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AD HOC OPEN-ENDED WORKING
GROUP ON ACCESS AND
BENEFIT-SHARING
Fourth meeting
Granada, Spain, 30 January-3 February 2006

INTERNATIONAL EXPERT WORKSHOP ON ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING, 20 TO 23 SEPTEMBER 2005, CAPE TOWN, SOUTH AFRICA

The Executive Secretary is pleased to circulate herewith, for the information of participants in the fourth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the co-chair's summary and record of discussion from the international expert workshop on ABS held in Cape Town 20 to 23 September 2005 and co-hosted by Norway and South Africa.

The paper is being circulated in the form and the language in which it was received by the Convention Secretariat.

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International Expert Workshop on Access to Genetic Resources and Benefit-Sharing, 20 to 23 September 2005, Cape Town, South Africa

Co-hosted by Norway and South Africa

Objective of the workshop

The International Expert Workshop on Access to Genetic Resources and Benefit-sharing was co-hosted by Norway and South Africa (the Ministries of Environment, Foreign Affairs and Food and Agriculture of Norway and the Department for Environmental Affairs and Tourism of South Africa). It was co-chaired by Ms. Maria Mbengashe of South Africa and Ms. Birthe Ivars of Norway.

In their opening statement the co-chairs stated that the purpose of the workshop was to contribute to the ongoing negotiations of an international regime on access and benefit-sharing under the Convention on Biological Diversity (CBD) and create a better understanding of the issues involved by bringing together government representatives, experts, indigenous peoples' representatives and stakeholders involved in ABS issues. The workshop was convened in response to paragraph 7 of Recommendation 3/1 of the third meeting of the Ad hoc Open-ended Working Group on Access and Benefit-sharing, which encouraged Parties to hold regional and other meetings to exchange views on, inter alia, the process, nature, scope, objectives and elements of an international regime (IR).

A Co-chair's summary and a Record of discussion is hereby submitted as an information document to the fourth meeting of the Open-ended Working Group on ABS in Granada, Spain, in January 2006. A side event will be organised at this meeting to present and review the workshop results. The workshop proceedings can be found at www.norsafmeeting.com

Co-chair's summary

Background

The International Expert Workshop on Access to Genetic Resources and Benefit-sharing was co-hosted by Norway and South Africa (the Ministries of Environment, Foreign Affairs and Food and Agriculture of Norway and the Department for Environmental Affairs and Tourism of South Africa). It was co-chaired by Ms. Maria Mbengashe of South Africa and Ms. Birthe Ivars of Norway.

The purpose of the workshop was to contribute to the ongoing negotiations of an international regime on access and benefit-sharing under the Convention on Biological Diversity (CBD) and create a better understanding on the relevant issues, by bringing together government representatives, experts, indigenous peoples' representatives and stakeholders involved in ABS issues. The workshop was held as in response to paragraph 7 of Recommendation 3/1 of the third meeting of the Ad hoc Open-ended Working Group on Access and Benefit-sharing, which encouraged Parties to hold regional and other meetings to exchange views on, inter alia, the process, nature, scope, objectives and elements of an international regime (IR).

Emerging issues for further clarification and elaboration

The following issues were identified at the Workshop as requiring further clarification and elaboration in the negotiations of an international regime (IR) on ABS:

Objectives

There is a need for a clear focus with regard to the objective of the international regime.

The link between benefit-sharing and the other two CBD objectives of conservation and sustainable use of biological diversity needs to be kept in mind throughout the development of an international regime.

Scope

The rapid technological change in biodiscovery research and development has to be taken into account in the development of the international regime. A growing interest in bioprospecting activities as regards marine genetic resources in the high seas and the seabed beyond national jurisdiction could be foreseen as a result of this.

Consequently, there is also a need for a common understanding of concepts and terminology relevant to the regime. The genetic resources to be included in the regime have to be defined, including the question of traditional knowledge and derivatives. Pre CBD material

and marine genetic resources beyond the limits of national jurisdiction were identified as challenges to be addressed within the negotiations of a regime.

Structure

The overarching structure of an international regime on ABS was discussed. The following was highlighted:

- The IR should support and strengthen national legislation and implementation in both user and provider countries.
- The mutually supportiveness and complementarity of an IR and existing international legal instruments and processes (ITPGRFA, WIPO, TRIPs Council etc.).
- The possibility of an umbrella instrument to address cross-cutting issues such as certificates of origin/source/legal provenance, capacity building/technology transfer, compliance issues, and dispute resolution.

Elements

There was a call for narrowing down the list of elements in the report from the 3rd meeting of the Working Group on Access and Benefit-sharing. The focus in the negotiations should be only on issues that need to be addressed at the multilateral level. In this context the following elements were raised:

- The development of International Certificates of origin/source/legal provenance as a means to track the origin of genetic resources across national boundaries. It was also considered as a possible means to ensure transparency and provide a guarantee that legal requirements in the Country of Origin or provider have been fulfilled. The Workshop recognised that progress was made in this area through the research on a system of virtual certificates of origin and provenance initiated recently in Australia. The Australian example is a Web-based inquiry tool to enable an inquirer to obtain key information about the provenance of a sample and terms and conditions under which it was collected (confirmation of PIC and MAT). Samples of material collected under a permit is given a unique identifier that could travel with the material. There are lessons to be learnt from this research.

- Disclosure requirements in patent applications were identified as possible elements and some existing national IPR regimes were referred to (Costa Rica, Venezuela, 486 Andean pact, Egypt, India, Denmark, Norway etc.). The proposal at the international level by the European Community and its Member states to WIPO with regard to disclosure of origin or source of genetic resources and associated traditional knowledge was presented. Several initiatives were referred to in the TRIPs Council by India, Brasil etc. The question is whether disclosure requirements would support ABS arrangements more effectively if they were part of both national laws and the international IPR regime.

- The question of notification provisions from users before patent applications are filed was also raised.

- It was recognised that there are several kinds of benefits to share, both monetary and non-monetary benefits. What is needed are components of a credible system to capture and share benefits. The development of standard benefit sharing provisions should be considered (default contract).

- In developing benefit sharing mechanisms, also other than bilateral means could be discussed. A reference was made to multilateral funding mechanisms for material of unknown origin (e.g. the multilateral system developed under the ITPGRFA).

- In developing Material Transfer Agreements (MTAs) lessons can be learned from the development of Standard MTAs for plant genetic resources (ITPGRFA) and the possible use of "shrink-wrap" and "click wrap" agreements. The use of a Uniform Biological Material Transfer Agreement was referred to as another possibility.

- There is a need for triggering mechanisms for PIC and MAT given the complexity of bioprospecting.

- Check points at various stages in the ABS process are needed in order to protect the rights of providers of genetic resources.

- Measures to be taken at the international level to support recognition and realisation of the rights of indigenous and local communities by national governments in the ABS process, including in PIC and benefit-sharing arrangements.

- Capacity-building and technology transfer were identified as elements of an IR.

- The development of compliance and enforcement mechanisms for PIC and MAT and for the enforcement of national legislation is necessary. Possible elements:

- Legally binding commitment from the user/user country to comply
- Access to justice

- Dispute resolution such as arbitration were identified as means to settle disputes between parties:

- Binding/voluntary

- Need to address critical issues for providers and users such as the creation of a mechanism under the CBD for industry involvement.

All proposed measures should be judged against feasibility, practicality and costs.

Record of Discussions

Exploring possibilities and success criteria in adopting and implementing national legislation, and possible gaps

Speaker: Dan Ogolla
Paper: Legislative regimes on access and benefit-sharing & Issues in national implementation
http://www.norsafworkshop.com/Media/Uploads/43253074979df.pdf

In his presentation Dan Ogolla examined the nature and content of the emerging national and regional legal frameworks on ABS and highlighted pertinent issues in national implementation. He noted that there appears to be little to indicate that Art. 15.7 has been implemented nationally in a sufficient manner. There appears to be limited legislative national frameworks put in place both in user and provider countries. The key challenges are in the field of enforcement and monitoring (including transboundary monitoring/compliance) as well as addressing the emergence of regional frameworks and legislative frameworks.

More critically, obligations under the Convention have not been implemented by Parties 12 years after its entry into force.

Speaker: Maureen Wolfson
Paper: Challenges and gaps in developing and implementing national legislation on access and benefit-sharing
http://www.norsafworkshop.com/Media/Uploads/43252f8b33f81.pdf
http://www.norsafworkshop.com/Media/Uploads/433a9d6b282f1.pdf

Dr. Wolfson presented the National Management Biodiversity Act no. 10 of 2004 which provides the central framework for the management and conservation of biodiversity in South Africa. Chapter 6 of the Act which is due to enter into force 1 January 2006 deals with bioprospecting and ABS and provides a framework for the regulation of ABS. Many concepts and definitions still need clarification. Dr Wolfson presented a fully-fledged picture of issues involved in the implementation of South African national implementation of ABS related provisions, including the Patent Amendment Bill of April 2005, which includes provisions on declaration of origin and prior informed consent (PIC).
Discussion and comments

It was noted that South Africa's Biodiversity Act refers to "indigenous biological resources" in the SA, as opposed to "biological resources" which is a much broader concept. The SA Biodiversity Act places focus on indigenous biological resources which are those that are gathered from the wild or accessed from any other source and which have been transformed or naturalised, not exotic resources per se. South Africa has 21,000 species, many endemic.

A question was also put forward as regards measures that user countries could put in place to aid South Africa in the implementation, i.e. are there gaps that need to be filled?
It was noted that most gaps are of national making and it is therefore difficult to predict where they are until proper implementation is up and running. However, one gap already identified is that there at present is no central focal point for ABS. to assist with receiving and processing bioprospecting applications. Requests for material may therefore have to be addressed to one of the nine different provinces and academic institutions and there is no general overview of the system.

Speaker: Lindis Nerbø (powerpoint)
Paper: Draft Norwegian Act on the Protection of the Natural Environment, Landscape and Biological Diversity
http://www.norsafworkshop.com/Media/Uploads/432eb680788d9.pdf

Lindis Nerbø presented the ABS provisions in the Draft Norwegian Act on the Protection of the Natural Environment, Landscape and Biological Diversity. The Draft Act was presented to the Minister of Environment by an Expert Committee in December 2004 and has recently been on a public hearing. The draft act is proposed to apply to Norwegian land territory, internal waters, the territorial sea, the continental shelf and in the Exclusive Economic Zone (the EEZ). The law as a whole contains overall principles for the conservation and sustainable use of biodiversity and a specific chapter on access to genetic resources dealing with access to genetic resources in Norway and the use of genetic material originating from other countries when used in Norway.

Ms. Nerbø also presented the draft Act on the Management of Living Marine Resources which was presented to the Minister of Fisheries in June 2004. This draft act is proposed to regulate all utilization of wild marine resources and genetic material.

Discussion and comments

- How should the precautionary principle be applied especially as regards access to genetic resources in the absence of specific provisions to that effect. It was responded that all activities should be in line with broader precautionary principle rules in the draft act.
- At present there are not many known cases on marine bioprospecting in Norwegian waters but there are indications that demand will grow in the future.
- The Norwegian revised Patent law specifies that if the country of origin is different from the provider country, it should be disclosed. There is also a requirement to disclose whether PIC has been sought, if this is required by the providing country. This is not, however, a condition for patentability, and sanctions for providing wrongful information lie outside patent law in the civil criminal code.

Speaker: Lilian M. Nfor
Paper: Exploring possibilities of adopting and implementing national legislation - Case of Cameroon
http://www.norsafworkshop.com/Media/Uploads/432fdb17d95f9.pdf

Lilian M. Nfor presented the general legal framework legislation on biological resources in Cameroon. She described the various legislative acts dealing with the access issue such as

the Framework Law relating to Environmental Management, the Forestry, Wildlife and Fisheries Law, decrees, the Finance Law, Ministerial Order etc. The institutional structure for ABS arrangements is in place but it was noted that in view of the "patchwork" legislative system, creating a comprehensive legislative framework is difficult. With regard to gaps, there have been reports detailing practical difficulties regarding benefit-sharing at the local level. Also measures to ensure compliance are needed. Cameroon has done much in this field, but a more comprehensive legislation is needed to govern and ensure appropriate access to genetic resources as well as fair and equitable sharing of benefits.

Comments and discussion

- It was noted that there are in Cameroon several national and international organisations involved in tracking down cases where genetic resources have been taken abroad. There have also been a few diplomatic cases involving genetic resources and their further development is based on information about remedial effects of local plants obtained from local communities. The value of these transactions is not known. It is a difficult issue to pin down as there is a general lack of knowledge of which companies are active in the field, and provisions for benefit sharing are not properly developed. The Forestry Law in Cameroon contains some provisions for channelling benefits back to the communities.

- It is clear that communities and the government do not benefit as much as they could from the activities. There is a need for specific ABS legislation and there are plans to start a GTZ&UNEP funded project in 2006.

Speaker: Tomme Young
Paper: Gaps and Obstacles in Developing/Implementing National ABS legislation
http://www.norsafworkshop.com/Media/Uploads/432a72d47409e.pdf

Tomme Young focused on a basic assessment of the primary national implementation needs that must be addressed if ABS and genetic resource systems are to function effectively. This is based on the recognition that ABS is intended to be *an international commercially-oriented system* for the governance of certain commercial relationships. As such, its primary gaps can be organised into four areas – specifically, the needs for –

- recognition that ABS, as transboundary commercial law, cannot be effectively implemented by source-country law alone and must be realized in user countries as well;

- an integrated set of *consistent legal concepts*, terms and (possibly) mechanisms;

- real and sufficient *practical incentives and inducements* to motivate both countries and companies to create and utilize ABS systems and mechanisms; and

- clarification of the relationship between ABS as a unifying principle, and the *specific application* of ABS in particular biomes, sectors and ownership structures.

Tomme Young emphasized that in order for a regime to function properly there needs to be a way to verify compliance objectively. There is a need to create some reasons for business to want and need the ABS system to function effectively. What does it take for an ABS

system to actually facilitate the flow of genetic resources? She called for a "Business Case for ABS Compliance" – a carefully reasoned commercially realistic evaluation of the reasons that ABS is good for the businesses that comply. The primary areas which have been identified in which benefits can be developed include user certainty, protection against claims of biopiracy, biopatenting and "irregular access", and integration of clear standards for ABS compliance. Another option might be to require proof of ABS compliance to other desirable commercial rights to operate in the source country.

Comments and discussion

- It was noted, with some bemusement, the different terminology used for unauthorised access, including biopiracy, irregular access, unusual access. It was also pointed out that "unusual access" in some instances has become "usual" or "habitual". There is a clear need for user measures, including checkpoints to verify compliance such as customs procedures to make companies think twice.
- What financial incentives are there for governments to create an efficient regime and what incentives should the business-community be given to comply with the regime? Should we strive for the regime to be market-based? Probably not solely, government insight is needed.
- Common tools are needed in order to secure compliance and provide companies with benefits to make it worth their effort, for example saleable rights and streamlining
- Should access and benefit - sharing necessarily be tied together?
- There is a general need for clarifying terminology and definitions

USER AND PROVIDER COUNTRY MEASURES IN THE CONTEXT OF AN INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

Speaker: José Carlos Fernandez
Paper: User and provider country measures in the context of the international regime (powerpoint)
http://www.norsafworkshop.com/Media/Uploads/433a9a85014e9.pdf

José Carlos Fernandez agreed that the third CBD objective is about incentives, in that we recognize an environmental service, an informational resource provided by nature, and accept that maintaining it has costs. There is therefore a need to come up with a business case for ABS.

National responses to dealing with this issue indicate poor implementation based on contractual models, comprehensive legislative provisions which can prove difficult to apply, costly procedures, few transactions under current regime compared with biotech activity, holes and limitations in regulation (pre-CBD, ex situ, derivatives). Industry is globalised, and characterized by rapid technological change.

CBD ABS needs to be more goal- and outcome-oriented. There is a real need to bring two worlds together of bioresources and bioinformation, with a clear legal link between the two; be it certificates or default contractual clauses.

Genetic resources are essential for biotechnology, but value of individual transactions is very small. The value lays in libraries (genomics and bioinformatics) not single accessions. Price and value differ greatly and the CBD ABS objective should be about recognizing "value", not "price". José Carlos Fernandez argued that the real value lays with the knowledge application, not within the genetic resources, per se. There is an inherent value in genetic resources, if there is almost none left, its value will increase. Value should therefore be seen as a conceptual question, as a nexus between the GR source- and providing country. It was pointed out that we need a basic coordinated response to effectively link access to use and components of a credible system to capture and share benefits.

Discussions and comments

- The link between national legislation and user legislation, is it a trade question?
- Implementation of the third objective entails incentives and recognising environmental costs. This may require markets to be developed and charges for certain services to be put in place.
- Internalisation of these costs is needed
- Taxonomy institutions; there is a fear of them collapsing as a result of an exhilarating process
- The contribution of GR to the GDP is an extremely complex issue and value cannot be measured beforehand. Value is decided by strategic decisions by industry as part of its portfolio.

- Also a need to connect species- and molecular-level bioinformatics to reduce costs and improve efficiency.

Speaker: Fernando Casas-Castañeda
Paper: User and provider country measures in the context of the international regime on access and benefit sharing
http://www.norsafworkshop.com/Media/Uploads/43292148bc935.pdf

Recognizing the long-term linkage between biodiversity and associated knowledge, innovations and practices of indigenous and local communities, and the relevance of the three objectives of the CBD in the context of the actual and potential value of bioeconomics, Fernando Casas argued that one could recommend the simultaneous adoption of an ABS international regime on benefit-sharing arising out of the scientific and/or commercial utilization of genetic resources and derivatives thereof. This should be applied together with a set of measures to support national legislation on access to these resources and on PIC requirements in benefit-sharing arrangements for associated traditional knowledge related to the conservation, collection, use and interchange of genetic resources and derivatives thereof in accordance with CBD provisions. The two proposed strategies for doing so are:

- A positive strategy to capture, in a fair and equitable fashion, the genetic, social, economic, scientific, educational, and cultural benefits arising out of the utilization of genetic resources and associated traditional knowledge, with particular emphasis on indigenous and local communities of developing countries of origin.
- A defensive strategy in order to prevent 'bio-piracy', or the misappropriation or unauthorized use of tangible and intangible genetic resources, derivatives thereof and associated traditional knowledge, and to enforce measures to prevent and control this type of activities.

There is also a need to clarify some terms such as distinctions between biological and microbiological organisms and processes as well as between biological and genetic resources and their components.

Discussions and comments

- Can current generations be held responsible for pre-CBD accessions/activities? It was noted that this depends on the information available and how benefits are shown. If, for example, ex situ centres know the origin of the resource and there are ways to share benefits, such as publicly funded research and results from the research, it could be achieved. This is, however, difficult in a lot of cases and there are temporal/generational issues.
- CBD considers ex situ conservation complementary to in situ conservation. We should therefore link ex situ and in situ with reference to ABS, not just conservation.
- A starting point would be for countries to declare what they have that may originate from other countries.
- The case for electronic certificates – virtual certificates as they allow a zero cost PIC and MAT verification at any stage in the chain of development and are easy for users to use.

- Do we need a new regime or could this issue be addressed for example within the CBD programme of work on Art 15? Are there really elements that require a new regime?

Speaker: Morten Walløe Tvedt
Paper: Legal Analyses of Challenges and Options for User-Country Measures in an ABS-regime
http://www.norsafworkshop.com/Media/Uploads/434a20d249d84.pdf

Morten Walløe Tvedt raised the following three main points in his presentation:

- The legally binding core qualifying term **fair and equitable** describes the level of benefit-sharing, but has so far received almost no attention. This needs to be developed further to achieve the obligation and objective of the CBD;
- If countries and companies are to comply with the benefit-sharing obligation, there is a need for an agreed manner/approach/methodology for **valuation** of the contribution made by genetic resources to biotechnology;
- If countries recognise that fair and equitable benefit sharing is an obligation and an objective to be achieved, there is a need to establish a **clear and enforceable legal obligation upon private party** users of genetic resources. Mr. Walløe Tvedt's paper discusses how disclosure of origin and/or certificates can be seen as a part of such legislation.

Discussion and comments

- It is an interesting idea to shift emphasis away from ABS legislation in provider countries and move towards an emphasis on uses and user measures, with a trigger mechanism on benefit sharing.
- Whether this would be a proposal of a tax and thus put an end to negotiations between providers and users is not clear. It could be seen as default legislation supplemented with contracts negotiated between two parties.
- Maintenance of the "library" does not preclude selling a book in the bookstore as well.
- Access rules are not necessarily difficult to enforce and the mechanisms to do so are in many cases in place already.

Speaker: Preston T. Scott
Paper: User and provider country measures in the context of the international regime: Some thoughts and observations based on the experience of the Uniform Biological Material Transfer Agreement Project
http://www.norsafworkshop.com/Media/Uploads/433a9f25b5e33.pdf

In his presentation Preston Scott argued that it seems that one of the greatest contributions that an ABS/IR could makes towards more widespread implementation of the ABS provisions of the CBD would be through development of an equitable, efficient, transparent, and enforceable instrument that would facilitate access to genetic resources, encourage research involving the use of those resources in ways that can generate added value through

new and useful discoveries and inventions, and provide for the sharing of benefits (as in any healthy cooperative joint venture).

He highlighted the history of the development and implementation of a Uniform Biological Material Transfer Agreement, UBMTA, as a useful lesson in this regard. The text of the UBMTA itself offers some carefully delineated terms and conditions that relate specifically to many of the concerns being discussed in connection with the ABS/IR. In addition, the master agreement implementation procedure urged by the US Public Health Service (PHS) also might suggest some ways forward that would address many of the efficiency concerns arising in connection with the ABS/IR. It also would provide for much needed flexibility required for widespread implementation in a world with so many different legal and administrative structures. At the same time it would also provide at least some fundamental level of uniformity that could help alleviate some of the administrative barriers towards more facilitated access to biological resources as well as recognized and enforceable benefit-sharing rights in both domestic and international contexts.

Discussion and comments

- There are a series of definitions needed, not only for the biological material but also for downstream uses
- Would the application of the uniform MTA accommodate all the issues raised as regards the IR?
- Could the Uniform MTA be a possible instrument to help clarify rights of providers and users once material goes abroad.
- The UBMTA work should be linked to the MTA work under the International Treaty on Plant Genetic Resources. Standard agreements linked to resources have good potential, and can contribute to the certifications idea, default contracts, etc.
- There is a fear that the cost of the system will be higher than the benefits.
- Genetic resources are usually not unique resources and have no IPR effect. A public instrument can therefore be much more restrictive in a system which essentially requires transparency and could therefore restrict research and discriminate against research results.
- Industry, biotechnology industry demands clear and consistent rules.
- A new instrument? Or common heritage of mankind? If we are to consider an instrument outside of the CBD, where could it be better placed?
- Sidelining IPRs and patents is not right. IPRs are the very basis for industrial, agricultural development, not only a share of the market. IPRs are very important for industry also in the developing countries, to protect the creativity of the innovators
- On the other hand, patents have not proven to be effective as mechanisms for benefit-sharing.

Speaker: Leonard Hirsch
Paper: Provider and User Country Measures—Do Two Wrongs Ever Make a Right?
http://www.norsafworkshop.com/Media/Uploads/4338f80b29f17.pdf

Leonard Hirsch argued that the case for a new binding agreement is unproven, and that the CBD, when coupled with existing trade and contract law, provides a sufficient base to

protect legitimate property claims of countries of origin. He said that the long and expensive debates over mandating country of origin for patents is based on a simplistic understanding of patents, their role, and their power in enforcement. He did not want to say that disclosure is bad but rather that it is not the remedy needed to a series of very complex questions.

He also argued that the CBD is a treaty which frames national implementation, and that the first fundamental need for a successful ABS regime is national answers with regard to provider and user measures.

Discussion and comments

- Maybe we should not get caught on the issue of ABS. There are also benefits from conservation and sustainable use. One cannot separate one objective from the other. The complexity of the issue is man-made and there is every reason to simplify the process. A better starting point would be to look at the matter holistically.
- Is the international regime a red herring? Is the CBD obsolete? Are we setting up a system that is too expensive and repressive? An inventory of exceeding expenses needs to be done.

Speaker: Brendan Tobin
Paper: Bootlegging and Bottlenecks: Securing compliance in ABS Governance
http://www.norsafworkshop.com/Media/Uploads/433a9c22d886b.pdf

Brendan Tobin in his presentation reinforced the need for an international regime to establish obligations, enforce compliance and set standards. He also argued that benefits would increase if pre-CBD collections were brought in. It would not be feasible to develop a regime based on voluntary compliance. The IR should set the standard, then look at gaps in national legislation, not the other way around. He raised the issue of access to justice and noted with concern that the legal costs of challenging a patent can run into millions, and that these cases involve unresolved issues as to accessibility, capacity, responsiveness etc. He put forth the idea of dealing with non-compliance cases in other fora or learning from experiences in these, such as the International Court of Justice, the Human Rights Commission, or the WTO's Dispute Resolution Mechanism. Alternative dispute resolution such as arbitration needs to be considered. CBD Reporting Requirements on implementation of (user) obligations, incentive-based measures, technology transfer, etc. could be included. He presented the idea of an Ombudsman to act as an ABS focal point and whether this could be linked to the SCBD and CHM. The functions of such an office would be to collect information on remedies, legal aid, information on use, breaches, aid in the collection of evidence, act on behalf of local and indigenous communities and support capacity building.

Discussions and comments

- It was noted that as long as there are measures lacking at the national level it would seem premature to address them at the international level.

- Process of establishing national legislation should not be put on hold as we develop an international regime. UNEP is supporting pilot projects on national ABS legislation, while also encouraging contractual agreements under CBD-type terms. We need to exploit all possibilities. If we do that, we can see what works and what doesn't. When you push forward with contracts, you identify the places where you need regulatory frameworks and rules for contracts to function within.
- It was pointed out that the CBD Article 27 already contains a dispute settlement mechanism but it is based on an opt-in clause in relation to accepting binding dispute settlement such as the International Court of Justice or arbitration.
- The international regime cannot wait, contracts take long to negotiate. We are not talking about massive benefits, and the Monsanto ICBG took 4 years to negotiate. How can resources be freed up for wider use: for example stating that "our resources are free to be used under these specific terms".
- Genetic resources should be circulated but there should be checkpoints to verify compliance at various stages in the ABS process.
- Disclosure at what price? Disclosure is not necessarily an advantage for the providing country. At times it is merely a measure to prevent abuses and implement compliance.

SYNERGIES BETWEEN THE ABS NEGOTIATIONS UNDER THE CBD AND THE FAO INTERNATIONAL TREATY, WIPO, TRIPS COUNCIL ETC.

Speaker: Shakeel Bhatti
Paper: Oral presentation

Shakeel Bhatti illustrated the synergies between the ABS negotiations and WIPO and the FAO- ITPGRFA.

As regards synergies with the FAO IT-PGRFA he said that WIPO did a study on interfaces with IPR issues and an assessment of global patenting trends for a number of crops. The outcome of this study was presented to the interim committee of IT, which welcomed it, and continuing cooperation with WIPO. The study highlighted the how interagency coordination can benefit from synergies for specific issues within negotiating processes.

The IGC work on traditional knowledge and folklore resulted, inter alia, in two drafts. No new property rights over traditional knowledge are being put forward. Protection against misappropriation is being discussed. The WIPO General Assembly will at the beginning of October consider whether and in what form the IGC should continue work on TK.

The scope of traditional knowledge in the WIPO process is is broader than the provisions in 8(j). The drafts, however are developed in full harmony and consideration of CBD and IT-PGRFA. Drafts have concretely built on advice from 8j WG and resulting COP decision VI/10, in accordance with Principle A7 – respect for and cooperation with other international processes. COP-7 invited WIPO to examine and address a number of issues

related to disclosure requirements. WIPO GA decided to respond positively, and WIPO prepared the draft to be considered next week, and will then be transmitted to COP8.

The lessons learned on synergies encompass ; translation between different terminological, conceptual and legal contexts, for cross-cutting policy issues achieved; ability to take more specificities of, e.g. agriculture, by working with FAO; drawing on expertise of other fora; access to different constituencies and stakeholder groups.

How should such synergies be further enhanced? Enhance coordination at national level; respect for mandates; avoid zero-sum thinking; focusing on substance leads to progress; communicating results and processes is important, and doing it the right way (e.g. ICG reporting to WIPO GA, which reports to COP).

Speaker: Jayashree Watal
Paper: Relationship between the TRIPS agreement and the CBD
http://www.norsafworkshop.com/Media/Uploads/4339008a7c02f.pdf

Jayashree Watal presented the background for the WTO TRIPS and CBD discussions. There are two main issues of deliberation: Whether or not there is a conflict between the two and whether or not something needs to be done on the WTO on the TRIPs side to ensure mutual supportiveness, and if this is the case, what should be done?

Watal outlined the 4 different positions amongst the Parties ranging from no-conflict to inherent conflict. She also referred to the various proposals on disclosure. The need for coordination with other organisations such as WIPO, FAO and CBD was underlined.

Speaker: Mathias Buck
Paper: Disclosure of origin or source of genetic resources and associated traditional knowledge patent applications - Proposal of the European Community and its Member States to WIPO
http://www.norsafworkshop.com/Media/Uploads/432956896c59d.pdf

In his presentation, Mathias Buck outlined the basic features of the proposal by the EC and its Member States to WIPO for the disclosure of origin or source of genetic resources and associated traditional knowledge (TK) in patent applications. He summarized the proposal to ensure an effective, balanced and realistic system for disclosure in patent applications as follows:

- a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications;
- the requirement should apply to all international, regional and national patent applications at the earliest stage possible;
- the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him;

- the invention must be directly based on the specific genetic resources;
- there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the concept of "traditional knowledge" is necessary;
- if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed;
- if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law;
- a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

Comments and discussion

- Whether the patent offices are able to collect and process required information? As it usually takes 7 - 10 years to manage patent applications, would the additional requirements increase the backlog? The assumption is that it is not for patent-offices to assess whether the applicant possesses PIC and has put in place a benefit-sharing process. Wrong information would generally, however, lead to an invalidation of the patent or result in sanctions outside the patent system. Not many studies have been done on this issue.
- It was questioned whether there is a real desire to discuss issues of disclosure in Hong Kong. At this point in time even if the issue is on the agenda it will only be for the purpose of deciding whether it should be taken forward during the negotiations.
- Which would the consequences of non-compliance with disclosure be?
- Would ABS contracts always be considered confidential?

Speaker: Clive Stannard
Paper: Aspects of multilateral access arrangements
http://www.norsafworkshop.com/Media/Uploads/43290dc4c7ed2.pdf

Clive Stannard focused on the instrument by which the Multilateral System will be operated—a *Standard Material Transfer Agreement*—and discussed some of the questions that governments are addressing in negotiating the Standard MTA. Some of the experience gained may be useful in the more general context of developing an international regime of access and benefit-sharing.

He emphasised that agricultural biodiversity is distinct from wild genetic resources. Agricultural biodiversity is essential for basic human needs and there is a strong moral objective to safeguard the availability of the genetic resources. FAO estimates that, on average, countries depend, for 70 % of their food energy from plants, on resources originated in another region. In the agricultural community, there is large consensus that, in most cases, the exchange of agricultural genetic resources is best approached through

multilateral arrangements, made by governments in exercising their sovereign rights, rather than through bilateral deals.

Mr. Stannard referred to a study by the FAO on the possible use of "shrink-wrap" and "click-wrap" agreements. These are contracts used particularly in the information technology sector. The advantage is that such contracts could reduce the transaction costs of the Multilateral System and facilitate the coherent management of information. The use of arbitration as part of an agreement using click-wrap or shrink-wrap acceptance procedures could be helpful also for parties who do not yet recognise such instruments. A further possibility would be to allow, at the decision of a Contracting Party, either signed MTAs or shrink- or click-wrap MTAs.

Speaker: Kent C. Nnadozie
Paper: Synergies
http://www.norsafworkshop.com/Media/Uploads/433a9ae0a9f8a.pdf

Kent Nnadozie described the current global trends in the ABS negotiations. There is an increasing convergence of issues and expansion of GR debate in other fora & new frictions. International policy developments increasingly determine national policy directions. For the time being there are no
effective mechanisms for handling complex issues that overlap jurisdictions. There is a sanctification of IPRs; we need to move from theory to the theology of IPRs.

He concluded that:
- Dimensions are diverse at this stage since it is a highly polarized issue. Does this mean new opportunities or bigger risks? What is the appropriate forum for all the issues under discussion? Institutions respond only to the extent that Parties push them.
- Parties must focus on the need to understand and respect the differences between sectors;
- There is a need bring to the discussions the perspective and needs of other sectors in a spirit of mutual respect for the respective mandates of the different institutions – CBD, FAO, WTO, etc;
- E.g. recognise that International Treaty provisions are different from contractual systems; origin of materials from the IT's Multilateral System.

Speaker: Francois Pythoud
Paper: The International Treaty on plant genetic Resources for food and agriculture, a key component of the International Regime on Access and Benefit Sharing
http://www.norsafworkshop.com/Media/Uploads/432969b5dc205.pdf

Francois Pythoud outlined the issues for consideration when developing the IR and referred to the matrix developed by the WG-ABS in order to identify gaps for consideration by national governments. An analysis of national feedback should enable the WG- ABS to answer questions such as:

- Are they groups of genetic resources with unique/distinct features that might need a specific additional international instrument to ensure open access and equitable sharing of benefits?
- Is there a specific type of use of genetic resources that might require additional international instruments to support implementation of CBD Art. 15?
- Is there a need for additional international recognized/established tools (like sMTA) and/or procedures to support national implementation of access and benefit sharing provision?
- What measures could be taken at international level to support recognition and realisation of the rights of indigenous and local communities by national government?
- What are the most efficient approaches to fulfil those gaps?

A future international regime could therefore take the form of a framework, an umbrella, encompassing the international treaty, Bonn guidelines and crosscutting issues. It should provide tools to support national implementation, technical assistance and capacity/building. It would contain guidelines, guiding principles and financial mechanisms, a database of genetic resources, database on disclosures and provide synergy between the different instruments.

Comments and discussions:
- The use of shrink&click wrap agreements was referred to and the perceived difficulties in getting the countries to accept these agreements.
- Dispute resolution, arbitration options, including using CBD Art. 27 on dispute procedures. The Cartagena Protocol on Biosafety also contains a compliance mechanism, and one of its tasks is to review national reports to assess compliance.
- Capacity needs to be enhanced on these issues.
- The reasons for lack of national implementation include financial constraints and lack of human resources
- What kind of guidance should be the international financial institutions be given
- There needs to be a multilevel approach to coordination, also at the national level, most of the efforts need to be directed there.
- Difficult to address all genetic resources in one instrument.
- With regard to arbitration, the role of existing international bodies should be considered.
- Compliance perceived as a way to ensure that when there are benefits they need to be shared.
- Certificate of origin/source/legal provenance would provide a legal link between the user and provider.

Speaker: Geoff Burton
Paper: Developing a system of Virtual Certificates of Origin and Provenance
http://www.norsafworkshop.com/Media/Uploads/432fdbd1d9640.pdf

Geoff Burton presented Australia's research on a system of virtual certificates of origin to assist its biotech industry and capital providers. It understands that small to medium

biotechnology companies have a market advantage if they are able to address the due diligence needs of the other players in the biodiscovery development chain. Australian authorities can provision readily verifiable evidence of PIC and MAT in relation to material originally collected for biodiscovery and seeks to support this by a developing a web based inquiry tool. The project's specifications describe a stand-alone system to be used as a decision support tool, a permitting database and a publicly accessible confirmation of legal access to genetic resources. The scope of the project is to design and develop an online application system to support management of applications for Genetic Resources. This includes:

- A publicly accessible on-line enquiry tool.
- A publicly accessible on-line application for access to Genetic Resources.
- An on-line application accessible only to authorized DEH users for managing applications for Genetic Resources.
- Limited on-line system administration.

Such a system could assist any party considering acquiring interest in the material collected or in any biodiscovery derived from that material to identify the identity of the permit holder, parties to the ABS agreement and the identity of the source material. The ability to resolve any questions about provenance increases the value of the material and any IPR derived from it.

OBJECTIVES AND ELEMENTS OF AN INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

Speaker: Geoff Burton
Paper: Objectives and Elements of the International Regime - A Personal View
http://www.norsafworkshop.com/Media/Uploads/432920736feaf.pdf

Debate of the objectives and elements of an international regime on genetic resources (GR) is in danger of being overtaken by events and rendered nugatory. Geoff Burton discussed two new considerations which are changing the way we must think about the utilization of GR.

From the perspective of national resource managers, a regime is necessary to ensure access is duly authorised. In addition, an international regime is necessary to ensure the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources" (the 3rd objective of the Convention on Biological Diversity (CBD)).

The perspective of industry may well be different insofar as such a regime serves industry's interests if it establishes legal certainty and supports an orderly process for access to genetic resources and subsequent research and development on those resources into profitable new products and innovations. This process is international in scale and a legal framework under which it occurs already exists. A mechanism for industry involvement in the IR process needs to be developed.

From an environmental point of view, genetic resources are a valuable ecosystem service. A regime is necessary to ensure that the biological diversity underpinning that ecosystem service is externally valued. Such valuing occurs when fair and equitable sharing of benefits derived from genetic resources takes place. This sends market signals to governments and land and sea managers about the importance of protecting and conserving the resource, ie biodiversity. Moreover it allows for benefits to be used directly for the conservation of the resource itself.

No matter which perspective is taken, the key to a successful regime has to be the successful encouragement of the maximum amount of research and development on genetic resources with the providers of the resources facilitating access on reasonable terms in return for a reasonable share in any benefits produced.

Speaker: Hadil Fontes Da Rocha Vianna
Paper: Objectives and Possible Elements of an International Regime, and its Nature
http://www.norsafworkshop.com/Media/Uploads/433911d4a9c35.pdf

Hadil Fontes Da Rocha Vianna offered comments on two important issues of the International Regime – Objectives and Possible Elements - taking into account the information contained in Annex I of Recommendation 3/1 of the third Meeting of the Working Group. He said that Brazil supports the establishment of an international regime as an appropriate means to ensure compliance with national legislation. As per Article 8 (j) of CBD, the International Regime should as well promote and safeguard the protection of traditional knowledge, innovations and practice as appropriate. The main challenge of creating an effective International Regime lies in the need to change the way in which business has been running so far. He believed there is a lot of misconceptions regarding what "fair and equitable" means. Some countries, both developing and developed, and companies believe that this will entail huge amounts of financial resources being directed to countries of origin and that an enormous amount of paperwork and problems will have to be overcome in order to implement an effective Regime. First and foremost there needs to a political will to approximate the negotiating positions and a clarification of the real concerns and expectations of both developing and developed countries.

Speaker: David Hafashimana
Paper: Possible objectives and elements of the international regime on access to genetic resources and benefit sharing
http://www.norsafworkshop.com/Media/Uploads/433911254b51b.pdf

David Hafashimana set out to further elaborate on the possible objectives and elements of an international regime in order to generate debate on the same and hopefully lead to a better understanding of the issues in preparation for the next round of negotiations.
He noted that the challenges ahead in negotiating the international regime include:

- Establishment of the country of origin where a species exists in more than one country

• Possible non-compliance by some countries disregarding whatever measures may be put in place.

• Identification of derivatives that are already processed or semi-processed

• Inadequate capacity in certain countries to ensure compliance with the regime.

• The issue of pre-convention acquisitions especially where they have gone through several countries before reaching their current location.

• Differentiating between pre-convention acquisitions and post-convention ones acquired illegally.

• Enforcement of the regime to counter illegal GRs acquisition in the face of modern technology where a few cells are enough material for micro- propagation.

• Ensuring benefits trickle to the indigenous and local communities especially where such communities interests are at variance with their national laws.

• Problem of disparity in requirements under different national laws with similar GRs.

Speaker: Preston T. Scott
Paper: Oral presentation

Preston Scott offered reflections and how to bring the discussions down to a more specific level and said that the IR should:

- be an enabling instrument, assists countries to implement national legislation, assist countries that do not do it at the present
- address mainly the critical issues, consensus among providers and users
- accommodate government and industry/private sector
- be incentive-driven and not based on sanctions

The elements should include scope, broken up in a series of definitions, including:

1. Downstream material, derivatives. Pre CBD material could be included in an annex.
2. Acknowledge and clarify the recipients and the proprietors of the material, rights should be clarified.
3. Documentation of linkages, certification of provenance/origin. In itself it does not create an obligation. Allow for third party transfers with PIC.
4. Benefit-sharing trigger mechanism, rights of the provider, front payment
5. IP expectations and clarification of these. Notification provisions, application. How to protect providers rights.
6. Compliance
7. Dispute resolution is routine and should be included.

Implementation mechanisms encompass execution of a side-letter agreement, evidence of PIC and MAT and a range of industries. Rights and obligations of providers and users should be spelled out as legally binding.

Speaker: Timothy Hodges
Paper: Deep Sea Genetic Resources and the International ABS Regime: Reflections on the Challenges Ahead
http://www.norsafworkshop.com/Media/Uploads/43391f208796c.pdf

In its 2004 Law of the Sea resolution, the United Nations General Assembly agreed to establish an ad-hoc open-ended working group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction (herein the UNGA WG). "Areas beyond national jurisdiction" comprise the high seas, as well as the seabed and its subsoil beyond the continental shelf of any coastal state. The mandate of the working group, which will meet in February 2006 in New York, consists of four tasks, namely: surveying the past and present activities of the U.N. and other international organizations re to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction; examining the scientific, technical, economic, legal, environmental, socio-economic and other aspects of these issues; identifying issues/questions for more detailed background studies; outline possible options and approaches to promote international cooperation and coordination for the conservation and sustainable use of marine biological diversity. He emphasized that the actions taking place in these for a have implications for the international ABS regime negotiations, for other international fora, for countries and their stakeholders, as well as for the future health of global biodiversity.

Comments and discussion

- The feasibility and practicality of virtual certificates was doubted. A permit database is valuable, however scepticism was expressed as to when one takes it past MTA level; multiples, duplicates, generations also collected. It was argued on the other hand that electronic certificates – virtual certificates allow a zero cost PIC and MAT verification at any stage in the chain of development and are easy for users to use.
- Challenges. Practical measures to ensure benefits, national sovereignty, pre-convention material.
- Pre-CBD collections, Forests FAO, genetic resources beyond national jurisdiction, migratory species, micro-organisms.
- Ex situ collections facing increasing pressure
- Countries with economies in transition where we see companies buying "open access" in return for paying salaries etc at the ex situ collections
- A combination of carrot & stick, risk of perverse outcomes, engaging in a much more informed way.
- ABS' connection to millennium goals for food security was put forward but questioned by others. Will ABS ever substantially contribute to poverty alleviation?

Speaker: Merle Alexander
Paper: The international regime from an indigenous peoples perspective

http://www.norsafworkshop.com/Media/Uploads/43254b53934bc.pdf

Merle Alexander said that in order to enable Indigenous laws that are an integral component of a prospective international regime on access and benefit–sharing; greater diversity in perspectives, positions and view points from Indigenous peoples needs to be encouraged. To move beyond the principled statements in ABS meetings, Parties must facilitate submissions by individual Indigenous Nations in addition to joint statements. He noted that the workshop is a positive step towards this broader inclusion. In his presentation Merle Alexander reflected on how traditional knowledge is held by Indigenous peoples in different regions of the world and the process for obtaining community–level prior informed consent in different countries. He discussed how community–level prior informed consent systems be incorporated into national ABS regimes and the prospective international regime as well as measures to ensure compliance with prior informed consent of Indigenous Peoples holding Traditional Knowledge with Genetic Resources. He pointed at potential options for redress if community–level prior informed consent is not obtained when accessing genetic resources and associated traditional knowledge; the need for capacity–Building and the need for sui generis protection for genetic resources and traditional knowledge. Merle Alexander concluded by urging Parties to advocate and facilitate greater opportunities for interventions from Indigenous Peoples of their regions in the negotiations.

Speaker: Johan Bodegard
Paper: ABS, indigenous and local communities – a history of distrust
http://www.norsafworkshop.com/Media/Uploads/434e29fd0df69.pdf

Plant genetic resources for food and agriculture (PGRFA) have been used by leading cultures in the world as a means of increasing political power, acquiring economic wealth and promoting national economic development. This is an important factor behind the present political debate over access to genetic resources and the sharing of benefits derived from their use in commercial development. History runs deep in the minds of many nations, as well as local and indigenous communities, and contributes to the deep controversies in international negotiations. Johan Bodegård said that in order to move forward we need a process of global reconciliation and for this we need to understand where we come from. The historic lessons are important. And in looking forward, we must bear in mind that the challenge that lies before us is not who benefits the most in technical or economical terms. What is at stake is whether we will be able to feed and sustain with the help of biological resources and the ecosystems perhaps 10 billion humans on the planet by the year 2030. Mr. Bodegård argued that this is best served by a strong public commitment to make genetic resources work for the benefit of all humans on all continents, in all countries and in all indigenous and local communities. We need a strong public-private partnership, based on mutual trust, in particular trust for indigenous and local communities

Speaker: Roger Chennells
Paper: The international regime, an indigenous people's perspective.
http://www.norsafworkshop.com/Media/Uploads/4339074719b10.pdf
http://www.norsafworkshop.com/Media/Uploads/432971fd74aec.pdf

Mr. Chennels presented the "Hoodia case" and the indigenous peoples involvement in the ABS arrangements at the local level. As is well known, the CSIR took out a patent over the appetite suppressant properties of the Hoodia succulent. Some years later, the San peoples discovered the fact of the patent, and took this up with the CSIR, who had admittedly used the traditional knowledge of the San as a primary research lead. Negotiations led to a benefit sharing agreement.

Mr. Chennells referred to certain practical aspects of the benefit sharing agreement from the perspective of the San, and touched on the subsequent legislation in South Africa that covered the ABS provisions of the CBD. San initiatives to preserve and manage their own genetic resources are discussed, in the light of the pending legislation on protection of Traditional Knowledge. The free-riders problem was referred to after the patent became public knowledge, since many companies have provided the international market with Hoodia based suppressant products. The San are clear that they have the primary benefit-sharing agreement, so any other product emerging from a company other than their sublicencee Unilever is probably in breach of the P57 patent. CBD Parties should therefore devise and implement a mechanism or regime that will prevent the sale of biopirated products within their jurisdiction.

Speaker: Marthinus Horak
Paper: The Hoodia case as an example of Indigenous People involvement in an ABS agreement
http://www.norsafworkshop.com/Media/Uploads/4338fa21ab744.pdf

Mr. Horak provided an oversight over the background to CSIR's research on Hoodia and the way up to a benefit-sharing agreement between CSIR and the San Council in 2003. The San Council also entered into a comprehensive Bioprospecting Agreement with CSIR in 2004 to allow development of a secure database of San indigenous knowledge on medicinal plants derived from plants of the Kalahari, creation of employment opportunities for San that may arise from implementation of CSIRs technology etc.

Speaker: Chee Yoke Ling
Paper: Oral presentation

Ms Ling emphasised that it is not possible to speak for environmental NGOs with one voice since the views are differing on this topic. Any established regime will need to tackle the three objectives of the CBD as they are interrelated, and there is a need to link access, benefit sharing and technology development. Article 20 has to be borne in mind and the financing issues it deals with.

The idea of an international regime is not new, it has been around for quite some time. The MAT versus regulatory debate plays into this as well. Contracts need certain framework standards, and they need to be done at the international level. Many aspects of the Bonn guidelines are useful, and if we were to create a legally-binding instrument, it would give a much stronger impetus to efforts at the national level.

Many NGOs want to see a legally-binding international regime which would cover genetic resources and their derivatives. The concept of "for environmentally sound uses" should be defined and addressed as part of Article 15. We need to address technology transfer as well, in both environmentally sound and development-related terms.

Integrity of the patent system is under threat through over-expansion, and there is a lot of discussion about its flaws in the US. Categories: (a) naturally-occurring GRs, wild and cultivars – what kind of ABS rules do we want for them?

It will include also parts of organisms, micro-organisms. Are these patentable? Many feel that naturally-occurring living things should not be patentable. (b) modified GRs – level of intervention varies up to GMOs. (c) products derived from GRs; (d) TK directly related to a GR; (e) TK related to modified GRs; (g) TK related to derivatives and products. (h) TK not directly related to GRs, but important for survival of indigenous communities and their culture, in a broader sense

Speaker: Susan Finston
Paper: American BioIndustry Alliance (ABIA) Views on the Establishment of an ABS/IR
http://www.norsafworkshop.com/Media/Uploads/435369b234be8.pdf

Susan Finston in her paper outlined the shared interests of all stakeholders (CBD members, industry, non-commercial researchers, and indigenous peoples) in having a system that will provide transparency, predictability, and reliability and identifies some key open issues—some of which remain controversial—that require further consideration.

A great deal of work remains, and agreement on basic terms and definitions is an important step in developing a broadly- acceptable approach to an ABS IR. Amongst elements of an ABS regime the following was put forward: technology transfer and capacity building; inclusion of indigenous peoples; appropriate incentives for in situ bio-prospecting to enhance knowledge; enforcement of an ABS IR across borders that provides effective redress for all parties in case of illegal or inappropriate activities related to the IR. The paper also states that the ABS IR should avoid the dilution of intellectual property rights through any patent disclosure obligation. It was proposed to establish an ABS IR based on a contractual approach, where each ABS agreement would include a legally enforceable memorandum of understanding (MOU) between CBD members and interested stakeholders.

Speaker: Kees Noome
Paper: Industry perspective
http://www.norsafworkshop.com/Media/Uploads/4327cf712ded1.pdf

Kees Noome presented the perspective of the plant breeding industry whose only tool and product are genetic resources. The example of pharmaceutical "blockbuster" drugs is completely a-typical for the worldwide situation on Access to Genetic Resources; it should not really play a role in our considerations for a regime. It is stated in the paper that if states are "commercialising" genetic gesources they should be aware that their major customers are probably the breeding industry (agriculture, horticulture, ornamentals, animals);

biotechnology companies including medical and possibly agchem and "fermentation" industries. But there are also many small-scale industries focusing on exploiting natural resources like extraction of flavours and fragrances from plants collected in nature.

Kees Noome pointed to consideration of several issues for an access contract, *inter alia* the unclear situation regarding "origin", is the provider the "competent authority" to agree on PIC and access; what rights will be conferred to the recipient; what is the value of the material and benefit-sharing etc. Amongst suggested solutions are joint early characterization of genetic resources, publication of genetic information, more cooperation between states on the approach to ABS, methods to encourage ABS best practice by companies etc. It is important that conditions for access and benefit-sharing are decided as early as possible in a regime that is simple, practical and competitive. The industry is motivated to support the process of development of an international regime and the contribution can be to clarify the practical situation and clarify the consequences of various proposals.

Speaker: Jorge Cabrera
Paper: Oral presentation

INBIO experience shows that ABS is an important tool for conservation and sustainable use. At the same time, ABS is not the goldmine that some have expected. There is potential in biodiversity. To promote conservation and sustainable use investment In R&D is needed in order to obtain benefits.

ABS should be seen as part of a broader package to support biodiversity conservation and sustainable use. The changes/transitional time to ABS has been difficult to accept for the research community in developing countries. The launch of IR should deal with issues on the claims and realities of biopiracy and the lack of resources flowing back to developing countries.

As regards the International regime there is also a need to narrow down the elements, and the list from the third ABS WG meting. A functional ABS regime requires user measures as part of the international regime and can promote facilitated access; can promote legal certainty as well as allow for a different group of commercial and non-commercial research. Here basic research can be some sort of link. There is a difficult line between commercial and non-commercial research. Simple and practical instruments are needed. Checkpoints are needed in various stages of the ABS process.

The supportive tools include capacity building, exchange of information and market information as part of IR. A permanent review and assessment of the IR needs to be established and included in the IR.

<u>Comments and discussions during the concluding session:</u>
- The importance of domestic/national implementation in combination with international, is not necessarily a successive one.
- Is there sufficient political will - is ABS high enough on the political agenda?

- The link between the 8j and the ABS – processes are important. This should be discussed at COP8. The 8j working group should feed into the ABS discussions. There are several elements such as sui generis regimes, PIC models, coordination by the bureaus etc. that need to be addressed.
- The Hoodia case could be seen as a perfect example of the prevailing legal vacuum and it does illustrate the need for an international regime.
- Mechanisms to channel benefits to the community should be developed. The range of benefits should be addressed as well in order to decide what percentage should go back to community vs. the state.
- Too broad property claims may have a negative impact on R&D.
- The issue at hand is about capturing value and there is a real concern that the part of TK & GR that cannot be patented will loose interest. However, the IR is needed in order not to stifle economic activity.
- Industry feels sidestepped and reference was made to three different categories of biotechindustry: Red biotech – pharmaceuticals; Green biotech: agroindustry: white biotech:enzymes. Mechanism for better industry involvement and representation is required. There is a need for: 1. transparency, what are the regulations, avoid discrimination, fairly and evenly; 2. predictability, sign of today should be the case tomorrow; 3.flexibility and durability.
- Enforcement issues include checkpoints such as disclosure of origin, declaration of origin, checking at customs.
- It is important to assess when benefit-sharing start. It's a long process, and there is a need for developing countries of origin to characterize GR and derivatives.
- The principle of transparency and predictability should apply also to users of GR.
- Patents could also be seen as a form of technology transfer. Open source systems could be used like in the information technology sector, and not to be locked up in expensive subscription journals.
- There are also non-commercial areas which should be fenced in, such as "the sacred" (TK). For example the NZ patent law includes a morality aspect Also UNESCO protection of cultural expressions. Body of law in Canada emerging. For example culturally modified trees. UNESCO's Convention on cultural heritage. Coordinated, synchronized with WIPO. Protection of cultural expression. WIPO works on combating misappropriation of cultural expressions. Draft provisions on traditional knowledge. As noted before, these drafts will be further discussed by the GA next week.
- Examples of projects where one has been successful in practising trust, international system to give support to such registers.
- If we are to include poverty alleviation and even more ambitious objectives, the process will drag out. We are risking building in failure into the process.
- On the other hand, we do have a strong moral imperative here. It is not only about chasing patents. We should not loose sight of the ethical issues and the right to economic development. Socioeconomic goals should be mentioned. That is why benefit-sharing is crucial, in monetary and non-monetary terms. As to poverty reduction, the avoidance of poverty depends on the management of biodiversity.
- Fundamental question. What is a regime? A set of norms, principles? In which case we already have a regime. The objectives should be those of the CBD. Binding document, mix of different products.