

Compliance mechanism under the Nagoya Protocol

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Article 15 - Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing Article 16 - Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources Article 17 - Monitoring the Utilization of Genetic Resources Article 18 - Compliance with Mutually Agreed Terms Article 30- Procedures and Mechanisms to Promote Compliance with this Protocol

SPREP Compliance Mechanism

- Article 15- to ensure that genetic resources utilized within a jurisdiction have been accessed in accordance with prior informed consent (PIC) and mutually agreed terms (MAT) have been established
- Article 16- to ensure that traditional knowledge associated with genetic resources (TKaGR) utilized within a jurisdiction has been accessed in accordance with PIC or approval and involvement of indigenous and local communities and that MAT have been established. Article 16 needs to be read in conjunction with Article 7 which establishes the obligation for each Party to take measures with the aim of ensuring that the traditional knowledge associated with genetic resources that is held by ILCs is accessed with PIC or with the approval and involvement of these ILCs and that MAT have been established.
- **Article 17-** to monitor and enhance transparency about the utilization of genetic resources, where designated checkpoints would collect or receive, as appropriate, information on PIC, source of the genetic resource, MAT and utilization of genetic resources.
- Article 18 ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms
- Article 30 ndicates that the aim of the compliance procedures and mechanisms will be two-fold: on the one hand, to promote compliance and, on the other hand, to address cases of non-compliance

SPREP Facific Regional Lance with national ABS legislation

Obligation to take measures:

- To provide that genetic resources utilized within a Party's jurisdiction have been accessed in accordance with PIC and MAT
- To address situations of non-compliance

Obligation to cooperate in cases of alleged violation of domestic ABS legislation or regulatory requirements



Obligation to:

- Encourage users and providers to include provisions in MATs 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
- To take effective measures regarding access to justice; and the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awar



Obligation to take measures to monitor the utilization of genetic resources:

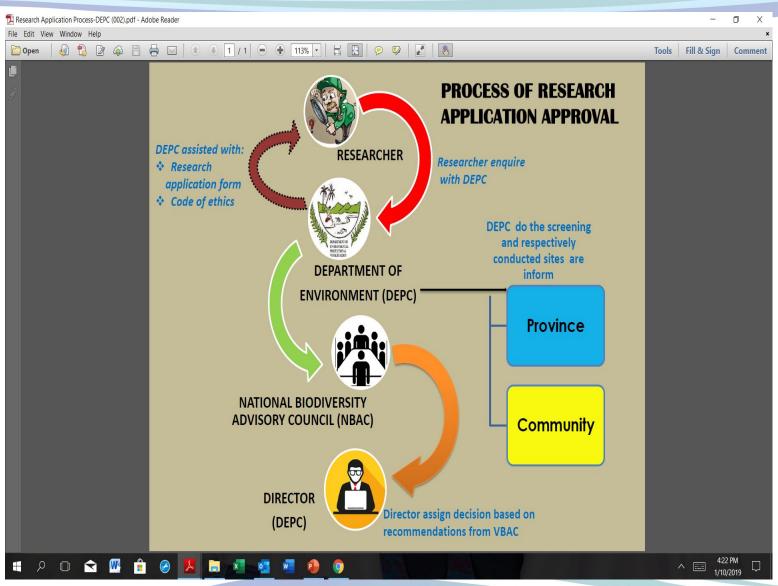
- Designation of effective check points for collection of information at any stage of research, development, innovation, pre-commercialization or commercialization
- Encouraging reporting requirements in MAT
- Encouraging cost-effective communication tools

Internationally recognized certificate of compliance as evidence that PIC was obtained, and MAT established



If prior informed consent (PIC) is required to access genetic resources in your country, please describe the procedures (steps) a user would typically follow.

Note the recent development to this permit process-recent improvement is that a research application must be submitted with signed (MAT) contract or if not submitted, DEPC will facilitate with the applicant to have the contract (MAT) with the local communities before BAC can approve the application. This applies to both commercial and non-commercial application.





ACCESS COMPLIANCE RULES

- s. 5002- Priorities for Access and Benefit Sharing agreements
- Sets out priorities for access and benefit sharing agreements
- s. 5003- Permit to access genetic resources
- 'Person' covered in this section- Individual, partnership, association, joint-stock companies, trust, corporation or other nongovernmental and governmental entity and any person/s desiring to obtain an extract must first apply for and receive national permit alongside ABS agreement. This section also provides for Ministry to establish regulations for national permits, permit fees, and initiate discussions for ABS Agreement pursuant to s5004.

Discussion Points: Rules of Access, Prior Informed Consent, Information to be provided for an ABS permit, Transfer of ABS permits, compliance with foreign ABS Permits & benefit sharing, register of permits, relations with other biodiversity law permits



Benefit Sharing Compliance Rules

s. 5011- Benefits Sharing between national and state government

- This section provides that all fees, royalties, profits and any other funds collected from any ABS Agreement shall be shared equally between the national government and the states being 50% goes to the state and 50% will be divided equally among the several states.
- **Discussion:** Possible benefits, common elements in agreements, monetary & non-monetary benefits

s. 5006. Procedures for Contract Formation

• This section provides ABS agreements must be contemplated by all relevant stakeholders including traditional leaders and traditional community based organisations. A working group will be assembled by the Committee once an application for ABS agreement is received.

Discussion: Long term access and benefit sharing agreements, benefit sharing with ex situ Institutions, compliance with foreign ABS Permits & benefit sharing



COMPLIANCE RULES

s. 5008- Third Party Use and the transfer of rights

This section provides that No ABS agreement may allow for the transfer of rights to a third party without any written amendment to the ABS Agreement and renegotiation with the Committee (Patenting & IP rights)

s. 5009- Notification and archiving

All ABS agreement shall digitally archived by the Ministry and comply with any international reporting obligations
pursuant to the CBD

s. 5010- Certificate of Compliance

• This section provides that the Ministry shall perform annual compliance reviews of all ABS agreements archived and ensure that all permit requirements have been met and that any extraction undertaken and utilization of resources is subject to a valid ABS agreement. The section also provide for Ministry to issue a certificate of compliance to the parties whose performance is consistent with the Convention and if the Ministry has reason to believe that ABS agreement may no longer valid and is non-compliant then the Ministry can proceed with legal action.



EU ABS compliance rules only apply when these six conditions are met:

- 1. Access to genetic resource or associated traditional knowledge "Genetic resources" means genetic material of actual or potential value. "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
- 2. Genetic resources accessed is under sovereignty of a State Access to GR outside of the jurisdiction of States e.g. in the Antarctica or the High Sea no compliance obligations in the EU
- 3. Acquisition occurs in a Party to the Nagoya Protocol Access to GR and aTK in non-Parties no compliance obligations in the EU Exclusion of any access before the entry into force of the NP for a specific country
- 4. ABS regulative framework exists in this Party which means No ABS framework / no ABS contract no compliance obligations in the EU Exclusion of access to any GR, including commodities, in EU countries without access regulation
- 5. Access after 12 Oct. 2014 Exclusion of all GR and aTK which were accessed before Exclusion of any future utilization of such GR and aTK
- 6. Utilisation in the EU "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention; Exclusion of any activity that is not R&D on the GR, e.g. several ecological and taxonomical methodologies, trade for use in production process



Implications on monitoring and evaluation-

- All users of EU genetic resources has to carry out due diligence-
- Access is according to applicable legal requirements
- 2. Benefits have been shared as relevant
- 3. All EU users are obliged to declare at specific check points that the correct procedures has been followed
- 4. Non-compliance with due diligence and other user obligations will be penalized by measures and provisions within the EU members' regulations (measures must be effective, specific and proportionate)

- ABS is available throughout the value chain B.
- Users need to seek, keep and transfer to subsequent users information on:
- Date and place of access;
- Description of the GR or associated TK used;
- Source from where they obtained them, as well as any subsequent users;
- Presence or absence of rights and obligations relating to ABS, including those regarding subsequent applications and commercialization;
- Any existing access permits; and
- MAT, including any benefit-sharing arrangements.
- Users must analyze if the information in their possession is sufficient and be certain that they comply with the applicable legal requirements in the provider country. If NOT sufficient, users must either: Obtain the missing information OR – Discontinue the use of the GR or the associated TK
- Users must keep all the relevant ABS information for a period of 20 years after the end of the period of use.



EU Regulations: Monitoring with user measures- The role of checkpoints

Monitoring compliance with user measures: the role of checkpoints

Parties to the Nagoya Protocol have to establish at least 1 national checkpoint for compliance

WHY?

To collect and receive relevant information related to PIC, MAT, the source of GR, including the associated TK, and its utilization

WHERE?

At any stage of the value chain

WHERE CAN I FIND ONE?

Checkpoints should be published at the ABS Clearing House Mechanism so that users and providers know of them.





Article 14-ABS CLEARING HOUSE

Understanding Article 14

- Access and Benefit-sharing Clearing-House serve as a means for sharing of information related to access and benefit-sharing. It shall provide access to information made available by each Party relevant to the implementation of this Protocol.
- Each Party shall make available to the Access and Benefit-sharing Clearing-House any information required. The information shall include:
- (a) Legislative, administrative and policy measures on access and benefit-sharing;
- (b) Information on the national focal point and competent national authority or authorities; and
- (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.
- 3. Additional information, if available, may include:
- (a) Relevant competent authorities of indigenous and local communities, and information as so decided;
- (b) Model contractual clauses;
- (c) Methods and tools developed to monitor genetic resources; and
- (d) Codes of conduct and best practices.



MALO/FA'AFETA'I LAVA

Q&A