

Draft Rules and Regulations of the Biodiversity Act of Bhutan, 2003

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Presentation Overview

- Overview of Bhutan's Biodiversity Act, 2003
- Status of development of Bhutan's Biodiversity Rules & Regulations
- Clarification of issues & concerns
- Implementation considerations
- Next steps

Why did Bhutan pass the Biodiversity Act, 2003 ???

- Bhutan is a biological 'hot spot' & has a huge base of Traditional Knowledge
- Many research firms have expressed interest in bioprospecting in Bhutan
- There is a need to protect against exploitation while also gaining shared benefits by allowing regulated access
- Bhutan is a party to the CBD & hopes to become a member of WTO (which requires countries to have their own laws on biodiversity & plant variety protection)

Summary of Bhutan's Biodiversity Act, 2003

- Bhutan's Biodiversity Act approved by the National Assembly in August 2003
- Specific authorization to adopt implementing Rules & Regulations approved by the National Assembly in July 2004
- Draft Rules & Regulations now under development & review

Biodiversity Act in a Nutshell: Six Chapters

- Ch. 1: Purposes, Objectives, Scope
- Ch. 2: Biodiversity Access & Benefit Sharing
- Ch. 3: Plant Variety Protection
- Ch. 4: Protection of Traditional Knowledge
- Ch. 5: Offences & Penalties
- Ch. 6: Amendments, Interpretation, Definitions

Purposes & Objectives

- Ensure nat'l sovereignty of RGOB over genetic resources existing in Bhutan consistent with CBD
- Ensure the conservation, sustainable use, and equitable sharing of benefits derived from Bhutan's genetic resources and associated Traditional Knowledge

Purposes & Objectives *cont'd*

- Promote tech transfer and scientific capacity building at nat'l & local levels in Bhutan relating to the conservation & sustainable use of genetic resources
- Recognize & protect uses of Traditional Knowledge associated with biodiversity

Purposes & Objectives *cont'd*

- Regulate & facilitate legal access to genetic resources existing in Bhutan
- Prohibit & penalize illegal taking & use of genetic resources & related Traditional Knowledge existing in Bhutan

Purposes & Objectives *cont'd*

- Recognize & protect farmers' & plant breeders' rights
- Protect plant varieties & promote Bhutan's access to foreign sources of improved plant varieties

Biodiversity Act, 2003: Some points to keep in mind . . .

- The biodiversity law is cross-cutting
 - Environmental considerations
 - Cultural & scientific considerations
 - Property rights considerations
 - Economic considerations
 - Trade & investment considerations
- No 'cook-book' answers . . .
- Buts sets course of action to follow

Biodiversity Rules & Regulations

- Organized according to Biodiversity Act
- Four main substantive sections
 - Introduction
 - Access & Benefit-Sharing
 - Plant Variety Protection
 - Traditional Knowledge
- Appendix (forms to implement Rules)

Biodiversity

Rules & Regulations: Introduction

- Preliminary
 - National Scope
 - Effective Date (???)
- Definitions
 - Incorporated from Biodiversity Act
 - More incorporated from CBD
 - Some new: "Commercial Use"

Biodiversity

Rules & Regulations: Introduction *cont'd*

- Official Procedures / Notifications
 - Discretionary authority of Ministry of Agriculture
- Forms & Annexes
 - Discretionary authority of Ministry of Agriculture ("necessary or appropriate")
- Applications, Permits & Certificates
 - Authorizations granted to 'Authorized Agency'
 - 'Authorized Agency' to be designated by MOA

Review of Issues on Access & Benefit-Sharing

Biodiversity Act, 2003: Access & Benefit-Sharing

- Access to Bhutan's biodiversity now requires 'Prior Informed Consent' (PIC)
- 'PIC' obtained & access authorized through Access Permit
- Applicants must submit an Access Permit Application to the RGOB consistent with the law

Biodiversity Act, 2003: Access & Benefit-Sharing

- RGOB ('Authorized Agency' to be determined by the Agriculture Ministry)
- Permit application requirements & access conditions specified by the law
- Benefit-sharing required as a condition of access (case-by-case basis)
- 30-day decision in writing on permit application (approval, revision, denial)

Rules & Regulations: Access & Benefit Sharing

- Biological specimen collection prohibited w/o permit issued in compliance with Rules
- Access Permit required to
 - "Obtain" / "Collect" / "Utilize" / "Export"
 - "Genetic or Biochemical Resources"
 - "Existing in Bhutan" for
 - "Conservation" / "Research" /
Bioprospecting" / "Commercial" Uses
- But, note 'exceptions' !!!

Rules & Regulations: Access & Benefit Sharing

- Permit Application = “Prior Informed Consent”
 - Applicant’s info (name, address, legal status, roles)
 - Applicant’s tech & financial capabilities
 - Applicant’s prior biospecimen collection experience
 - Description of biospecimens to be collected
 - Research purposes / objectives
 - Potential uses of research results
 - Compliance acknowledgement / agreement
 - Other info required by RGOB

Rules & Regulations: Access & Benefit Sharing

- 'Access Permit Application' Formalities
 - Language (Dzongkha or English)
 - Legibly written / typed / printed
 - Signed by applicant(s)
 - Signature(s) constitute certification of legal compliance
 - Fees to be paid / submitted with application

Rules & Regulations: Access & Benefit Sharing

- *How will an Access Permit Application be processed & reviewed ???*
 - The 'Competent Authority' (Minister/MOA) needs to designate the 'Authorized Agency' to process biodiversity Access Permit Applications as intended by the Act
 - The Authorized Agency will consult with a scientific review committee to evaluate applications
 - The review committee will be comprised of representatives from relevant MOA and other agencies as appropriate

Rules & Regulations: Access & Benefit Sharing

- The Competent Authority through the Authorized Agency may approve, require revisions / additional information, or deny an Access Permit Application
- The Biodiversity Act requires the Competent Authority to notify the applicant of its decision w/in 30 days of receipt of the Access Permit Application

Rules & Regulations: Access & Benefit Sharing

- 'Permit Approval' conditioned on finding of no adverse impact on
 - Public health / safety
 - Environmental / scenic / cultural values
 - Natural / cultural resources
 - Scientific research
 - RGOB management responsibilities
 - Equitable allocation / use of resources
 - Avoidance of conflict

Rules & Regulations: Access & Benefit Sharing

- Permit Denial
 - Based on finding of adverse impact on ONE or more factors required for Permit Approval
 - Explanation provided in writing to applicant (upon applicant's request)
- Amendments / Reconsideration
 - Must be in writing
 - Must provide all information requested by RGOB

Rules & Regulations: Access & Benefit Sharing

- Benefit-Sharing
- Can be required for . . .
 - Specimen collection and use ('up-front')
 - Commercial use of research results ('downstream')
- 'Unauthorized Commercial Use Prohibited' (legally binding & enforceable !!!)

Rules & Regulations: Access & Benefit Sharing

- Benefit-Sharing Options
 - Two Types
 - Monetary
 - Non-Monetary
 - Short-term ('now') / Long-term ('later')
 - Package approach (mix of monetary and non-monetary benefit provided now and later (all subject to negotiation!))

Rules & Regulations: Access & Benefit Sharing

■ Monetary Benefits

- Access ('permit') fee / specimen collection payments
- Cooperative Research Project Budget (cost-sharing)
- Milestone payments (eg, IP applications / IP grants)
- Royalties
 - Creditable annual ???
 - Product-specific ???
 - 'Value-added' ???
 - 'Know-how' (TK) ???
- Other ???

Rules & Regulations: Access & Benefit Sharing

- Non-Monetary Benefits
 - Scientific information / data
 - Joint IP ownership options (negotiable)
 - Joint R&D activities (tech transfer)
 - Technical training / licensing / capacity-building
 - In-kind transfers of equipment / material
 - Acknowledgement of Bhutanese origin
 - Other ???

Rules & Regulations: Access & Benefit Sharing

- Benefit-Sharing: Non-Compliance Penalties
 - Legally binding & enforceable permit condition (essential 'trigger' mechanism)
 - Sale or transfer of specimens, components, products or research results developed from specimens or their components is PROHIBITED w/o approval ('license') from RGOB
 - Non-Compliance Penalty
 - 20% non-compliance payment (on gross revenues)
 - Damages / injunctive relief
 - Other (specified in Act)

Review of Issues
on the
Protection of
Plant Varieties

Biodiversity Act, 2003: Plant Variety Protection

- Establishes legal protection for plant varieties that are
 - Novel
 - Distinct
 - Identifiable
 - Uniform
 - Stable
- A type of 'IP' protection specifically for plant breeders only

Biodiversity Act, 2003: Plant Variety Protection

- Plant Breeders' Rights obtained by filing an application with the Ministry of Agriculture
- Any natural ('individual') or legal ('corporation' / 'partnership') person may file an application
- Application requirements & procedures to be established by Rules & Regulations

Biodiversity Act, 2003: Plant Variety Protection

- Rights protected: Requires recognized plant breeder's authorization for
 - Production or reproduction of protected plant varieties for commercial marketing
 - Offering for sale, selling, or marketing
 - Exporting
 - Importing
 - Stocking for any of the foregoing purposes

Biodiversity Act, 2003: Plant Variety Protection

- Exceptions guaranteed for
 - Farmers' Rights
 - Allows small farmers to propagate seed they have harvested on their own land
 - Exchange seed with other farmers on non-commercial basis
 - Breeders' Exemptions
 - Allows breeders to conduct research activities for purposes of breeding new ('not-essentially-derived') varieties

Biodiversity Act, 2003: Plant Variety Protection

- Plant Breeders' Rights guaranteed for
 - 20 years from date of grant of right (for most plants)
 - 25 years for trees & vines
- Plant Breeders' Rights can be nullified & cancelled if law violated

Rules & Regulations: Plant Variety Protection

- Rules & Regulations establish the application procedures & guidelines required to implement the Plant Variety Protection provisions of the Biodiversity Act
- Includes detailed guidelines to determine eligibility based on new varieties that are
 - Novel
 - Distinct
 - Identifiable
 - Uniform
 - Stable

Rules & Regulations: Plant Variety Protection

- Detailed procedures required for
 - Review of applications
 - Challenging applications / rights
 - Revocation of rights
- Intended to comply with UPOV standards and practices
- Requires substantial human & institutional capacity to implement (!)
- Next steps ???

Putting
Traditional Knowledge
in context of
Biodiversity Act / Rules & Regs

Biodiversity Act, 2003: Traditional Knowledge

- Biodiversity Act recognizes & establishes enforceable legal rights in TK associated with biodiversity in Bhutan
- Procedures for Protection of TK
 - 'Prior Informed Consent'
 - Two-step application process
- Documentation
 - Authorization for TK Inventory / Documentation Activities

Biodiversity Act, 2003: Traditional Knowledge

- Biodiversity Act defines TK as “knowledge, innovation and practices of local communities relating to the use, properties, values and processes of any biological and genetic resources or any part thereof”
- Biodiversity Act applies to TK in Bhutan
 - Existing *before* the Act
 - Created *after* the Act
- TK in material form (‘tangible expression’) *not* required

Biodiversity Act, 2003: Traditional Knowledge

- Continued “customary use” of TK by “local communities” not affected by TK provisions of the Biodiversity Act
- “Customary Use” and “Local Communities” *not* defined by Biodiversity Act
- Biodiversity Act provides that “Owners” of TK are the “Rights Holders”
- But, the term “Owners” is *not* defined !

Biodiversity Act, 2003: Traditional Knowledge

- Access-applicant must obtain PIC of TK rights holders ('owners') for use of TK for any *non-customary* use
- PIC accomplished through an "application" to be defined by the Rules & Regulations
- If access application accepted, a 'user agreement' must be negotiated & approved
 - Protects rights of TK owners
 - Authorizes access & defined use of TK

Biodiversity Act, 2003: Traditional Knowledge

- Biodiversity Act authorizes the 'Authorized Agency' to conduct TK "inventory" and "documentation" activities in collaboration with TK owners
- Procedures for TK documentation not defined (but limited to TK "relating to the use, properties, values and processes of any biological and genetic resources or any part thereof")
- 'Access' to documented TK to be defined in Rules & Regulations

Rules & Regulations: Traditional Knowledge

- Establishes two-step procedure to access Traditional Knowledge (TK) for any *non-customary* use
 - Requires 'application' that must be accepted by relevant TK owners
 - If 'application' accepted, requires additional negotiation of written authorized user agreement (must be approved by TK owners and Ministry of Agriculture)

Rules & Regulations: Traditional Knowledge

- Application contents and requirements specified in Rules
- Required information submitted on standardized TK application form (similar to ABS Permit Application)
- Application form first submitted to Authorized Agency to verify identity of relevant TK owners before being submitted to relevant TK owners for consideration

Rules & Regulations: Traditional Knowledge

- TK owners have option to
 - Reject PIC application (“right to say ‘No’”)
 - Accept application
- Acceptance of application triggers negotiation for “written user agreement” with appropriate benefit-sharing terms and conditions
- Competent Authority *may* provide advice during review of access application or negotiations of draft TK user agreement

Rules & Regulations: Traditional Knowledge

- Owners of TK must submit draft TK “user agreement” to Competent Authority for “comments”
- “Competent Authority” defined by Biodiversity Act as “Head of Ministry of Agriculture / RGOB”
- Competent Authority may approve, request revisions, or deny proposed user agreement based on “nat’l interests”

Rules & Regulations: Traditional Knowledge

- Approved TK “user agreement” means that PIC requirement is satisfied
- Copy of final approved TK user agreement *must* be filed with the Competent Authority

Rules & Regulations: Traditional Knowledge

- Biodiversity Act also authorizes the 'Authorized Agency' to conduct TK "inventory" and "documentation" activities in collaboration with TK owners
- Procedures for TK documentation not defined (but limited to TK "relating to the use, properties, values and processes of any biological and genetic resources or any part thereof")

Rules & Regulations: Traditional Knowledge

- TK documentation procedures may supplement TK access & use procedures to protect TK owners' proprietary interests and ensure compliance with access & use agreements
- TK documentation requires specialized human & institutional capacities to accomplish TK-protection objectives (!)

Rules & Regulations: Traditional Knowledge

- TK Documentation Objectives
 - 'Defensive' objectives, such as
 - *Prevent others from claiming IP rights involving use of documented TK*
 - *Prevent others from using TK in unauthorized, unintended or inappropriate ways*
 - *Preserve TK in documented form for future generations*
 - 'Offensive' objectives, such as
 - *Develop IP rights in TK as basis for new potential economic opportunities*
 - *License use of documented TK for limited purposes*
 - *Manage TK dissemination to broader public (including other TK owners)*

Rules & Regulations: Traditional Knowledge

- Basic Issues for TK Documentation
 - TK documentation has *potential benefits* for TK owners if properly managed
 - TK documentation also has *potential risks* to TK owners' cultural, economic and IP interests
 - Documentation does *not* automatically guarantee legal protection for TK (but can be part of a strategy of protection)

Rules & Regulations: Traditional Knowledge

- Potential Benefits of TK Documentation
 - Documentation *process* may help refine IP interests of TK owners
 - Documented TK and related resources *may* create new economic opportunities for TK owners
 - TK 'preserved' through documentation / saved from loss

Rules & Regulations: Traditional Knowledge

- Potential Risks of TK Documentation
 - Potential for misappropriation (copying) of documented TK and associated resources ('piracy')
 - Potential for misuse of documented TK contrary to objectives of TK owners
 - Potential loss of confidentiality associated with TK

Implementation Considerations / Next Steps

- Review, revision, and finalization of Rules & Regulations
 - Draft TK regulations to be discussed through consultative workshop
 - Other sections of draft Rules & Regulations discussed at MOA workshop in November 2003
 - Completed final draft of Rules & Regulations to be submitted to the BMB for review
- The 'Competent Authority' (Minister/MOA) needs to designate the 'Authorized Agency' to process biodiversity & TK access applications as intended by the Act

Implementation Considerations / Next Steps

- Discussions with potential applicants concerning development of pilot project proposals to allow evaluation of the Rules & Regulations and build technical & scientific capacity required to implement & achieve the objectives of the Act

Biodiversity Act, 2003: Offences & Penalties

- Biodiversity Act specifies six offences under the law
 - Unauthorized collection of biodiversity
 - Non-compliance with permit conditions
 - Non-compliance with benefit-sharing
 - Breach of confidentiality requirements
 - Non-compliance with TK rights
 - Non-compliance with any other provision of the Act or Rules & Regs

Biodiversity Act, 2003: Offences & Penalties

- Penalties for violations of the Act or Rules & Regulations
 - Imprisonment
 - Fines
 - Confiscation of material collected
 - Damages
 - Revocation of permits
- Penalties determined on case-by-case basis

Biodiversity Act, 2003: Amendments, Interpretation, Definitions

- Biodiversity Act subject to amendment by the National Assembly
- Dzongkha text determines interpretation of legal requirements
- Definitions
 - Some adapted from CBD
 - Others unique to Bhutan ('RGOB', etc.)
 - Govern implementation of the Act and Rules & Regulations

Thank You

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