Proceedings of the International Vilm Workshop on Matters related to Traditional Knowledge associated with Genetic resources and the ABS Regime 6.-10. July 2009

Introduction

CBD COP Decision IX/12 para. 18 encourages Parties to provide the ways and means to allow for sufficient preparation and to facilitate effective participation of indigenous and local communities in the process of the negotiation and elaboration of the international ABS regime. Accordingly, the Federal Agency for Nature Conservation on behalf of the German Federal Ministry of Environment, Nature Conservation and Nuclear Safety has organized an International Workshop on matters related to Traditional Knowledge associated with Genetic Resources and the International ABS-Regime.

The goal of the expert meeting was to exchange information and discuss practical implications of different views and options of draft text within the parameters of the Annex (UNEP/CBD/COP/DEC/IX/12 Annex 1) in order to support indigenous and local communities in the negotiations of the International ABS Regime.

The discussions took into account the results of the Vienna Workshop (Dec. 2008) as well as the results of the Seventh Ad hoc Open ended Working Group on ABS (ABS 7) and the Ad hoc technical Expert Group on Traditional Knowledge associated with Genetic Resources, held in Hyderabad, India., in June 2009.

In particular, the Workshop was meant to facilitate the preparation for, and progress at, the 8th meeting of the Ad Hoc Working Group on ABS (ABS 8), due to be held in Montreal, Canada on 9-15 November 2009.

The workshop took place at the Isle of Vilm, Germany from 06.-10. July 2009 and was attended by 25 participants.

In order to facilitate open discussions it was agreed that the meeting was held under Chatham House Rule. This means, participants are free to use the information received but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed. All participants attended in his/her personal capacity. In the sense of open discussions the aim of the workshop was <u>not</u> to reach a consensus on individual positions but rather to have an exchange of technical options and ideas.

As a starting point for discussions participants had been asked to submit ideas, views or options for operational text on the basis of a questionnaire that was circulated to participants

before the meeting. The discussions were based on but in no way restricted to these submissions. Furthermore, participants were given the possibility to address the meeting with presentations of information and views on specific topics.

Comments

As an outcome of the meeting some proposals for operational text are annexed to this document. They are available for free distribution, future use and reference and are intended to provide an informal input to the ABS negotiating process under the Convention on Biological Diversity.

The text proposals do not constitute negotiated text but try to capture main ideas that were discussed during the meeting.

There are a few considerations to be kept in mind with respect to these text proposals:

Participants were aware that the CBD uses the term 'Prior Informed Consent' (PIC), whereas the UN Declaration on the Rights of Indigenous Peoples (DECRIPS) uses the term 'Free Prior Informed Consent' (FPIC). How these terms will be used in the IR is subject to further negotiation. The text proposals use the term 'FPIC'.

Participants were aware that the CBD has used the term 'Indigenous and Local Communities' (ILC) which has become increasingly uncertain since the adoption of the UN Declaration of the Rights of Indigenous Peoples. More recent CBD papers like e.g. the report of the AHTEG (UNEP/CBD/WG-ABS/8/2) use the term 'Indigenous Peoples and Local Communities'. How these terms will be used in the IR is subject to further negotiation. The text proposals use the term 'Indigenous Peoples and Local Communities'.

Participants felt that term 'misappropriation' needs a definition, that the concept needs further clarification (e.g. versus misuse). Also, participants felt that there is a difference between misappropriation and breaches of contract. Misappropriation would e.g. be the failure to comply with national access rules and legislation or the failure to meet FPIC requirements of indigenous peoples and local communities. Some experts pointed to the close link between the current discussions in the negotiations of an international ABS-regime under the CBD and the work on protection of TK associated with GR that has been done within the framework of WIPO. A reference was made to the definition of the term "misappropriation" in WIPO Document WIPO/GRTKF/IC/9/5, Draft Provisions for the Protection of Traditional Knowledge: "Any acquisition, appropriation or utilization of traditional knowledge by unfair or

illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge."

Participants felt that the relationship between national competent authorities and legitimate representatives of ILCs needs to be further clarified, inter alia with respect to granting of access, distribution of benefits or issuing of certificates, particularly concerning traditional knowledge.

Participants agreed not to discuss the use of the terms 'shall' or 'should' with respect to the text proposals, because the use of these terms will depend on the negotiations on the nature of IR. The text proposals use the term 'shall'.

Participants agreed not to discuss the use of the terms 'GR and associated TK' or 'TK associated to GR' with respect to the text proposals, because the use of these terms will depend on the negotiations on the scope of IR.

It was discussed that benefit sharing should not be used so broadly as to be used by States to avoid their responsibility to supply basic community services and infrastructure such as roads, water, sewages, schools or hospitals to the same level as provided to the rest of the population (refer International Covenant on Economic, Social and Cultural Rights, Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 *entry into force* 3 January 1976, in accordance with article 27 and International Covenant on Civil and Political Rights. Adopted and opened for signature, ratification by General Assembly resolution 2200A (XXI) of 16 December 1966 *entry into force* 3 January 1976, in accordance with article 27 and International Covenant on Civil and Political Rights. Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 *entry into force* 3 January 1976, in accordance with article 27 and International Covenant on Civil and Political Rights. Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 *entry into force* 23 March 1976, in accordance with article 49).

Participants felt that paragraph 64 of the report of the AHTEG (UNEP/CBD/WG-ABS/8/2) contains useful language with respect to access and FPIC and referred to that paragraph in the discussion under of item 2 of the Annex to this proceedings.

With respect to certificates it was discussed that countries that provide free access to GR and therefore require no PIC may not want/need to issue a certificate of compliance. Participants decided not to address the question of the type of certificates (compliance/origin/legal provenance).

Annex

Proposals for operational text

Item 1: Benefit Sharing

Fair and Equitable Benefit Sharing: Ensuring TK holders obtain benefits arising out of the utilisations of TK

Relevant bricks and bullets:

- Measures to ensure the fair and equitable sharing with TK holders of benefits arising out of the utilization of TK in accordance with Art. 8(j) of the CBD (brick D/1/1)
- Measures to address the use of TK in the context of benefit-sharing arrangement (brick D/1/3)

Proposal for operative text:

Each contracting party shall take legislative, administrative or policy measures ensuring the sharing with indigenous peoples and local communities in a fair and equitable way the benefits arising from the commercial and other utilization of

i) genetic resources, when the indigenous peoples and local community has collective rights to such genetic resources under national and/or international law, and

ii) traditional knowledge, when the indigenous peoples and local community has built such traditional knowledge.

These benefits shall be based on MATs with the indigenous peoples and local communities concerned.

Equitable sharing and distribution of benefits shall be guided, as far as possible and appropriate, by respect for the holders of the traditional knowledge, including their cultural, spiritual, ecological and economic values, customary norms, laws, community protocols and understandings of the holders of such knowledge.

Comment: Terms as 'customary norms' or 'community protocols' need further explanation with respect to their definition and scope. (See Alexander, M and Hardison, P & Ahren, M (2009) Study on Compliance in Relation to Customary Law of Indigenous and Local Communities, National Law, Across Jurisdictions, and International Law. UNEP/CBD/WG-ABS/7/INF/5.)

When the state, under national and international law, is the owner/holder of a genetic resource, indigenous peoples and local communities are still entitled to benefit-sharing with regard to traditional knowledge, when the indigenous people or local community has created such.

Traditional knowledge of indigenous peoples and local communities accessed prior to the entering into force of the CBD, shall be subject to the International Regime on ABS with: a) All continuing benefits arising from the pre CBD use of such traditional knowledge to be fairly and equitably shared with the relevant indigenous peoples and local communities.

b) All new uses of such traditional knowledge arising post the entry into force of the CBD to be subject to FPIC and MAT negotiated with the relevant indigenous peoples and local community concerned in accordance with their community level procedures, customary laws or community protocols.

c) In cases where the origin of the traditional knowledge is unclear, regional traditional knowledge funds shall be established and administered by the representatives of indigenous peoples and local communities and a fair and equitable share of the benefits arising from the use of such TK shall flow into such funds.

Comment: concerning the paragraph a) above, some experts considered that such measures can only be voluntary because it addresses the question of preCBD access to GR associated with TK.

Parties shall take measures to address transboundary and shared traditional knowledge. In instances when more than one indigenous people and local community share traditional knowledge, and an ABS agreement is reached with one indigenous people or local community, Parties shall take measures to ensure that benefits are shared also with other indigenous peoples and local communities holding the same traditional knowledge, when applicable through the Indigenous Peoples Competent Authorities (IPCA). This however does not preclude indigenous peoples and local communities that are the holders the transboundary and shared traditional knowledge to enter into separate ABS agreements with the users of such TK on the condition that such agreements are non-exclusive and do not adversely affect the rights and customary laws of other indigenous peoples and local communities that share such traditional knowledge.

Comment: concerning the paragraph above, some experts considered that such measures can only be realised though bilateral/multilateral cooperation agreements between parties.

Parties, in agreement with indigenous peoples and local communities, shall develop minimum conditions and standards for MAT relating to transboundary and shared traditional knowledge that would have to be complied with by users of such traditional knowledge when negotiating MAT with any of the communities sharing such knowledge.

Parties shall establish mechanisms to provide information to potential users of traditional knowledge concerning their obligations regarding access to and benefit sharing arising from the use of such traditional knowledge.

Fair and Equitable Benefit Sharing: Community-level distribution

Relevant bricks and bullets:

• Community-level distribution of benefits arising out of TK (bullet D/2/4)

Proposal for operative text:

Where benefits arise from the use of traditional knowledge, Parties shall support ILCs to facilitate the fair and equitable sharing of such benefits at the community level in accordance with the customary laws, values or community protocols of the holders of such knowledge.

Fair and Equitable Benefit Sharing: Development of Model Clauses

Relevant bricks and bullets:

Incorporation of TK in development of model clauses for material transfer agreements (brick D/1/5)

Proposal for operative text:

Parties shall incorporate TK in the development of sectoral model clauses for material transfer agreements, based on best practices, after the adoption of the Regime.

Item 2: Access Access: Free Prior Informed Consent

Relevant bricks and bullets:

- Access with approval of traditional knowledge holders (brick D/1/7)
- No engineered or coerced access to traditional knowledge (brick D/2/8)
- PIC of, and MAT with, holders of TK. Including ILC's, when TK is accessed (Bullet D/2/1)

Proposal for operative text:

Parties shall respect, recognize and protect the collective rights of indigenous peoples and local communities to their genetic resources and associated traditional knowledge, and shall establish an appropriate national regulatory framework to effectively protect and implement such rights. Until, and to the extent such policies and measures have not been put in place, the state shall nonetheless uphold obligations with respect to indigenous peoples and local communities' collective rights to genetic resources and traditional knowledge.

Each contracting party shall take legislative, administrative or policy measures ensuring FPIC by indigenous peoples and local communities before access is granted to:

i) genetic resources, when the indigenous peoples or local communities have rights to such under national and/or international law, and

ii) traditional knowledge, when the indigenous people or local communities has built such.

If FPIC is granted, this shall be documented in MATs with the indigenous people or local community concerned.

Also when IP and LC don't have rights to FPIC with regard to GR, States shall take measures to ensure appropriate participation by relevant indigenous peoples and local communities when the GR is being accessed and used, and when access to and use of genetic resources affects their knowledge, innovations and practices.

When seeking to access indigenous peoples' or local communities' genetic resources and traditional knowledge, FPIC shall be obtained from their authorities pursuant to their customary laws, or otherwise appointed by them.

Upon request by the indigenous people or local community concerned, the national competent authority can assist them in FPIC/MAT procedures.

Contracting Parties shall:

(a) Ensure that any access to and use of traditional knowledge shall be based on the free prior informed consent of indigenous peoples and local communities who are the holders of such knowledge

(b) Ensure that the commercialization and any other use of genetic resources and traditional knowledge should not prevent traditional use of such genetic resources and traditional knowledge

(c) Make available all relevant information in order to facilitate the effective participation and informed consent of indigenous peoples and local communities in any ABS agreement relating to their traditional knowledge

(d) Ensure that any documentation of traditional knowledge of indigenous peoples and local communities should be subject to the free prior informed consent of the indigenous peoples and local communities;

(e) Ensure that decisions regarding access to traditional knowledge made by competent indigenous peoples or local communities authorities established by IP or LC are made available to relevant indigenous peoples and local communities and other relevant stakeholders;

(f) Require that MAT address scope of use of TK and GR, and that substantially new or changed uses of traditional knowledge and GR beyond the intended use of what has been consented by FPIC and agreed to under MAT, shall be subject to new prior informed consent and mutually agreed terms from the indigenous peoples and local communities who are the holders of such knowledge.

(g) Provide support for capacity-building, in order for indigenous peoples and local communities to be actively engaged in various stages of access and benefit-sharing arrangements, such as in the development and implementation of mutually agreed terms and contractual arrangements.

Access: Identification of appropriate authority

Relevant bricks and bullets:

 Identification of individual or authority to grant access in accordance with community level procedures (brick D/1/6)

Proposal for operative text:

Parties shall designate an ABS national focal point and/or competent national authority who shall direct users of traditional knowledge to the legitimate indigenous or local community authorities for the purposes of FPIC and MAT.

Parties shall support ILCs to establish their own legitimate authorities and recognize them.

Comment: Some experts have explained their concern on the question of legitimate authorities and the recognition in a second step.

Access: Community level procedures

Relevant bricks and bullets:

 Measures to ensure that access to TK takes place in accordance with community level procedures (brick D/1/2)

Proposal for operative text:

The legitimate indigenous or local authorities shall provide potential users of traditional knowledge with clear information on how to obtain FPIC and negotiate MAT to traditional knowledge based on community level procedures, customary laws and/or community protocols.

Parties shall, with the full and effective participation of the indigenous peoples and local communities concerned, support and facilitate local, national and/or regional community protocols regulating access to genetic resources and associated traditional knowledge, taking into consideration the relevant customary laws and ecological values of indigenous peoples and local communities in order to prevent the misappropriation of their associated TK.

If an agreement on access to genetic resources and/or traditional knowledge has been reached between an indigenous people or a local community and a user, when applicably through an Indigenous Peoples Competent Authority and/or the use of community protocols, the existence of the agreement shall be registered with the competent national authority.

Access: Transboundary TK or GR

Relevant bricks and bullets:

No brick or bullet in TK section but important issue raised in discussions.

Proposal for operative text:

States shall take measures to address transboundary and shared genetic resources and associated traditional knowledge. In instances when more than one indigenous people or local community share genetic resources and/or traditional knowledge, States shall prevent potential users from gaining access from an indigenous people/local community with no or limited access regulation, if this causes harm to other indigenous peoples/local communities holding the same genetic resources/traditional knowledge.

Parties shall take measures to address transboundary and shared traditional knowledge. In instances when more than one indigenous people and local community share traditional knowledge, and an ABS agreement is reached with one indigenous people/local community, Parties shall take measures to ensure that FPIC is obtained from other indigenous peoples/local communities holding the same traditional knowledge, when applicable through the Indigenous Peoples Competent Authorities. This however does not preclude indigenous peoples and local communities that are the holders the transboundary and shared traditional knowledge to give FPIC and to enter into separate ABS agreements with the users of such TK on the condition that such FPIC and agreements are non-exclusive and do not adversely affect the rights and customary laws of other indigenous peoples/local communities that share such traditional knowledge.

Comment: concerning the two paragraphs above, some experts considered that such measures can only be realised though bilateral/multilateral cooperation agreements between parties.

Parties shall encourage and support the development of community protocols that will provide potential users of traditional knowledge with clear and transparent rules for access to genetic resources and traditional knowledge where such is shared between:

- (i) indigenous peoples and local communities spread across national boundaries and
- (ii) between indigenous peoples and local communities with different values, customary norms, laws and understandings.

Compliance: International Certificates

Relevant bricks and bullets:

Declaration to be made on the international recognized certificate as to whether there is any associated TK and who owners of TK are (bullet D/2/3)

Proposal for operative text:

The international regime shall establish a system of an internationally recognized certificate of compliance, which shall establish that genetic resources and associated traditional knowledge has been duly acquired. Each party, upon request, shall issue a certificate of compliance with international legal effectiveness and applicability that certifies that genetic resources and traditional knowledge have been acquired in accordance with the laws of the provider country and the FPIC of relevant indigenous peoples or local communities. The certificate shall denote whether there is traditional knowledge associated with a genetic resource and who are the holders of relevant genetic resources and traditional knowledge, documented in MATs.

The international regime shall establish a system of an internationally recognized certificate of compliance. For tracking access to TK associated with genetic resources, the certificate shall include the following minimum information:

a) Licensing terms, including permitted uses and restrictions of use, for:

- Research not aiming at commercialization
- Research and development aiming at commercialization; and
- Commercialization;
- b) Conditions of transfer to third parties including licensing terms.

Alternative or complement to certificate.

A Contracting Party shall provide a FPIC decision for access to genetic resources in writing and make this available through the ABS Clearing House Mechanism. This written FPIC decision could serve as a certificate of compliance with national legislation in order to support monitoring and tracking of access to genetic resources. In cases where TK is associated with this genetic resource, the written FPIC decision shall also state whether the appropriate procedures for obtaining the free, prior and informed consent from the relevant TK holders where observed and complied with, and who the relevant TK holders are.

Compliance: Misappropriation

Relevant bricks and bullets:

No specific brick or bullet in TK section, but issued raised in Part C on Compliance, section 3 (Annex to report of ABS 7)

Proposal for operative text:

For the purposes of the international regime, it constitutes an act of misappropriation/unauthorized access to:

1) access and/or use genetic resources and/or associated traditional knowledge without obtaining the relevant indigenous peoples or local community's FPIC, or

2) when an indigenous people or local community has rights to a genetic resource and this genetic resource is found ex situ, and/or the traditional knowledge is already in the public domain, and when no FPIC requirements apply, use the genetic resource and/or traditional knowledge without providing fair and equitable benefit sharing with the relevant indigenous people or local community.

Comment: In addition to acts of misappropriation as defined above there may be other situations that constitute inappropriate use that cannot be addressed by contractual remedies and therefore should be addressed by IR, e.g transfer of GR and associated TK to 3rd Parties without FPIC.

Concerning the paragraph 2) above, some participants considered that when accessing GR found in ex situ conditions prior to the entry into force of the CBD, and/or traditional knowledge which is already in the public domain, the use of the genetic resource and/or traditional knowledge without providing fair and equitable benefit sharing with the relevant indigenous people or local community is <u>not</u> a situation of misappropriation.

Compliance: Non-commercial research

Relevant bricks and bullets:

Identification of best practices to ensure respect for TK in ABS related research (brick D/1/4)

Proposal for operative text:

Parties shall encourage the application of measures and best practices to respect the rights of the holders of TK also in non-commercial research.

A community protocol can provide special rules for access to traditional knowledge for noncommercial purposes.

Contracting Parties shall encourage users to observe international guidelines and/or codes of conduct relating to indigenous peoples and local communities and TK, when requesting for access to TK for non-commercial purposes.

The effectiveness of the system shall be monitored and reviewed at a regular basis. The international certificate of compliance shall be monitored through an independent review.

States shall respect indigenous peoples' and local communities' customary laws, norms and protocols pertaining to genetic resources and associated traditional knowledge.

Further points under compliance

Proposal for operative text:

The Governing Body of the International Regime should recommend that rules and measures should be introduced aiming at ensuring that users disclose the country providing the resources/country of origin, the identity of the TK holders and evidence of FPIC, where available in applications for intellectual property rights.

Lack of PIC, where required by national legislation or community level procedures, shall be ground for disqualification in patent applications and applications for plant variety protection.

Parties shall ensure that any benefits arising out of the inappropriate use of GR and/or associated TK are directed towards the holders/owners of such TK and/or GR.

Comment: Further consideration of the term 'inappropriate use' would be useful.

Further points of discussion

In the discussions following presentations or held in smaller working groups issues were raised which in the understanding of participants need further reflection.

It was mentioned that the disclosure of origin of the genetic resource may be checked case by case for the consequences in different IPR systems. It was also noted that the Eighth Session United Nations Permanent Forum on Indigenous Issues adopted a recommendation for the disclosure of the origins of knowledge and resources of indigenous peoples in patent applications (Recommendation 21, E/2009/43E/C.19/2009/14).

It was discussed that TK could be treated as special chapter in the IR or be addressed throughout all chapters. There may be inherent dangers of restricting TK to a separate/single chapter.

It was mentioned that there should be made a distinction between public availability and public domain. It might happen that e.g. a certain TK is publicly available but still is not in public domain, because it still belongs to it's original holders.

With respect to certificates it was mentioned that the objective of such certificates should be further discussed by Parties, e.g. to what extent do certificate provide legal certainty. Another issue mentioned in connection with compliance was the role that voluntary self declarations could play.

With respect to Prior Informed Consent question were raised including inter alia:

- what means prior? (only 'Prior to access application'?)
- What about access between 1992 and 2010?
- What about access prior to 1992?
- What to do if TK and GR are encountered at different points in time?

Which information should be included in an informed consent?

- Information about the user?
- Information about possible effects of commercialisation (e.g. disclosure via scientific publication)?
- Information about possible benefits (maybe hard to predict)?
- Information about possible effects of benefits on ILCs?
- Inclusion of milestones, checkpoints?

It was discussed that the relationship between Article 8j and Article 15 needs further reflection e.g. the question was raised whether Article 8j refers to TK on ecosystems in a broader sense while 15 refers to utilisable TK only. The AHTEG in India provided some light on this.

It was also discussed if license models could be a complement or in part a substitute for certificates. The models of 'creative commons' and 'science commons' were mentioned as examples. A detailed discussion paper and operational text proposals relating to commons/open source models were provided to accompany the workshop presentation on this issue and have been submitted to the CBD Secretariat for inclusion in the compilation for ABS 8. (Oldham, P (2009) An Access and Benefit-Sharing Commons? The Role of Commons/Open Source Licenses in the International Regime on Access to Genetic Resources and Benefit-Sharing. *Initiative for the Prevention of Biopiracy*, Research Documents, Year IV, No. 11. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1438027)

It was also mentioned that ILCs shall be included in the technology transfer section of the IR, inter alia with respect to sharing of results of research and development and with respect to collaboration in research activities.