

The Development of National ABS frameworks Key Issues for Consideration

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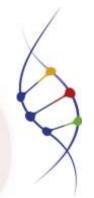
Outline

Background:

- National assessment/gap analysis
 - Existing measures
 - Stakeholder mapping
- National strategy and policy clear objective
- Regulatory approach

ABS legislative/regulatory framework

- Institutional arrangements
- Access
- Benefit-sharing
- Compliance



National assessment

National assessment/Gap analysis

- Review of existing measures dealing with ABS or relevant to ABS
 - E.g. Existing permitting systems for access to biological resources for research purposes
- Mapping of ILCs and stakeholders
 - ILCs
 - Botanical gardens, ex situ collections
 - Universities, research institutions
 - Private sector (natural products, exporters)

National strategy/policy

Issues for consideration

- National context
 - Demand for genetic resources
 - What type of genetic resources (forest, marine)
 - For what use (e.g. cosmetics, pharmaceuticals)
 - Potential (e.g. marine bioprospecting)
 - Research and development capacity at national level desire to build national capacity/enter into partnerships
- -Stakeholder consultation
- -Market oriented approach vs protective approach
 - Desire to attract foreign investors (e.g. Australia)
 - Desire to protect from biopiracy (e.g. Philippines)
 - **➤** Desired Outcome: Clear policy objective



Legal approach

What instrument can best achieve objective?

Considerations

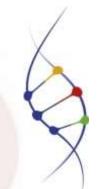
- Overall policy guidance
- Governmental system (unitary, federal)
- Pre-existing laws, policies, administrative measures on ABS and related fields
- Amendment of existing laws and administrative measures (e.g. ABS, IPR, protected areas, forest, research)
- Design and implementation of comprehensive ABS regime

Examples of existing options:

- ABS law (e.g. Ethiopia)
- ABS measures in environmental law (e.g. Dominica)
- ABS law and regulations (e.g. Uganda, South-Africa, India)



Institutional Arrangements



Key provisions of the Nagoya Protocol

Obligation to establish national focal points responsible for:

- Liaison with the Secretariat
- Providing information on:
 - Applicable procedures for obtaining prior informed consent and establishing mutually agreed terms, including from ILCs.
 - Competent national authorities, relevant ILCs and relevant stakeholders

Institutional Arrangements

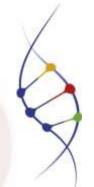
Key provisions of the Nagoya Protocol

Obligation to designate one or more national competent authorities responsible for:

- Granting access or issuing evidence that access requirements have been met
- Advising on applicable procedures for obtaining PIC and entering into MAT

Obligation to provide contact information on NFP and CNAs to the Secretariat:

- No later than the entry into force of the Protocol
- When more than one CNA, indicate the type of genetic resource is responsible for and information on responsibilities
- Notify the Secretariat of any changes



Institutional Arrangements

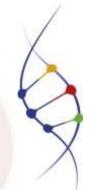
Issues for consideration

Centralised vs decentralised approach

- What is the level of expertise on ABS/ What authorities are currently dealing with access to genetic resources?
 - One CNA: if limited capacity, more likely to centralize management
 - Several CNA: If technical expertise in different institutions (e.g. research, protected areas, marine) may consider decentralised approach - will require efficient coordination mechanisms

Variety of options in light of national circumstances:

- One or several CNAs
- Technical body
 - For coordination and/or technical guidance
 - Composition may vary (e.g. inter-ministerial, multistakeholder)



Key provisions of the Nagoya Protocol

Obligation to establish ABS measures that provide for: (Art. 6 NP)

- Legal certainty, clarity and transparency
- Fair and non-arbitrary rules and procedures on access
- Information on how to apply for PIC
- A clear written decision by a CNA in a cost-effective and timely manner
- The issuance at the time of access of a permit or equivalent and notification of ABS Clearing-House accordingly
- Clear rules and procedures for MAT





Obligation to take measures in accordance with domestic law:

- Access to traditional knowledge associated with genetic resources
 - Ensure PIC or approval and involvement of ILCs and establishment of MAT
- Access to genetic resources where ILCs have the established rights to grant the access
 - Set out criteria and/or processes for obtaining PIC or approval and involvement
 - Ensure that PIC or approval and involvement of ILCs is obtained



Access – special considerations

Key provisions of the Nagoya Protocol

When developing and implementing the ABS measures Parties are to:

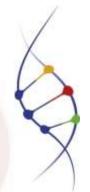
- Create conditions to promote research for the conservation and sustainable use of biodiversity
 - Simplified measures on access for non-commercial research
- Pay due regard to cases of health emergency as determined nationally or internationally
- Consider the importance of genetic resources for food and agriculture

Objective:

streamlined process for certainty, clarity and transparency



- Scope of ABS measure
 - Utilization of GR: research and development on the genetic and/or biochemical composition of GR (art. 2 NP)
- Ownership of genetic resources (e.g. public or private)
- Procedure for involvement of ILCs when access to TK or to GR over which they have rights and in negotiation of MAT



Issues for consideration - options

- -Authority to grant access/permit: CNA
- -Centralised vs decentralised access/permitting system
 - related to institutional arrangements
 - Access/permit granted by one CNA or through several
 (e.g. protected areas, forest, marine, research)
 - pros: benefit from existing expertise, institutions
 - cons: confusion, increased costs, inconsistencies in implementation, challenge for monitoring and compliance
- -PIC of provider may be required
- -Requirement to collaborate with national institution



Issues for consideration - options

- Access for non-commercial vs commercial research
 - Simplified access procedure for non-commercial research
 - Two step process (MAT for research/discovery phase, MAT for commercialisation)
 - MAT at time of access covering research and commercialisation

- MAT

- Requirements for dispute settlement, benefit-sharing, third party use,
 change of intent
- To be negotiated with provider or CNA, with CNA oversight?

Relationship with ITPGRFA

 If Party to International Treaty on Plant Genetic Resources for Food and Agriculture - SMTA automatically applies



Benefit-sharing

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Key provisions of the Nagoya Protocol

Obligation to take measures:

 For benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization to be shared with the provider country. Benefits to be shared on mutually agreed terms (MAT)

Monetary and/or non-monetary

 Access fees, milestone payments, licence fees, royalties, transfer of technology, sharing results of research, effective participation in research

Benefit-sharing

Key provisions of the Nagoya Protocol

Fair and equitable benefit-sharing:

Obligation to take measures for the sharing of benefits with indigenous and local communities:

- With respect to genetic resources held by ILCs upon MAT, in accordance with domestic law.
- With respect to TK associated with genetic resources held by ILCs upon MAT.



Benefit-sharing

Issues for consideration

- Negotiation of MAT to include benefit-sharing
 - Role of CNA in negotiation of MAT (e.g. party/endorsement)
- Type of benefits
 - NP annex
 - Importance of non-monetary benefits
- **Timing** (short, medium, long term)
- Mechanisms for benefit-sharing (e.g. Trust Funds)
- Beneficiaries (provider, State)
- Who is responsible for benefit-sharing?
 - Final user, intermediary?



Compliance

Key provisions of the Nagoya Protocol

Similar provisions for access to genetic resources and for TK associated with genetic resources

Obligation to take measures:

- •To provide that the GR or TK utilized within a Party's jurisdiction have been accessed in accordance with PIC and MAT has been established as required by the domestic ABS legislation
- To address situations of non-compliance

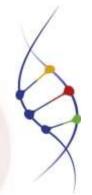
Obligation to cooperate in cases of alleged violation of domestic ABS legislation

Compliance with MAT

Key provisions of the Nagoya Protocol

Obligation to:

- Encourage users and providers to include provisions in MAT to cover dispute resolution
 - Including the jurisdiction; the applicable law; and/or options for alternative dispute resolution
- Ensure that opportunity to seek recourse is available under each Party's legal systems
- Take effective measures regarding:
 - Access to justice
 - The utilization of mechanisms of mutual recognition and enforcement of foreign judgments and arbitral awards

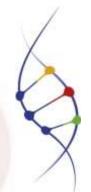


Monitoring

Key provisions of the Nagoya Protocol

Obligation to take measures to monitor utilization:

- **Designate of one or more checkpoints** that are effective and relevant to the utilization of genetic resources or to the collection of relevant information.
 - Require users to provide the information required at a designated checkpoint
 - Take measures to address non-compliance with this requirement
 - Provide this information to national authorities, provider Party and to the ABS Clearing-House
- Encourage reporting requirements in MAT
- Encourage the use of cost-effective communication tools



Monitoring

Key provisions of the Nagoya Protocol

Obligation to issue a permit or equivalent at the time of access as evidence that PIC has been obtained and MAT has been established

- Parties are to make the permits available to the ABS
 Clearing-House and thus becoming an internationally recognized certificate of compliance
- The internationally recognized certificate of compliance is to contain certain minimum information, when is not confidential.

Compliance and Monitoring

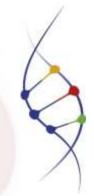
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Issues for consideration

- Reporting requirements in MAT
 - Regular intervals, language of reporting
- Check points designate at least one
 - Publications, funding agencies, IPR offices
- •Permits awarded at time of access notified to ABS CH for internationally recognised certificate of compliance.

Training opportunities

- IDLO training course
 - 5 day training
 - Based on national experience in a number of countries
 - Presents different approaches to the implementation of ABS (learning by doing)
 - Tools:
 - IDLO toolkit (being finalised)
 - Training material





Thank you for your attention!