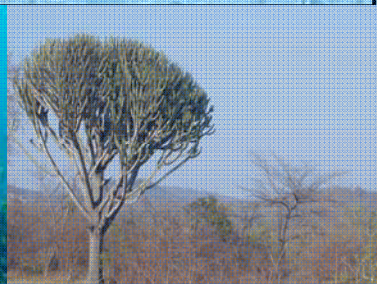
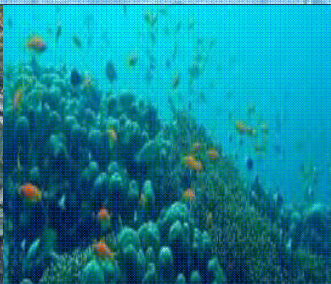




**Policy Framework on
Access and Benefit Sharing Arising
from the Use of Genetic Resources
in the ARIPO Member States:
A Guide for ARIPO Member States**



**POLICY FRAMEWORK ON
ACCESS AND BENEFIT SHARING
ARISING FROM THE USE OF
GENETIC RESOURCES IN THE
ARIPO MEMBER STATES:
A GUIDE FOR
ARIPO MEMBER STATES**

**ARIPO Office
Harare, Zimbabwe
2016**

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FORWARD

Prior to the commencement of the Convention on Biological Diversity (CBD) in 1992, access to genetic resources and associated traditional knowledge was free for all mankind. Genetic resources associated with traditional knowledge (GR & TK) were often taken from communities and countries by organizations and individuals who monopolised the benefits. The commercialization of GR associated with TK has existed for hundreds of years, i.e. the explorers travelled different parts of the world looking for exotic plants, medicinal herbs, new types of foods, spices, etc. This was one way of transfer of knowledge with biological knowledge from local communities, without exchange of knowledge or compensation for those communities. Medicinal plants (from local communities) were taken outside of a country, processed and returned back in the form of patented drugs which were expensive to buy for local communities and at the same time there was no acknowledgement of the owner (source of traditional knowledge).

In 1992, the United Nations organised a big international conference on environment that came out with the international Convention on Biological Diversity (CBD). The said conference took place in Rio De Janeiro, Brazil. CBD has integrated access and benefit sharing in the objectives that include conservation, sustainable use and benefit sharing. It balances the rights of resource-providing countries to share the benefits with the rights of technology-rich countries to access biodiversity resources with biodiversity rich countries. CBD recognizes the importance of knowledge, practices and innovations of indigenous and local communities as enshrined in Article 8(j).

Since that time, different initiatives at international level (e.g. Bonn guidelines), regional level i.e. African Union (AU models) and national levels have been tried in order to come out with legal binding legislation to regulate access to genetic resources and benefit sharing, but all these efforts failed because they were not legally binding. In 2010, the Tenth Conference of Parties (COP 10) of CBD that took place in Nagoya, Japan, succeeded to negotiate the legally binding instrument called Nagoya Protocol that came into force on 12 October 2014. The Nago-

Since most of the ARIPO Member States are party to the CBD and others are already party to the Nagoya Protocol, ARIPO decided to establish Regional Policy Guidelines on Access and Benefit Sharing of Genetic Resources in order to assist and guide its Member States on what to include in their national legislation in order to domesticate this international instrument.

These ARIPO Policy Guidelines contain definitions of terms, fundamental principles underlying the policy framework, objectives of the policy framework, scope and coverage, how to establish a competent national authority in order to regulate access, how to access the GR, environmental and social impact to the access of GR, prior informed consent (PIC) and engagement of local communities in negotiation processes, equitable benefit sharing, trans-boundary cooperation, national fund for GR&TK, disclosure requirement, sanctions and remedies, development of databases, implementation, monitoring, compliance and enforcement as well as capacity building.

Member states of ARIPO are encouraged to use these ABS Guidelines when domesticating and implementing the Nagoya Protocol into their national laws. In case of any difficulties or enquiries on these matters, please do not hesitate to contact the ARIPO Office at the address given below.

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1.0

LIST OF TERMS USED IN THE POLICY FRAMEWORK

1.1 In this Framework,

Associated Traditional Knowledge/Traditional Knowledge Associated with Genetic Resources

“Associated traditional knowledge” means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, that [subsist in] [that are associated with] genetic resources.

“Traditional knowledge associated with genetic resources” means any knowledge or innovation in relation to genetic resources and their use that constitute part of the common, traditional or customary patrimony of indigenous peoples and local communities.

Access

“Access” in relation to genetic resources, includes the collection, use and exploitation of those resources.

Biotechnology

“Biotechnology” means any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use.

Country of Origin

“Country of origin” is the first country which possesses genetic resources in in-situ conditions.

Country Providing Genetic Resources

“Country providing genetic resources” is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

Derivative

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Ex-Situ Conservation

“Ex-situ conservation” means the conservation of components of biological diversity outside their natural habitats.

Genetic Material

“Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic Resources

"Genetic resources" are genetic material of actual or potential value.

In-Situ Conditions

“In-situ conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

Intellectual Property Office

“Intellectual property office” means the authority of a Member State entrusted with the granting of intellectual property rights.

Internationally Recognized Certificate of Compliance

“Internationally recognized certificate of compliance” shall mean the instrument foreseen in Article 17.2 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

Member State

“Member State” refers to a Member State of ARIPO.

Misappropriation

“Misappropriation” is the acquisition/utilization of genetic resources, their derivatives and/or associated traditional knowledge/traditional knowledge associated with genetic resources without the free/prior informed consent of those who are authorized to give such consent to such acquisition/utilization, in accordance with national legislation of the country of origin or providing country.

Source

“Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, gene bank or botanical garden.

Utilization

“Utilization” of Genetic Resources means to conduct research and development including commercialization on the genetic and/or biochemical composition of genetic resources, their derivatives and associated traditional knowledge/traditional knowledge associated with genetic resources including through the application of biotechnology as defined in Article 2 of the Convention on Biological Diversity.

- 1.2 Specific choice of terms to denote the subject matter of this Framework may be determined by the Member States.

2.0

FUNDAMENTAL PRINCIPLES UNDERLYING THE POLICY FRAMEWORK

- 2.1. The main objectives of the Convention on Biological Diversity, i.e., the conservation of biological diversity, the sustainable use of natural resources, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources, as well as the provision of the Convention that declares nation states as having sovereignty over genetic resources are cardinal to the implementation of the ABS system.
- 2.2 The maintenance of this biological and cultural diversity is of immense and crucial common interest owing to—
 - (a) identity, cultural and spiritual value for the peoples of the region;
 - (b) livelihood and economic value (e.g., for food, medicinal substances, building and handicraft materials, commercial and industrial applications, tourism, etc; and
 - (c) strategic value for medicinal purpose and ecological maintenance.
- 2.3 The biological and cultural diversity are profoundly inter-related and that local and traditional communities of the region have historically contributed to the conservation of such biodiversity and its enrichment through the selection and development of new cultivars and breeds (agrobiodiversity).
- 2.4 The local and traditional communities and indigenous peoples of the region have historically developed a variety of institutions for the governance of local biodiversity, and that such institutions comprise traditional knowledge, skills, practice, organizations, values, worldviews and languages adapted over time to the local context and generally acting as a whole.

- 2.5 Adhere to the fundamental principles that the Prior Informed Consent (PIC) of provider countries and communities needs to be secured before regulated access can take place.
- 2.6 Ensure the provision of PIC for utilization of genetic resources and associated traditional knowledge only to users who are domiciled in their own jurisdiction, or in the jurisdiction of a Party to the Nagoya Protocol that has adequate compliance and mutual support measures in place.
- 2.7 Develop Mutually Agreed Terms (MAT) to regulate access to genetic resources, their derivatives and associated traditional knowledge within the Member States of the organization and to ensure a fair sharing of the related monetary and non-monetary benefits among the concerned countries and indigenous and local communities, the stewards of that biodiversity and providers of that knowledge.
- 2.8 Encourage the coordinated development and use of sectoral and cross-sectoral model contractual clauses for MAT as well as codes of conduct, guidelines, best practices and/or standards for benefit-sharing, in accordance with Articles 12, 19 and 20 of the Nagoya Protocol.
- 2.9 Uphold the basic principle that the benefits from access to genetic resources, their derivatives and associated traditional knowledge should reward both the countries and the traditional and local communities that actively engage in stewardship, conservation and sustainable use of these resources and knowledge, and that traditional knowledge should be accessed in conformity with the customary institutions and laws of the concerned communities.
- 2.10 Promote increased utilization of genetic resources and associated traditional knowledge by instituting transparent, functional access regulations in accordance with Article 6.3 of the Nagoya Protocol, thereby stimulating the creation of benefits to be shared.

2.11 Encourage community activities that support sustainable use and conservation of biodiversity ARIPO Member States should–

- (a) adopt laws, regulations or policies that give Indigenous and Local Communities (ILCs)/resource custodians clear legal rights to genetic resources and associated traditional knowledge where such rights do not already exist;
- (b) support and guide MAT negotiations between ILCs and users, and subsequently monitor fulfillment of the agreed terms;
- (c) ensure that all Access and Benefit Sharing (ABS) benefit payments received by the State are directed to the sustainable use and conservation of biodiversity;
- (d) support ILCs with capacity development and technical assistance to improve their position in the value chain, thereby empowering them to capture more of its benefits; and
- (e) support the development by ILCs of community protocols, minimum requirements for mutually agreed terms and/or model contractual clauses for the sharing of benefits, in accordance with Article 12.3 of the Nagoya Protocol.

3.0

OBJECTIVES OF THE POLICY FRAMEWORK

- 3.1 To preserve the biological and cultural diversity of the Member States of the organization, promote the use of its natural resources in ways that are sustainable and equitable, and promote human wellbeing and food security through the maintenance of ecosystem functions and integrity.
- 3.2 To strive towards food sovereignty and security based on local food crop germplasm and traditional knowledge already widely dispersed and utilized in the Member States of the organization.
- 3.3 To provide certainty about origin/source/legal provenance and set the minimum requirements for access to, and benefit sharing from, genetic resources, derivatives and associated traditional knowledge in Member States of the organization.
- 3.4 To ensure and enforce the rights and obligations of users who comply with agreed requirements and prevent the misappropriation and misuse of genetic resources, their derivatives and associated traditional knowledge in the Member States of the organization.
- 3.5 To enhance economic and social welfare and ensure that maximum and equitably shared benefits from access to genetic resources, their derivatives and associated traditional knowledge accrue to countries of origin (Member States), consistent with the principle of prior informed consent.
- 3.6 To ensure that the customary uses of biological and genetic resources, their derivatives and associated traditional knowledge by traditional and local communities are maintained in accordance with customary practices and local traditions.
- 3.7 To promote scientific, technical and economic cooperation and ensure that access regulations to genetic resources, derivatives and associated traditional knowledge are uniform and consistent with the policy framework.

4.0

SCOPE AND COVERAGE

In accordance with international obligations and national laws, this Policy Framework–

- (a) applies to all biological and genetic resources that originate in the Member States of the organization (ARIPO) and the traditional knowledge associated therein [access to biological and genetic resources shall not automatically mean access to the traditional knowledge associated with the resource, which shall be explicitly indicated in the application for access]; and
- (b) does not apply to the uses and sharing of biological and genetic resources by indigenous peoples and local communities of the region in accordance with their customary practices and traditions.

5.0

ESTABLISHMENT OF COMPETENT NATIONAL AUTHORITIES/ APPROPRIATE AUTHORITY

The Member States of the organization shall designate their respective competent national authorities to be responsible for–

- (a) formulating and implementing national legislation on ABS;
- (b) establishing procedures for the granting of PIC at the national and local levels with the direct involvement of the resources providers;
- (c) disseminating information on ABS regulations;
- (d) establishing links with the Global ABS mechanism and clearinghouse once established and providing relevant information where applicable.

6.0

ACCESS TO GENETIC RESOURCES, DERIVATIVES AND PRODUCTS

- 6.1 The Member States of the organization have sovereign rights over their own genetic resources and the authority to determine access rests with national governments subject to national legislation and the prior informed consent of the provider communities.
- 6.2 A set of minimum terms and conditions – in relation to access applications, procedures for PIC and MAT, types of contracts, benefit sharing arrangements, the execution of contracts, and limitations, violations, sanctions – shall be developed by the National ABS Mechanism.
- 6.3 Access to genetic resources, their derivatives and products shall be dependent upon PIC and benefit sharing arrangements as part of MAT.
- 6.4 Access procedures shall be clear, simple, and transparent and provide legal certainty to users and providers of genetic resources.
- 6.5 MAT for access to and specific uses of genetic resources, their derivatives and products should include conditions for their transfer to third parties, subject to national legislation of countries of origin; in case such conditions are explicit, transfer to third parties shall be considered illegal. Member States shall exempt from their national ABS legislation or regulatory requirements all trade in bulk commodities, including indigenous commodities, when such commodities are not utilized as genetic resources as defined in Article 2 of the Nagoya Protocol, and further provided that benefits derived from the utilization of any associated traditional knowledge are shared fairly and equitably on MAT with the holders of such associated traditional knowledge.

- 6.6 In accordance with Article 12.4 of the Nagoya Protocol, Member States shall exempt from their domestic ABS legislation or regulatory requirements the customary use and exchange of genetic resources and associated traditional knowledge within and amongst ILCs.
- 6.7 In accordance with Article 8 of the Nagoya Protocol and subject to national development strategies, Member States shall strive to encourage and facilitate the utilization of genetic resources and associated traditional knowledge for–
- (a) non-commercial research that contributes to the sustainable use and conservation of biodiversity;
 - (b) addressing human, animal or plant health emergencies; and
 - (c) food, agriculture and food security.

7.0 ENVIRONMENTAL AND SOCIAL IMPACT OF ACCESS TO GENETIC RESOURCES

The member states shall adopt measures aimed at impeding genetic erosion or the degradation of the environment and bicultural diversity as consequences of access. Such consequences shall be examined by considering both local (community-related) and non-local foreseeable phenomena and changes. In all cases in which extended extraction is envisaged, an Environmental and Social Impact Assessment (ESIA) should be conducted at the national level with the active involvement of the provider communities before access to a genetic resource is granted. If a danger of serious and irreversible damage exists, the precautionary principle should apply and the lack of scientific certainty shall not be considered as a valid reason for postponing the adoption of effective measures to prevent such damage.

8.0 PRIOR INFORMED CONSENT AND ENGAGEMENT OF INDIGENOUS AND LOCAL COMMUNITIES IN NEGOTIATION PROCESSES

- 8.1 The PIC of the member countries providing the biological and genetic resources is necessary before access to genetic resources can take place. The competent national authorities/appropriate authorities shall establish procedure for the granting of PIC up to the local level, with the active engagement of the traditional institutions that embody traditional knowledge, skills, practices, values, languages and world views related to the genetic resources at stake.
- 8.2 The PIC process shall respect and comply with the customary laws, practices and protocols of traditional and local communities and the disclosure of much information pertaining to the access shall be in a language understandable to the local communities.
- 8.3 The applications for PIC should be accompanied by a full disclosure, at a minimum, of the following information:
- (a) name of the researcher, collector and collaborators;
 - (b) specific area and location of the proposed bio-prospecting activity;
 - (c) defined period when the collection activities will take place;
 - (d) specific purposes, objectives, resources to be used, activities and methodologies;
 - (e) expected outputs;
 - (f) names and background of local collaborators;
 - (g) potential environmental and ecological impact of bio-prospecting activities; and
 - (h) potential benefits to the region, countries and communities of origin.

9.0

EQUITABLE BENEFIT SHARING

- 9.1 Minimum conditions for the equitable sharing of the benefits arising out of the use of trans-boundary genetic resources, their derivatives and products from more than one signatory country shall be regionally stipulated and be based on the prior informed consent of the providers of such resources.
- 9.2 Mutually agreed terms will be developed between the National ABS Mechanism and the access seekers with the active involvement of concerned traditional and local communities and the competent national authorities/appropriate authorities of the Member States.
- 9.3 MAT may stipulate monetary and/or non-monetary benefits and conditions for the use of genetic resources, their derivatives and products, and associated traditional knowledge and practices.
- 9.4 The Member States shall establish measures to ensure the fair and equitable sharing of benefits from the results of research and development, including through facilitating access to the results of such research and development, and differentiating between commercial and non-commercial uses of genetic resources.
- 9.5 Benefits shall be directed in such a way as to promote the conservation and sustainable use of biological diversity and associated cultural diversity.
- 9.6 In accordance with Article 5 of the Nagoya Protocol, Member States shall ensure that benefits arising from the utilization of genetic resources and associated traditional knowledge are shared fairly and equitably. Member States shall cooperate, share information and coordinate policies with a view to establishing transparent, fair, equitable and uniform benefit sharing standards that uphold the intrinsic, cultural and socio-economic values of genetic resources and associated traditional knowledge.

10.0

TRANS-BOUNDARY COOPERATION

- 10.1 In instances where the same genetic resources, their derivatives and associated traditional knowledge are found in in-situ conditions within the territory of more than one country, the relevant Competent National Authority (CNA) of the Member States shall endeavor to cooperate, as appropriate, with the involvement of indigenous peoples and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this Policy Framework.
- 10.2 In accordance with Article 11 of the Nagoya Protocol, when genetic resources and/or associated traditional knowledge can be sourced from two or more countries ARIPO Member States shall cooperate and coordinate with neighbouring countries around minimum benefit sharing terms that will be accepted in MAT governing the utilization of such shared genetic resources.

11.0 NATIONAL FUND FOR GENETIC DIVERSITY AND ASSOCIATED TRADITIONAL KNOWLEDGE

- 11.1 ARIPO Member States shall create National Funds dedicated to the conservation of bio-cultural diversity, and in particular of genetic diversity and associated traditional knowledge. Contributions to this Fund shall be sourced from a share in the revenue derived from access to and use of genetic resources and associated traditional knowledge held by the ARIPO Member States. This will be negotiated as part of the benefit-sharing arrangements in each MAT. Funds shall also be sourced from a portion of the fees and charges imposed on each access application submitted.
- 11.2 The Fund shall be used to compensate communities for their engagement in support of bicultural diversity. The disbursement of the financial resources to communities shall be implemented in a manner that fully recognizes and respects the customary institutions of these communities and in compliance with their diverse customary laws and practices.

12.0

DISCLOSURE REQUIREMENT

Where the subject matter within Intellectual Property Rights application includes utilization of genetic resources, their derivatives and/or associated traditional knowledge, each Member State shall require applicants to—

- (a) disclose the country of origin and or if unknown, source of the genetic resources, their derivatives and/or associated traditional knowledge/traditional knowledge associated with genetic resources.
- (b) provide relevant information, as required by the national law of the Intellectual Property Office, regarding compliance with ABS requirements, including PIC, in particular from indigenous peoples and local communities, where appropriate.
- (c) make a declaration, where this is so, if the source and/or country of origin is not known.

13.0

SANCTIONS AND REMEDIES

Each Member State shall put in place appropriate, effective and proportionate policies, legal and administrative measures to address non-compliance of the provisions of this Policy Framework including dispute resolution mechanisms. Subject to national legislation, sanctions and remedies should include:

- (a) Pre-Grant.
 - (i) Preventing further processing of Intellectual Property/patent applications until the disclosure requirements are met.
 - (ii) An Intellectual Property/patent office considering the application withdrawn in accordance with national law.
 - (iii) Preventing or refusing to grant an Intellectual Property right/patent.
- (b) Post-Grant.
 - (i) Publication of judicial rulings regarding failure to disclose.
 - (ii) Fines or adequate compensation for damages, including payment of royalties.
 - (iii) Other measures including revocation may be considered depending on the circumstances of the case, in accordance with national law.

Failure to fulfill the disclosure requirement, in the absence of fraud, should not affect the validity or enforceability of granted or registered Intellectual Property rights.

14.0

DEVELOPMENT OF DATABASES

- 14.1 Member States are encouraged to facilitate the establishment of databases of genetic resources, their derivatives and associated traditional knowledge/traditional knowledge associated with genetic resources for the purposes of search and examination of patent applications, in consultation with relevant stakeholders and taking into account their national circumstances, as well as the following considerations:
- (a) With a view towards interoperability, databases shall/should comply with minimum standards and structure of content.
 - (b) Appropriate safeguards shall/should be developed in accordance with national law.
 - (c) These databases will be accessible to patent offices and other approved users.
- 14.2 To facilitate such information exchange the ARIPO Office may establish a confidential database of relevant ABS information and make it available for consultation by Member States and ILCs. Member States, ILCs and other relevant stakeholders shall provide information for inclusion in this database.

15.0

IMPLEMENTATION, MONITORING, COMPLIANCE AND ENFORCEMENT

- 15.1 National legislations should provide for sanctions to prevent the use of genetic resources, derivatives and associated traditional knowledge without compliance with the provisions of this Framework. Member States shall monitor the utilization of genetic resources and associated traditional knowledge and encourage compliance with PIC requirements and MAT through the use of checkpoints and internationally recognized certificates of compliance in accordance with Article 17 of the Nagoya Protocol, as well as through regular and systematic information exchange.
- 15.2 MAT shall always include a provision obliging any user who applies for Intellectual Property to disclose in the summary of the Intellectual Property application the origin and source of any genetic resources and associated traditional knowledge utilized in its creation, and to declare that PIC has been obtained and MAT have been agreed in compliance with the domestic ABS legislation or regulatory requirements of the provider country. Member States shall safeguard and protect the collective rights of ILCs and farmers to their genetic resources and associated traditional knowledge, including the right to derive economic development benefits from the utilization of their genetic resources and associated traditional knowledge.
- 15.3 Member States shall ensure that benefits arising from the utilization of genetic resources and associated traditional knowledge, especially non-monetary benefits, contribute to national and regional capacity building and technology transfer.
- 15.4 Member States shall ensure that utilization of genetic resources and associated traditional knowledge does not exceed sustainable harvesting limits, deplete biological resources or otherwise threaten the sustainability of biodiversity and ecosystems.

16.0


CAPACITY BUILDING

ARIPO in collaboration with the Member States as well as relevant stakeholders shall develop modules and training programs for building capacity in the Member States of the organization, in particular to support fair procedures for PIC and MAT involving traditional institutions at the community level and to support effective ESIA studies regarding specific access proposals. At both national and local level, issues of gender equity will be taken into particular consideration, as well as concerns of traditional and local communities.

17.0

RELATIONSHIP WITH THE SWAKOPMUND PROTOCOL

This Framework should be complementary to the Swakopmund Protocol.



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