations of the resources.
- Potential economic and other benefits including those resulting from any Intellectual Property Rights (IPR) and patent obtained out of accessed biological resources and knowledge that are intended, or may accrue to the applicant or to the country he/she belongs.

Section 6. Declaration

The undersigned, being duly authorized, declare to the best of my knowledge and belief that the information contained in this application is correct and complete and I authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application.

In case, the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed:	
Date:	
Name:	
In the capacity of:	

Form IV: Prior Informed Consent

Form for Prior Informed Consent		
Section 1. Details of the Provider of Genetic Resources or holder of associate	ted Trad	itional
Knowledge		
Name:		
Dzongkhag:		
Gewog:		
Village		
Works Tel Home Tel		
E-mail address:		
Mobile:	_	
Section 2. Category		
(Tick the relevant information)		
Phase		
□ Scoping □ Access and Benefit Sharing □ others (specify)		
Type of Resources		
□ Genetic Resources □ Associated Traditional Knowledge		
Section 3: Details of the Genetic Resources or Tradition Knowledge		
1. Scientific description of genetic resources to be collected or associa	ited trad	itional
knowledge:		
Purpose for which access is requested:		
3. Location where activities will take place:		
4. Proposed starting & ending date:	vear)	
5. Describe the economic, social, technical, scientific, environmental and oth		its that
this activity may likely accrue to Bhutan and other relevant stakeholders:	cr ocner	iis tiitt
Section 4: Consent		
Do you agree to the following?	Yes	No
Use of genetic resources or traditional knowledge by	103	110
research on new compound and product development.		
Sharing of genetic resources or traditional knowledge with others.		
Others (specify)		
I/we have voluntarily decided to select the option or options which I/we have to	intend of	
Twe have voluntarity decided to select the option of options which I we have	ickeu au	ove.
Name of Provider		
Date Signature of National	1 E1 E	
Signature of Nationa	1 FOCAL P	OIII

Form V: Scoping Agreement

SCOPING AGREEMENT

Date ____, ___,

Reference No_____

This Agreeme	ent is made between:			
and r autho	Ministry of Agriculture and Livestock, Royal Government of Bhutan acting through and represented by the Program Director, National Biodiversity Centre being the authorised officer of the National Focal Point having its office at Serbithang, Thimphu, Bhutan (hereinafter referred to as "the NFP")			
	And established and existing under the laws with a capital of having gistered office at			
	Article 1 – Preamble			
1.1	The NFP has been established by the Royal Government of Bhutan (hereinafter referred to as RGoB) under the powers granted to it by Section 16 of the Biodiversity Act of Bhutan 2022 under which, the NFP is the entity vested with the responsibility to regulate the access to genetic resources and benefit sharing in the country and authorized to permit access to any genetic resources and /or associated traditional knowledge found within the territory of Bhutan upon the approval of the Competent National Authority (CNA) established under Section 13 of the Biodiversity Act of Bhutan 2022 (hereafter referred to as the Act).			
1.2	The NFP through this agreement furnishes the Prior Informed Consent (PIC) from providers of genetic resources and/or associated traditional knowledge for granting the access.			
1.3	The User acknowledges that the RGoB retains legal ownership of Bhutan's genetic resources and /or associated traditional knowledge and the associated intellectual property rights unless determined under this Agreement.			
1.4	This Agreement is for granting approval for the scoping phase of access to Bhutan's genetic resources and /or associated traditional knowledge specified under Section 4 of this Agreement.			
1.5	User seeks to engage in the scoping phase of the utilization of Bhutan's genetic resources and /or associated traditional knowledge and has made an application to the NFP for approval.			
1.6	Access to Bhutan's genetic resources shall be divided in two phases: a Scoping Phase and an Actualization Phase with differing conditions for each phase.			

- 1.7 The Scoping Phase to conduct exploratory research will require a Scoping Permit which shall be in the form of a Scoping Agreement and contain a set of conditions for utilization of such resources.
- 1.8 Based on the outcome of the Scoping Phase if User intends to undertake any step to commercialize or engage in focused research on such resources and/or research results which may include but is not limited to applications for intellectual property rights, product development and testing and marketing; User shall enter into an Access and Benefit Sharing (ABS) Agreement and secure Actualization Permit prior to engaging in such steps or the Actualization Phase of utilization of such resources.
- 1.9 Benefit sharing under the ABS Agreement during Actualization Phase shall be based on each party's contribution, fairness and mutual consensus.
- 1.10 The NFP and User shall jointly be referred to as "Parties" and now therefore, the "Parties" hereto hereby agree as follows:

Article 2- Definitions

2.1 In this Agreement, unless the context otherwise requires, the expression set out below shall have the following meaning:

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

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

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

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

Bhutan Access and Benefit Sharing Fund (BABS Fund) means a fund established under section 128 of the Act to receive monetary benefits derived from the research and

- 1.7 The Scoping Phase to conduct exploratory research will require a Scoping Permit which shall be in the form of a Scoping Agreement and contain a set of conditions for utilization of such resources
- 1.8 Based on the outcome of the Scoping Phase if User intends to undertake any step to commercialize or engage in focused research on such resources and/or research results which may include but is not limited to applications for intellectual property rights, product development and testing and marketing; User shall enter into an Access and Benefit Sharing (ABS) Agreement and secure Actualization Permit prior to engaging in such steps or the Actualization Phase of utilization of such resources.
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Genetic Resources means all material of plant, animal, microbial or other origin containing functional units of heredity and include the biochemical composition of genetic resources, genetic information and derivatives.

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

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

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

Bhutan Access and Benefit Sharing Fund (BABS Fund) means a fund established under section 128 of the Act to receive monetary benefits derived from the research and

commercial utilization of Bhutan's genetic resources and/or associated traditional knowledge including processing fee and commitment fee payable at the Scoping phase.

Act means the Biodiversity Act of Bhutan 2022 and includes any subsequent amendment or re- enactment of the Act

Rules means the Biodiversity Rules and Regulations 2023

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

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

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

Third Party means any person or institution other than the National Focal Point, the User or any collaborator under their control or supervision.

User means a person (individual or organization) named as the User and includes their authorized representative, where the context permits.

Article 3- Grant of Access

- 3.1 The NFP hereby grants approval for access to genetic resources and/or associated traditional knowledge listed under annex-1 for the scoping phase for the purpose of...... subject to the terms and conditions set forth in this Agreement.
- 3.2 Any activity/usage involving the genetic resources and/or associated traditional knowledge that is not expressly authorized by the provisions of this Agreement and any additional annexure (s) hereto is deemed as prohibited.
- 3.3 User hereby agrees that, this Agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Parties hereto or make them in any way liable as partners of or as agents for one another. No Party has the authority to act for or to assume any obligation or responsibility on behalf of the other Party and the relationship between the Parties is that of a legal or natural person and a statutory authority competent to approve access to genetic resources under the Act.

Article 4- Conditions for Access

4.1 User shall have access only to the genetic resources and/or associated traditional knowledge approved by the CNA and listed under Annex-1 of this agreement and only for the purpose approved under this Agreement.

- 4.2 User shall pay such sum of US dollar 500.00 (US dollar five hundred only) as a processing fee for the Scoping Permit/Agreement and sum of US dollar 5000.00 (US dollar five thousand only) as a commitment fee as specified section 80 of the Act. The processing fee and the commitment fee shall be deposited in Bhutan ABS Fund dedicated to support conservation and sustainable use of Bhutan's biodiversity and associated traditional knowledge, and enhancement of rural livelihoods as specified in section 130 of the Act.
- 4.3 User undertakes to abide with the provisions of the Act and other related legislations in force in Bhutan and as amended in the future.
- 4.4 User undertakes to facilitate measures for the conservation and sustainable use of genetic resources and to minimize any negative environmental or social impact of the collecting the genetic resources and other research activities.
- 4.5 User shall not distribute, transfer or part with the accessed genetic resources and associated information to any third party without prior written approval of CNA nor engage in the 'actualization phase' of the accessed resources under this Agreement and signing of appropriate Agreement and issuance of Actualization Permit.
- 4.6 User undertake to submit a status report in English on yearly basis on the progress of the scoping phase to the NFP for submission to the CNA by 31st of December.
- 4.7 The CNA reserves its right to supervise the access process to the genetic resources and/or associated traditional knowledge, and the research as it may deem fit.
- 4.8 Any violation of above conditions will be deemed to be material breach of this Agreement making the Agreement voidable at the option of the NFP.

Article 5- Third Party Transfer and Assignment

- 5.1 Without the prior written approval of the CNA through NFP in each instance, neither this Agreement nor the approval granted hereunder shall be transferred or assigned in whole or in part by User to any natural or legal person whether voluntarily or involuntarily, by operation of act or omission on the part of User or otherwise.
- 5.2 In the event of any substantial changes in the management or shareholding of User, that alters the control structure of User and includes changes brought by a transfer of business units, merger, demerger or any other kind of corporate restructuring, User shall ensure that the obligations under this agreement perpetuate and provide written notice to the NFP not less than ninety (90) days prior to initiating such changes.

Article 6- Other Conditions

6.1 User shall submit in English a hard and soft copy of its scoping findings in the form of reports, publications, thesis or any other documents to the NFP as soon as the scoping is completed or published or expiry of the term of the Agreement whichever is earlier. The NFP on behalf of the RGoB shall have full ownership of the results of the scoping phase if User decides not to enter into an 'actualization'.

phase' of the utilization of Bhutan's genetic resources and/or associated traditional knowledge.

Article 7- Liabilities and Indemnification

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

Article 8- Term of the Agreement and Termination

- 8.1 This Agreement, unless terminated as provided herein, shall remain in effect for a period of five (5) years from the date of signing of this Agreement by the Parties. However, the obligations of User with respect to the utilization of Bhutan's genetic resources and/or associated information under this Agreement will remain in perpetuity.
- 8.2 The NFP upon approval of CNA may terminate the rights under this Agreement and revoke the Scoping Permit by a written notice if User defaults in the performance of any obligations under this Agreement and the default has not been remedied within ninety (90) days after the date of notice in writing of such default by NFP.
- 8.3 User agrees to forfeit its deposit in situations where the NFP terminates this Agreement and revokes the Scoping Permit under the conditions listed in 8.2 of this Agreement.
- 8.4 User may terminate this Agreement by giving ninety (90) days advance written notice stating valid reasons for the same. However, such termination shall come into effect only on acceptance of the same by the NFP given in writing not later than thirty (30) days after the notice period and payment of all outstanding dues and submission of mandatory reports on scoping conducted until then by User.
- 8.5 User agrees to transfer to the NFP all the data/results/conclusions of the scoping phase in the instance of the termination of this Agreement.
- 8.6 User agrees to return the genetic resources remaining and/or associated information to NFP no later than thirty (30) days after the termination of this Agreement. The costs incurred in transferring these resources back to the NFP will be borne by User.

- 8.7 The NFP shall not be liable for any loss or damage whatsoever caused to User due to revocation of approval for access and/ or termination of this Agreement on any ground whatsoever.
- 8.8 User on termination of the Agreement, agrees not use any of the data/results/conclusions from the research on the accessed material for any purpose whatsoever without the prior approval of the NFP.

Article 9- Notice

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

The addresses of the Parties for communication:

NFP	User
Program Director National Biodiversity Centre Ministry of Agriculture and Livestock P.O. Box 875, Serbithang Thimphu, Bhutan	

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

Article 10- Confidentiality

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

Article 11-Interpretation

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

Article 12- Arbitration

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

Article 13- Governing Law and Jurisdiction

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

Article 14-Severability

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

Article 15- Modification

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

Article 16-Entirety of Agreement

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

Article 17-Representations

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

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

Article 18 - Signature and Acceptance

In witness thereof, the parties have executed this Agreement on the dates set forth below.

Seal & Dated Signature [Seal & Dated Signature []
For the NFP	Witness
Name:	Name:
Designation:	Designation:
Nationality ID Number:	Nationality ID Number:
Mailing Address:	Mailing Address:
For the User	Witness
Seal & Dated Signature [Seal & Dated Signature [
Name:	Name:
Designation:	Designation:

Ma	iling Address:	Mailing Address:			
Annex-1					
Sl. No	Botanical Name	Common Name	Local Name	Family	

Form VI: Form for seeking approval for third party transfers of the accessed genetic resources and/or associated Traditional Knowledge.

	r iniru party transfers of the accessed gen	
and/or a	ssociated Traditional Knowledge.	
Section 1. Details of the Third		
Name:		
Address:		
	_ Home Tel	
E-mail address:		_
Mobile:		
Name and address of principal re	esearcher:	
Section 2. Details of the First P	arty	
Name:		
Address:		
Works Tel	_ Home Tel	
E-mail address:		
Mobile:		

Section 3. Third Party Checklist

The following list outlines all of the information necessary to provide a timely decision on your application. All items on the list must be provided with the application. We are unable to accept applications that do not have all of the required items.

- Profile of the organization including Board of Directors and Shareholders.
- Company's Article of Incorporation.
- Copy of passport of foreign applicant (if investor is individual).
- Power of Attorney for the authorized representative or contact person.
- Identity and responsibilities of all entities who will be involved in the activities, if any.
- Annual turnover of the organization in Ngultrum or US dollars (including Tax return or audited accounts of foreign investors for the last 3 years).
- Equipment and laboratories relevant to the activity.

Section 4: Application Details

The application shall include:

- a) Identification (scientific name) of genetic resource and its use, description and nature of traditional knowledge (oral/documented).
- b) Purpose of the intended third party transfer including the type and extent of research.
- c) Details of the contract entered with the first party (Copy to be enclosed).
- d) Details of the benefits and mechanism/arrangements for benefit sharing already implemented, if any.
- Estimation of benefits that would flow to Bhutan arising out of the third party transfer of accessed biological resources/associated traditional knowledge.
- f) Proposed mechanism and arrangements for benefit sharing arising out of the proposed third party transfer.
- g) Nature of legal rights including any intellectual property rights the third party intends to seek over the accessed genetic resources and ensuing innovations.

- h) Information on the primary destination of the resources and any expected subsequent destinations of the resources.
- i)
- j) Work plan and timeframe within which the project is to be completed.

Section 5. Declaration

The undersigned, being duly authorized, declare to the best of my knowledge and belief that the information contained in this application is correct and complete and I authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application.

In case, the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.

Signed:		
Date:		
Name:		
In the capacity of:		

Form VII: Access and Benefit Sharing Agreement

Reference No	Date,,
This Agreement is made between:	
User, a business entity holding trade license no, with its r Changangkha Thimphu Bhutan[hereinafter referred to as the "Use	
Provider, [hereinafter referred to as the "H	Provider"]; in presence of

Ministry of Agriculture and Livestock, Royal Government of Bhutan acting through and represented by the Program Director, National Biodiversity Centre being the authorised officer of the National Focal Point having its office at Serbithang, Thimphu, Bhutan (hereinafter referred to as "the NFP")

Article 1 - Preamble

- 1.1 The NFP has been established by the Royal Government of Bhutan (hereinafter referred to as RGoB) under the powers granted to it by Section 16 of the Biodiversity Act of Bhutan 2022 under which, the NFP is the entity vested with the responsibility to regulate the access to genetic resources and benefit sharing in the country and authorized to permit access to any genetic resources and /or associated traditional knowledge found within the territory of Bhutan upon the approval of the Competent National Authority (CNA) established under Section 13 of the Biodiversity Act of Bhutan 2022 (hereafter referred to as the Act).
- 1.2 The Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) to which Bhutan is a party gives the responsibility to manage biological diversity to ensure fair and equitable sharing of the benefits arising from the use of genetic resources.
- 1.3 Realizing the benefits that the country may accrue from regulating access to its genetic resources and ensuring fair and equitable sharing of benefits, the Biodiversity Act of Bhutan 2022 was enacted to provide for detailed provisions relating to access to genetic resources and benefit sharing.
- 1.4 The User intends to access genetic resources specified in this Agreement from the Kingdom of Bhutan.
- 1.5 The NFP through this agreement furnishes the Prior Informed Consent (PIC) from providers of genetic resources and/or associated traditional knowledge for granting the access.

- 1.6 The User acknowledges that the RGoB retains legal ownership of Bhutan's genetic resources and /or associated traditional knowledge and the associated intellectual property rights unless specified under this Agreement.
- 1.7 In consideration of the grant of access to genetic resources and/or associated traditional knowledge, the User is entitled to access and use the genetic resources and/or associated traditional knowledge in accordance with this Agreement and shall agree to share the benefits specified herein.
- 1.8 The Provider and User shall jointly be referred to as "Parties" and now therefore, the "Parties" hereto hereby agree as follows:

Article 2- Definitions

2.1 In this Agreement, unless the context otherwise requires, the expression set out below shall have the following meaning:

Access Area means the area from which the User will have access to biological resources.

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

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

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

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

Bhutan Access and Benefit Sharing Fund (BABS Fund) means a fund established under section 128 of the Act to receive monetary benefits derived from the research and commercial utilization of Bhutan's genetic resources and/or associated traditional knowledge including processing fee and commitment fee payable at the Scoping phase.

Act means the Biodiversity Act of Bhutan 2022 and includes any subsequent amendment or reenactment of the Act Rules means the Biodiversity Rules and Regulations 2023

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

Commercial utilization means applying for, obtaining or transferring intellectual property rights by sale or license or in any other manner, or commencement of product development, conducting market research or the sale of any resulting product.

Product means material produced, obtained, extracted or derived through research and development activity.

Prior Informed Consent means a process through which the National Focal Point seeks the consent of the providers of genetic resources or holders of associated traditional knowledge.

Provider means a person (individual or organization) named as Provider and includes their authorized representative, where the context permits.

Third Party means any person or institution other than the Provider, the User or any collaborator under their control or supervision.

User means a person (individual or organization) named as the User and includes their authorized representative, where the context permits.

Article 3- Interpretation

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

Article 4- Prior Informed Consent

4.1 This Agreement is made pursuant to the Prior Informed Consent (PIC) given by the Provider granting the access to genetic resources and/or traditional knowledge associated with genetic resources as specified in section 66 of the Act

Article 5- Grant of Access

5.1 The User shall have access to the genetic resources and/ or traditional knowledge associated with genetic resources as specified in Schedule A of this Agreement. 5.2 The User shall pay such sum of US dollar 500 (US dollar five hundred only) as a processing fee for the ABS Agreement and sum of US dollar 5000 (US dollar five thousand only) as a commitment fee as specified section 80 of the Act. The processing fee and the commitment fee shall be deposited in Bhutan ABS Fund dedicated to support conservation and sustainable use of Bhutan's biodiversity and associated traditional knowledge, and enhancement of rural livelihoods as specified in section 130 of the Act.

Article 6- Conditions for Access

- 6.1 The User shall have access only to the genetic resource specified in Schedule A of this Agreement and undertakes to access the same in accordance with the conditions specified in this Agreement.
- 6.2 The User shall attach details of the commercial utilization of the genetic resources and/or associated traditional knowledge accessed in accordance with Schedule B of this Agreement.
- 6.3 Any use involving the genetic resource and/or associated traditional knowledge that is not expressly authorized by the provisions of this agreement shall be deemed to be expressly prohibited.
- 6.4 The User undertakes that it shall not allow any persons other than its authorized employees under its direct control and supervision to have access to the genetic resource and/or associated traditional knowledge.
- 6.5 The User shall not obtain, transfer, and distribute any form of intellectual property rights associated with the genetic resource accessed under this agreement in any manner without obtaining the prior written approval of the CNA through NFP.
- 6.6 The User undertakes to comply with the existing national laws, regulatory mechanisms and international agreements or treaties for the access to genetic resources. Provided that in case of conflict between the national laws and international agreement, the national laws shall prevail.
- 6.7 User undertakes to abide by the provisions of the Act and other related legislations in force in Bhutan and as amended in the future.
- 6.8 The approval given under this agreement is without prejudice to any other permits or approval that may be required for the purpose of access to the genetic resources and/or associated traditional knowledge from any other authorities under any other laws in force in the territory of Bhutan.
- 6.9 The failure to acquire such permit or approval under clause 6.8 shall be deemed as a material breach of this agreement and shall result in the termination of this agreement. However, upon an application by the User, the User may be given the opportunity to rectify the default and obtain the required permit or approval within such time as may be granted by the CNA through NFP.

Article 7- Third Party Transfer

- 7.1 The User shall not transfer the results of research relating to any genetic resources and or associated traditional knowledge that is the subject of this Agreement to a third party without obtaining the approval of the CNA through NFP.
- 7.2 Without the prior written approval of CNA through NFP, neither this agreement nor the approval granted hereunder shall be transferred or assigned in whole or in part by the User to a third party.
- 7.3 In the event of any substantial changes in the management or shareholding of the User that alters the organizational or control structure of the User and includes changes brought by acquisition, merger, demerger or any other kind of corporate restructuring, the User shall ensure that the obligations under this agreement perpetuate and provide written notice to the NFP not less than ninety (90) days prior to initiating such changes.

Article 8– Liabilities and Indemnification

- 8.1 A relevant Party shall be solely responsible for any claims by third parties arising from its acts or omissions in the course of performing this agreement and under no circumstances shall the other relevant Party be held responsible or liable for any such claims by third parties.
- 8.2 A relevant Party shall indemnify the other relevant Party and its employees from and against all claims, losses, damages, costs (including attorney fees), actions, suits or other proceedings, in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of the relevant Party, its employees or agents, (whether by reason of negligence or otherwise) in the performance by or on behalf of the relevant Party of the provisions of this agreement or any activity undertaken or purported to be undertaken pursuant to the terms of this agreement.

Article 9- Benefit Sharing

- 9.1 The User shall pay to the Provider 15 % of annual gross ex-factory sales of the product on such date as may be agreed between the relevant parties.
- 9.2 Two (2) % of the total monetary benefits specified in clause 9.1 shall be paid to the BABS Fund.
- 9.3 The User shall adopt sustainable management of genetic resources while sourcing the genetic resources.
- 9.4 The User shall pay a premium price at a mutually agreed rate and quantity which shall be stipulated in a separate supply agreement executed between the User and the Provider under the guidance of NFP.
- 9.5 The User shall provide details of other benefits in the Schedule C

Article 10- Obligation of the Provider

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

Article 11- Termination

- 11.1 This agreement, unless terminated as provided herein, shall remain in effect for a period of years from the date of signing this agreement. In case the User continues the commercial utilization of the genetic resource mentioned in the agreement beyond the period initially agreed upon, the User shall apply for renewal to the NFP for subsequent required period at which time a new agreement has to be effected with relevant provisions agreed mutually.
- 11.2 The relevant Parties may terminate this agreement at any time by mutual agreement in writing by giving ninety (90) days advance written notice of termination. or either relevant Party may terminate this agreement by a written notice on the happening of any of the following:
 - a. if the User does not make a payment due and fails to clear such nonpayment within thirty (30) days after the date of notice in writing of such non-payment; or
 - b. if the User becomes insolvent or has a petition in bankruptcy, winding up filed for or against it, such termination shall be effective immediately upon the NFP giving written notice to the User.
- 11.3 The NFP may upon seeking approval of CNA revoke access or approval granted to the applicant, if any of the following circumstances arise:
 - a. on the basis of reasonable belief that the person accessing the said genetic resource has violated any of the provisions of the Act or the condition on which approval was granted;
 - b. when the person has failed to comply with the terms of the agreement;
 - c. on failure to comply with any of the use conditions; or
 - d. on account of overriding public interest with reference to protection of environment and conservation of biological diversity and protection of the rights, livelihoods and knowledge of communities.

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

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

- 11.5 The NFP shall not be liable for any loss or damage whatsoever caused to the User due to revocation of approval for access and/ or termination of this agreement as provided in section 11.3 of this agreement.
- 11.6 The User upon termination of the Agreement, agrees not to use any of the data, results, or conclusions from the research on the accessed material for any purpose whatsoever without the prior approval of the CNA.

Article 12- Reports and Audit

- 12.1 The User shall submit to the National Focal Point yearly reports on the following:
 - a. the quantity of genetic resource accessed;
 - the total quantity of the products produced by the use of the accessed genetic resources and associated traditional knowledge;
 - c. audited financial statements; and
 - d. any other related information sought by the NFP by a written notice.
- 12.2 The User shall keep accurate records (together with supporting documentation) appropriate to determine all amounts due to the Provider. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate.
- 12.3 In conducting audits pursuant to section 12.1 and 12.2, such person shall have access to all records which he reasonably believes to be relevant to the calculation of monetary benefit.

Article 13- Confidentiality

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

Article 14- Notice

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

For the NFP:

Program Director National Biodiversity Centre Ministry of Agriculture and Livestock Serbithang Thimphu Tel # 02-351417/351218 Fax # 02-351219 Post Box No. 875

For the Provide

For the Use

- 14.2 Notice will be deemed to have been delivered:
 - i. if delivered by hand, upon receipt;
 - ii. If sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation of weekends and public holidays; or
 - iii. If sent by post, seven (7) days after the mailing thereof.
 - 14.3 The Parties may change their respective addresses for delivery by delivering notice of change as provided in this paragraph.

Article 15– Governing Law and Jurisdiction

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

Article 16- Arbitration

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

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

Article 17- Severability

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

Article 18- Severability

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

Article 19- Benefit of Agreement

19.1 This Agreement shall bind and inure to the benefit of the successors and assignees of the parties. However, none of the relevant Parties may assign or delegate any of its rights or obligations herein without the prior written consent of other relevant party and the NFP.

Article 20- Representations

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

Article 21- Miscellaneous

- 21.1 The User hereby agrees that this agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Relevant Parties hereto or make them in any way liable as partners of or as agents for one another.
- 21.2 The documents attached hereto as Schedules form an integral part of this agreement, and consists of:

Schedule A: Access to Genetic Resources

	Schedule B: Details of Commercial Utilization of genetic resources								
	Schedule C: mechanism	Details	of	Benefit	Sharing	mutually	agreed	and	delivery
21.3	Payments to instruments a					nall be cha	nneled th	rough	banking
	ent has been ex etained by the								
		Article 1	8 – S	ignature a	and Accep	tance			
In witness the	reof, the parties	have exect	uted	this Agree	ment on the	e dates set fo	orth below	7.	
Seal & Dated S	ignature [] Seal &	Dated Sign	iature []
For the Provi	ider				Witness				
Name:					Name:				
Designation:					Designati	on:			
Nationality ID	Number:				Nationalit	y ID Numbe	er:		
Mailing Addres	ss:				Mailing A	ddress:			
For the User					Witness				
Seal & Dated S	ignature [] Seal &	Dated Sign	ature []
Name:					Name:				
Designation:					Designati	on:			
Nationality ID	Number:				Nationalit	ty ID Numb	er:		
Mailing Addres	ss:				Mailing A	ddress:			
For the NFP					Witness				

Seal & Dated Signature [] Seal &	Dated Signature []					
Name:	Name:					
Designation:	Designation:					
Nationality ID Number:	Nationality ID Number:					
Mailing Address:	Mailing Address:					
Schedule A: Access to genetic resources						
Sample of biological resources to be collected: level of taxon, to which the resources belong; mention (leaves, stem, flower, roots etc.]	[include name of species or lowest on form of biological resource to be collected					
Access Area: sample will be taken]	[state the area from which the					
Time and Frequency of entry to access area: of entry to access area]	[state the anticipated dates and times					
Purpose of Access:	[provide a brief description of the					
purpose(s) of collecting samples including end prod Labelling of Samples: means of labelling the samples]	[include a statement setting out the					
Schedule B: Details of commercial utilization of g	genetic resources					
(Please provide detail the detail of what type of products will be made. A brief background)						
Schedule C: Details of benefit sharing mutually agreed and delivery mechanism						
(Please provide detail the detail of what type of bene	efits)					

Form VIII: Certificate of Compliance

Reference No	Date,,
Certificate of Complia	nce to the ABS legislation in Bhutan
	has legitimately accessed the following genetic knowledge in accordance to the Access and Benefit requirement of Prior Informed Consent (PIC) and
Name of the genetic resources and/ or assort Name of the provider of the genetic resour Purpose of access: Name of the contract agreement: Reference number of the contract agreement	ces and/ or associated traditional knowledge:
	of certificate of compliance to the Biodiversity Act of r permits or clearances required under other laws in force in
	(Signature and Seal) National Focal Point

Form IX: Application form for Material Transfer Agreement

Application form for Material Transfer Agreement
Section 1. Details of the User
Name:
Address:
Works Tel Home Tel
E-mail address:
Mobile:
Section 2. Purpose (tick the relevant box)
□ specific academic research □ exchange of samples
□ sample testing □ others (specify)
Section 3: Details of the Genetic Resources
Scientific description of genetic resources:
a. If it is for academic research:
i) name of the university:
ii) name of the institution:
iv) name of the supervisor:
v) purpose of the study:
vi) affidavit from the institution affirming that it shall not be put to commercial use.
vi) amount from the institution arithming that it shall not be put to commercial use.
b. If it is for exchange of samples: i) Name of the institution providing the genetic resources: ii) Name of the institution receiving the genetic resources: iii) location of the institution: iv) affidavit from the institution affirming that it shall not be put to commercial use.
c. If it is for sample testing: i) purpose of the testing: ii) name of the laboratory: iii) location of the laboratory: iv) affidavit from the user affirming that it shall not be put to commercial use.
Section 4. Declaration
The undersigned, being duly authorized representatives, declare to the best of my knowledge and belief that the information contained in this application is correct and complete and I authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application. In case the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.
Signed:

Name:	
In the capacity of:	

Form X: Application for Standard Material Transfer Agreement

Application form for Standard Material Transfer Agreement
Section 1. Details of the User
Name:
Address: Home Tel
Works Tel Home Tel
E-mail address: Mobile:
Membership to ITPGRFA: □ Yes □ No
Section 2. Purpose:
Section 2.1 dispose.
Section 3: Details of the Genetic Resources
Scientific description of genetic resources: Scientific name:
Common name:
Cultivar/Land Races:
a. If it is for academic research:
i) name of the university:
ii) name of the institution:
iii) location of the institution:
iv) name of the supervisor:
v) purpose of the study:
vi) affidavit from the institution affirming that it shall not be put to commercial use.
b. Sample testing for non-commercial breeding for food security.
i) purpose:
11) Name of the institution:
iii) name of the laboratory: iv) location of the laboratory:
v) affidavit from the user affirming that it shall not be put to commercial use:
v) afficavit from the user affilming that it shall not be put to commercial use.
Section 4. Declaration
I/We, the undersigned, being duly authorized representative, declare to the best of my/our knowledge and belief that the information contained in this application is correct and complete and I/We authorize the National Focal Point to make all necessary inquiries and to conduct all necessary checks in relation to this application. In case the information provided in the application form is found to be false, the National Focal Point may take appropriate action as per the laws of the land.
Signed:
Date:
Name:
In the capacity of:

Form XI: SAMPLE TRANSFER CERTIFICATE

SAMPLE TRANSFER CERTIFICATE (Certificate of Origin for Genetic Resources) Reference No Date ___, ___, ___ This Certificate is issued pursuant to regulation 93 of the Biodiversity Rules and Regulations of Bhutan 2023. _____ (Name) is permitted to transfer _____ (genetic material) accessed from _____ (Dzongkhag), Bhutan to _____ (Place of Destination). The details of the material are as follows: Material Description: Quantity of Material to be transferred: Purpose of transfer: Name of the contract agreement: Reference number of the contract agreement: This Certificate is valid for one time transfer of the genetic resources only. (Signature and Seal) National Focal Point



श्रु.षश्र.रम्भु.पुरःसेथःप्रव

ROYAL GOVERNMENT OF BHUTAN Ministry of Agriculture and Livestock

National Biodiversity Centre Serbithang: Thimphu, Bhutan



Refere	ence No:					Date,,
Nation Minist Serbit	hang Thimpl	ity Centre lture and Livesto	ock,			
I.	Mr./Ms.		holding	CID	No	
			under			Dzongkhag
would		to transfe		0 t og		to Mr./Ms.
						do hereby confirm to
the fol	llowing:					- 1
2.	and consur approval fi Centre (NE AND WHI will remain that the ma of research AND WHI and comm: and Regula laws. IN THE W	mption and in ca com the Compet BC). EREAS I take fit it liable for any so terial is intended nor transfer to a EREAS I underst its breach of any titions. I shall be	use of a change ent National Au all responsibility of of misuse arised for direct use my third party for that in the expression of the accountable for	of intent, the of intent, the office of the safe of th	e undersigned s IA) through the lety and protect: e transferred get ption, and it wi intent. ot adhere to afor lity Act of Bhut and may held liab	be used for direct use shall seek prior written e National Biodiversity ion of the material and netic resources. I affirm Ill not undergo any sort rementioned conditions tan, 2022 and its Rules ble as per the applicable ing in the presence of
Name CID N Phone	d: :: No:	np)		_		Witness

Program Director: +975-2-351416; PABX: +975-2-351218; 351417; 350268; FAX: +975-2-351219; Royal Botanical Garden: +975-2-351278; Post Box #: 875; Email: nbc.moaf@gmail.com; www.nbc.gov.bt (NBC); www.biodiversity.bt (Biodiversity Portal)

