Access to Biological Resources

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Outline

- 'Biopiracy'
- Convention on Biological Diversity
- International Treaty on Plant Genetic Resources for Food and Agriculture
- The Bonn Guidelines
- The Nagoya Protocol.

International proposals to deal with biopiracy

Convention on Biological Diversity (CBD) 1992

- prior informed consent for bioprospectors
- Equitable benefit sharing
- Technology transfer to source countries

Problem: bio-exploiting countries (eg USA) have not ratified or implemented CBD

Convention on Biological Diversity

Article I. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity. the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

CBD Art 2 Definitions

- "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
- "Genetic resources" means genetic material of actual or potential value.

- Art. 15(1) affirms "the sovereign rights of States over their natural resources" and provides that "the authority to determine access to genetic resources rests with the national governments"
- Art. 8(j) envisages "equitable sharing" of benefits with indigenous and local communities, arising out of the use of the traditional knowledge, innovations and practices of those communities.
- Art.19(2) "take all practicable measures to promote ...access on a fair and equitable basis...,especially developing countries, to the results and benefits arising from biotechnologies based upon [their] genetic resources" on mutually agreed terms.

Working Group on ABS Bonn, October 2001

The COP should invite Parties and Governments to encourage, in application for IPR, the disclosure of:

- the country of origin of genetic resources, as a possible contribution to tracking compliance with PIC and MAT on which access to those resources was granted;
- relevant TK, where an invention concerns or makes use of such knowledge in its development.

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, 2002

- 7. The present Guidelines are voluntary and were prepared with a view to ensuring their:
- (a) Voluntary nature: they are intended to guide both users and providers of genetic resources on a voluntary basis;

• • • • •

(f) Evolutionary approach: the Guidelines are intended to be reviewed and accordingly revised and improved as experience is gained in access and benefit-sharing;

• • • • •

(h) Transparency: they are intended to promote transparency in the negotiation and implementation of access and benefit-sharing arrangements.

Prior informed consent Procedures

- 36. An application for access could require the following information to be provided, in order for the competent authority to determine whether or not access to a genetic resource should be granted. This list is indicative and should be adapted to national circumstances:
- (a) Legal entity and affiliation of the applicant and/or collector;
- (b) Type and quantity of genetic resources to which access is sought;
- (c) Starting date and duration of the activity;
- (d) Geographical prospecting area;
- (e) Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;
- (f) Accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization);
- (g) Identification of where the research and development will take place;

Introduction on access and benefit-sharing

 The International ABS Regime adopted at the tenth Conference of the Parties to the CBD in October 2010 in Nagoya, Japan





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

TEXT AND ANNEX

SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY MONTREAL

Nagoya Protocol

Conference of the Parties to the Convention on Biological Diversity

CoP 10 Nagoya, Japan, 18-29 October 2010

- Protocol opened for signature at the UN Headquarters in New York from 2 February 2011 to 1 February 2012;
- Parties to the CBD invited to sign the Protocol at the earliest opportunity and to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, with a view to ensuring the entry into force of the Protocol as soon as possible;
- States that are not Parties to the CBD invited to ratify, accept, approve or accede to it, as appropriate, thereby enabling them also to become Parties to the Protocol;

NAGOYA PROTOCOL

ARTICLE 1 OBJECTIVE

 The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article 3 Scope

1. This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article 5 FAIR AND EQUITABLE BENEFIT-SHARING

1. ... benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

- 3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:
 - (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
- (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
- (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

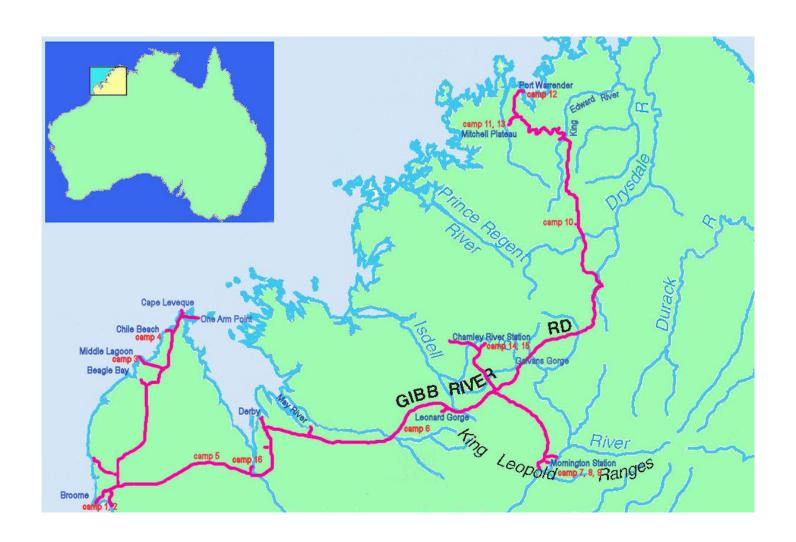


Kimberley Land Council

Intellectual Property and Traditional Knowledge Policy

KLC Research, Ethics and Access Committee (REAC)
Kimberley Land Council Aboriginal Corporation (KLC)

Kimberley Region



KLC's Intellectual Property and Traditional Knowledge Policy

- 1.2. The Policy applies to all researchers conducting or wishing to conduct research with Kimberley Aboriginal people and/or on traditional Aboriginal lands and/or waters in the Kimberley, and on plants and animals on Kimberley land and/or waters, or using their Traditional Knowledge and Traditional Cultural Expression.
- It also must be followed by Researchers including government officers, filmmakers and all people who collect, record or deal with Kimberley Aboriginal people's Intellectual Property, Heritage, Traditional Knowledge and Traditional Cultural Expression.

Access

14.2 Researchers will not collect or conduct research on Biological Resources, including plants and animals occurring on Kimberley lands or waters, without first obtaining the relevant Traditional Owners' Free, Prior and Informed Consent (in addition to other relevant licences or permits).

Access

- 14.3 The Researcher must disclose the sites, areas and places to be visited and:
- 14.3.2 permission must be obtained from the KLC before accessing land and waters for the purpose of research; and
- 14.4 The Researcher must disclose if any Biological Resources such as plants and/or animals are to be collected, accessed or removed and if so:
- 14.4.1 Written permission is required from the KLC, in addition to any permits required by the Department of Environment and Conservation (WA) and Department of Indigenous Affairs (WA); and
- 14.4.2 The KLC, or the Traditional Owners, may require the Researcher to sign a non-disclosure agreement or a specimen's agreement with the relevant Traditional Owners or their prescribed body corporate.

- 14.9.2 the nature of the benefits that might flow from the use of the Traditional Knowledge, particularly considered in strategic terms of "a total benefits package". This may comprise a mix of monetary and non-monetary benefits, including:
 - access fees and milestone payments;
 - upfront payments;
 - licence fees;
 - special fees to be paid to trust funds supporting knowledge conservation and sustainable use of biodiversity;
 - salaries and preferred terms;
 - education and training opportunities;
 - use of facilities and databases;
 - transfer of technical knowledge back to Kimberley Aboriginal People;

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Article 10 Global Multilateral Benefitsharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

16 Compliance with Domestic Legislation or Regulatory Requirements on ABS for TK Associated With Genetic Resources

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

Article 8(j)-COP 10 decisions

Notes the clear relationship between effective sui generis systems as may be developed adopted or recognized at various levels, implementation of access and benefitsharing provisions and the need to prevent the misuse and misappropriation of traditional knowledge, innovations and practices of indigenous and local communities, as stated in decision VII/16 H;

Elements of a code of ethical conduct to ensure respect for the cultural and intellectual heritage of indigenous and local communities -Decision as adopted (Advance unedited version) 2 November 2010

Section 1 Rationale

1. The following elements of a code of ethical conduct are voluntary and are intended to provide guidance in activities/interactions with indigenous and local communities and for the development of local, national, or regional codes of ethical conduct, with the aim of promoting respect, preservation and maintenance of traditional knowledge, innovations and practices relevant for the conservation and sustainable use of biodiversity. They should not be construed as altering or interpreting the obligations of Parties to the Convention of Biological Diversity or any other international instrument.

Code of Ethical Conduct

These elements of a code of ethical conduct aim to promote respect for the cultural and intellectual heritage of indigenous and local communities relevant for the conservation and sustainable use of biological diversity. In this way, they contribute to the achievement of the objectives of Article 8(j) of the Convention on Biological Diversity and its Plan of Action for the retention and use of traditional knowledge, innovations and practices of indigenous and local communities.

Section 2 Ethical Principles

6. It is highly desirable that activities/interactions with indigenous and local communities be based on the following:

Intellectual property

8. Community and individual concerns over, and claims to, cultural and intellectual property relevant to traditional knowledge, innovations and practices related to the conservation and sustainable use of biodiversity should be acknowledged and addressed in the negotiation with indigenous and local communities, prior to starting activities/interactions.

Transparency/full disclosure

Indigenous and local communities should be 10. adequately informed in advance, about the nature, scope and purpose of any proposed activities/interactions carried out by others that may involve the use of their traditional knowledge, innovations and practices related to the conservation and sustainable use of biodiversity, occurring on or likely to impact on, sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities. This information should be provided in a manner that takes into consideration and actively engages with the body of knowledge and cultural practices of indigenous and local communities.

Implementation of Nagoya Protocol in EU

 Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance

I. Background

- The European Union and all of its 27 Member States are Parties to the Convention on Biological Diversity
- The Nagoya Protocol was adopted by the consensus of the Parties to the Convention on Biological Diversity on 29 October 2010.
- The Council of the EU and the European Parliament repeatedly urged the Commission to propose measures for Union implementation and ratification of the Nagoya Protocol
- The EU and 24 Member States signed the Nagoya Protocol while it was open for signature (2/2011- 2/2012), expressing their political commitment to swift implementation and ratification.

Prior informed consent and/or approval and involvement

Any activities/interactions related to traditional knowledge associated with the conservation and sustainable use of biological diversity, occurring on or likely to impact on sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities and impacting upon specific groups, should be carried out with the prior informed consent and/or approval and involvement of indigenous and local communities. Such consent or approval should not be coerced, forced or manipulated.

Inter-cultural respect

Traditional knowledge should be respected as a legitimate expression of the culture, traditions, and experience of indigenous and local communities and as part of the plurality of existing knowledge systems. It is highly desirable that those interacting with indigenous and local communities respect the integrity, morality and spirituality of the cultures, traditions and relationships of indigenous and local communities and avoid the imposition of external concepts, standards and value judgments, in inter-cultural dialogue. Respect for cultural heritage, ceremonial and sacred sites, as well as sacred species and secret and sacred knowledge ought to be given specific consideration in any activities/interactions.

Safeguarding collective or individual ownership

13. The resources and knowledge of indigenous and local communities can be collectively or individually owned. Those interacting with indigenous and local communities should seek to understand the balance of collective and individual rights and obligations. The right of indigenous and local communities to safeguard, collectively or otherwise, their cultural and intellectual heritage, tangible and intangible, should be respected.

Fair and equitable sharing of benefits

Indigenous and local communities ought to receive fair and equitable benefits for their contribution to activities/interactions related to biodiversity and associated traditional knowledge proposed to take place on, or which are likely to impact on, sacred sites and lands and waters traditionally occupied or used by indigenous and local communities. Benefit-sharing should be regarded as a way of strengthening indigenous and local communities and promoting the objectives of the Convention on Biological Diversity and ought to be equitable within and among relevant groups, taking into account relevant community-level procedures.

Traditional guardianship/custodianship

20. Traditional guardianship/custodianship recognizes the holistic interconnectedness of humanity with ecosystems and obligations and responsibilities of indigenous and local communities, to preserve and maintain their traditional role as traditional guardians and custodians of these ecosystems through the maintenance of their cultures, spiritual beliefs and customary practices. Because of this, cultural diversity, including linguistic diversity, ought to be recognized as keys to the conservation and sustainable use of biological diversity. Therefore, indigenous and local communities should, where relevant, be actively involved in the management of lands and waters traditionally occupied or used by them, including sacred sites and protected areas. Indigenous and local communities may also view certain species of plants and animals as sacred and, as custodians of biological diversity, have responsibilities for their well-being and sustainability, and this should be respected and taken into account in all activities/interactions.

International Treaty on Plant Genetic Resources for Food and Agriculture 2001

- Overall Objectives same as CBD
 - Conservation of biodiversity
 - Sustainable use of its components
 - Equitable sharing of benefits
- Adds specific rules applicable to food and agriculture based on specified crops & wild relatives in member countries

Parties to the Treaty and CBD

(July 2012)



= CBD not Treaty: www.cbd.int/convention/parties/list

Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) 2001

- Art 5. Each Contracting Party shall ..., in cooperation with other Contracting Parties ..., promote an integrated approach to the exploration, conservation and sustainable use of plant genetic resources for food and agriculture
- Art. 6 The Contracting Parties shall develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture.

The Multilateral System of Access and Benefit-sharing

- The Treaty establishes a multilateral system, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from their use.
- It applies to a list of crops established according to criteria of food security and interdependence

Art. 12 - Facilitated access to PGRFA within the Multilateral System

12.3 Such access shall be provided in accordance with the conditions below:

• • • • •

- d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the PGFRA, or their genetic parts or components, in the form received from the Multilateral System;
- e) Access to plant genetic resources for food and agriculture under development, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development;
- f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;

Art. 12 - Facilitated access to PGRFA within the Multilateral System

12.4 facilitated access... shall be provided pursuant to a standard material transfer agreement (SMTA), ...and contain the provisions of Articles 12.3a, d and g, as well as the benefit-sharing provisions set forth in Article 13.2d(ii) and other relevant provisions of this Treaty, and the provision that the recipient of the PGFRA shall require that the conditions of the MTA shall apply to the transfer of PGFRA to another person or entity, as well as to any subsequent transfers of those PGFRA.

the Governing Body of the Treaty, in its Resolution 1/2006 of 16 June 2006, adopted the SMTA, which comprises:

- Preamble
- > Parties
- Definitions
- Subject Matter
- General Provisions
- Rights and Obligations of Provider
- Rights and Obligations of Recipient

- Applicable Law
- > Dispute Settlement
- Additional Items
- Signature/Acceptance
- > Annexes

FAO Commission on Genetic Resources for Food and Agriculture, The Second Report on the State of the World's PGRFA, 2010

TABLE 7.1

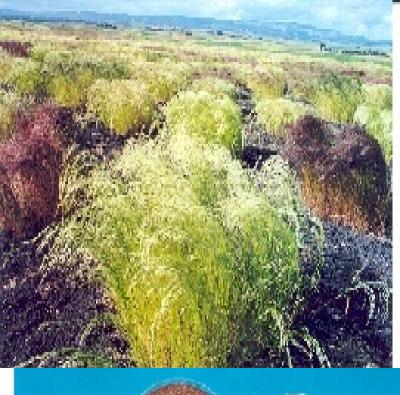
Experience of the CGIAR centres with the SMTA from 1 January 2007 to 31 July 2007 (first line) and 1 August 2007 to 1 August 2008 (second line)

Acquisitions	Transfers of raw PGRFA	Transfers of PGRFA under development	Total transfers	Shipments	Countries	Rejections
3 988	38 210	48 848	97 669	833	155	3
7 264	95 783	348 973	444 824	3 267		0



2. The Genetic resource

- Teff (Eragrostis tef) is a crop species of Ethiopian origin and has various attributes of interest to the food industries.
- Traditional uses:
- Flour: Injera (pancake), Teffbread, "Chechebsa" (Pieces of cracker with butter & spices), "Genfo" (Pudding) etc.
- Grain: "Tela, Katikala" (Local drinks)
- Straw: feed for cattle, to reinforce mud and plaster the walls of tukuls and local storage facilities "gotera"





1. Parties

- Institute of Biodiversity Conservation, Ethiopia (Provider)
 - » Authority to grant and regulate access to GR and effecting the sharing of benefit

The Ethiopian Institute of Agricultural Research (EIAR),

- » National Teff Research Institution And
- The Health and Performance Food International bv. (HPFI) (recipient)
 - » Company

3. Agreement of access

- The Provider agreed to grant the company access to Teff to develop new applications of Teff.
- The Company agreed to share benefits arising out of the use to the Provider.

4. Scope of access

- The Provider agreed to grant the Company accesses to 12 varieties of Teff specified in the agreement.
- The purpose of access is for developing nontraditional Teff-based food and beverage specified in the agreement.
- The company cannot use the Teff for any other purposes (e.g. chemical, pharmaceutical, etc.) without further negotiation.
- The Provider will not grant these varieties to other parties for the same product with that of the Company.
- The Company is not permitted to access the TK of Ethiopian communities, it shall not claim any rights over, nor make commercial benefit out of, such TK

5. Effect of the Agreement

- The agreement shall not affect the sovereign rights of Ethiopia over Teff genetic resources.
- The agreement shall not affect any traditional products of Teff in Ethiopia or abroad.

6. Transfer to third Parties

 The company cannot transfer Teff seed samples or their genetic components to third parties without consent from the Provider.

7. Intellectual Property Ownership

- The company cannot claim IPR over genetic resource of Teff or its component.
- the company and EIAR shall co-own plant breeders' rights over new Teff varieties.
- Research results be owned jointly by both parties.