International Dialogue

Key Challenges and Practical Ways Forward for the Implementation of the Nagoya Protocol on Access and Benefit-Sharing

4th-6th August, 2014, Goa, India

Hosted by: the Ministry of Environment, Forests and Climate Change of India

REPORT

The Goa Dialogue was the latest of a series of activities carried out to support the implementation of the Nagoya Protocol. Other activities included a first dialogue on Practical Ways Forward for the Implementation of the Nagoya Protocol, held in Cape Town in January 2014 and national studies on ABS implementation carried out in Brazil, India and South Africa. Further information on these activities are available on the ABS Initiative's website (www.abs-initiative.info/countries-and-regions/global/ibsa/).

The ABS Capacity Development Initiative is

Table of Content

Background

The Access and Benefit-Sharing Capacity Development Initiative (ABS Initiative) is facilitating a series of activities that involve an exchange of experiences with Access and Benefit-Sharing (ABS) implementation to support the implementation of the Nagoya Protocol on the Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising from their Utilisation to the Convention on Biological Diversity (Nagoya Protocol). Against this background, a Dialogue on Practical Ways Forward for the Implementation of the Nagoya Protocol was organised and hosted by the South African government in Cape Town on 30th and 31st January 2014. This first dialogue focussed on the sharing of experiences on past ABS implementation and reflected on the lessons learnt so as to provide practical guidance to the development or revision of ABS national legislation taking into account the provisions of the Nagoya Protocol. The discussions revealed that a number of countries attending the meeting faced similar issues and common challenges in setting up comprehensive ABS systems that will address effectively the Protocol's obligations.

At the kind invitation of the Indian delegation, a second ABS Dialogue on the Key Challenges and Practical Ways Forward for the Implementation of the Nagoya Protocol took place in Goa, India from 4th to 6th August 2014. This second edition of the dialogue was co-organised by the Ministry of Environment, Forests and Climate Change of India, the National Biodiversity Authority, the ABS Initiative, and the "Indo-German Biodiversity Programme" of GIZ.

Objectives

Building on the key outcomes of the first dialogue, the overall objectives of the second dialogue were to share information on the progress made to advance the implementation of the Nagoya Protocol at national level and provide a further opportunity for government representatives and relevant stakeholders to:

- Share views on the common challenges and learn from one another's experiences with respect to the implementation of the Nagoya Protocol;
- Discuss the different views and approaches being considered or adopted at national level to meet the obligations under the Protocol; and
- Reflect on the possible options to support a coherent approach for the implementation of the Nagoya Protocol, taking into account all the above.

Participants

The Second Dialogue on the Key Challenges and Practical Way Forward for the Implementation of the Nagoya Protocol brought together 70 representatives of government and relevant stakeholders involved in ABS implementation from seventeen different countries including Brazil, Ethiopia, India, Kenya, Malaysia, the Maldives, Mexico, Mongolia, Morocco, Nepal, Namibia, Norway, South Africa, Sri Lanka, Switzerland, Thailand, and Vietnam as well as a representative from the Secretariat of the Convention on Biological Diversity (CBD).

Outcomes

The active involvement of the participants contributed to the success of this event and provided a good basis for fruitful and practical discussions to advance the implementation of the Nagoya Protocol. As in the first dialogue, the second dialogue provided a platform for the exchange of experiences and innovative approaches for implementing ABS national legislation and regulatory frameworks.

During the three day dialogue, participants shared the progress made in their country for implementing the provisions of the Nagoya Protocol, in particular those related to access to genetic resources and associated traditional knowledge, the fair and equitable sharing of the benefits arising from their utilisation, compliance by users with the ABS legislation and regulatory frameworks of provider countries and monitoring of the utilisation of genetic resources. Learning from each other, participants discussed pressing issues, common challenges, different approaches and strategic options that may assist them in reviewing existing legislation or developing clear, efficient and user-friendly national ABS systems that are aligned with the Nagoya Protocol and foster innovation.

Through the diversity of cases presented as well as constructive exchanges and group work, the participants:

- Acquired a better understanding of ABS mechanisms and new obligations related to access, benefit-sharing, compliance and monitoring;
- Enriched themselves with knowledge and multi-country experiences of ABS implementation and related challenges;
- Gained a better understanding of the benefits of a regional approach to the implementation of the Nagoya Protocol;
- Acquired a better understanding of the status of compliance and user country measures through the experience of Norway and Switzerland;
- Touched on new aspects such as, among others, the role of intermediaries; the acknowledgement that all countries are also potentially users of genetic resources and should develop national ABS compliance measures accordingly; and the value of a bio-economy approach to maximise the economic potential of biodiversity;
- Discussed innovative measures and approaches considered by fellow countries and shared thoughts on the possible options to support a coherent approach for the implementation of the Nagoya Protocol across regions; and
- Reiterated the usefulness of such a dialogue to build each other's capacity to further the implementation of the Nagoya Protocol and the development of effective ABS systems that will foster innovation and contribute to economic development.

Process

National Approaches to Implement the Nagoya Protocol

Introduction

This first session started with a brief overview of the outcomes of the first Dialogue on which the objectives of this second dialogue were built in order for the participants to continue the discussion and the exchange of experiences in implementing ABS and the Nagoya Protocol. Presentations by Brazil, India and South Africa on progress made in the implementation of the Nagoya Protocol followed.

Country Examples

Brazil, India and South Africa reported in turn on a) the progress made so far to implement the Nagoya Protocol; (b) the key changes in relation to the ABS approach adopted in the light of past experiences in implementing ABS and the provisions of the Nagoya Protocol and c) the process underway and new developments towards the implementation of the Nagoya Protocol. Some key measures undertaken and lessons learnt to advance the implementation of the Nagoya Protocol included the following:

- Conducting a legal gap analysis on the differences and similarities between existing ABS legislation based on the CBD provisions and the new provisions under the Nagoya Protocol;
- Establishing an expert committee in charge of drafting and implementing new measures to address the identified gaps, thereby overcoming the issue of competing ministries or competing responsibilities;
- Acknowledging that all countries are also potentially users of genetic resources and/or associated traditional knowledge and should develop ABS compliance measures accordingly;
- Recognising the importance of ratifying the Nagoya Protocol before the first meeting of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP 1) in the Republic of Korea, in October 2014, in order to be part of the decision-making process;
- Promoting the economic benefits of ABS on development and establish ABS measures that attract users/industries to develop the potential of biodiversity in partnership with provider countries; and
- Maximising the benefits and potential of biodiversity in provider countries by stimulating value chain creation and giving a particular attention to bioprospecting and biotrade and to the formulation of a National Biodiversity Economy Development Strategy.

Open Plenary Discussion

Participants sought clarifications regarding the main challenges faced by Brazil, India and South Africa in implementing the Nagoya Protocol, differentiating access for commercial research and non-commercial research and the different approaches considered to regulate bioprospecting and biotrade.

Access

Introduction

The aim of this session was to discuss how to develop simple, clear, efficient and user-friendly national systems to foster innovation. To do so, a short presentation provided a brief introductory overview of access related provisions under the Nagoya Protocol which can be found under Articles 2, 3, 6, 7, 8, 13, and 14.

Panel Discussion and Open Exchange with the Plenary

Representatives from Kenya, Nepal, Indonesia and Mexico provided a brief overview of current and future measures planned to regulate access in their respective national ABS legislation in accordance with the Nagoya Protocol. Developments underway under the African Union regarding Guidelines for a coordinated implementation of the Nagoya Protocol were also presented. The open plenary discussion that followed highlighted a number of cross-cutting issues and challenges without necessarily providing any fixed solutions to address them but rather pointing out various issues to consider while developing an access and benefit-sharing regime. The following highlights the key issues discussed:

- *The need to adopt a differentiated approach for access to commercial research and non-commercial research:* Views on this issue differed. Some countries reported to have adopted a differentiated approach to deal with access for commercial and non-commercial research while others indicated to have implemented the same access requirements for both types of research. For example, Mexico and Kenya indicated that they do not make any distinction between commercial and non-commercial research and that access requirements were applicable to both nationals and foreigners equally, although there was a slight difference in the application fee. In contrast, the draft African Union Guidelines for a Coordinated Implementation of the Nagoya Protocol (draft AU Guidelines) differentiate between utilisation for commercial or non-commercial research. There was a broad agreement among participants that national ABS legislation must provide clear information about the scope of access and access requirements for both commercial and non-commercial research. Since the development of a new product usually starts with basic research and because the outcomes of such research are unpredictable, some participants felt that there was no need to differentiate access between the two types of research as in any case no utilisation of genetic resources should be allowed without a proper due process that involves obtaining Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). Generally speaking, the difficulty to differentiate non-commercial research from commercial research in most cases and to monitor the outcomes of research, especially when resources had left the country of origin, was seen as some of the biggest challenges to overcome.
- *Assessing whether a differentiated approach is detrimental or beneficial to collaboration between national and foreign institutions:* A number of countries reported that they were making a distinction between national and foreign users by requiring foreign research institutions or individuals to partner with national research institutions. Some indicated that differentiating access fees between foreigners and nationals was unsuccessful and unnecessary as it resulted in more foreign access applications made through nationals. Other countries indicated that they did not want to discourage potential users. As a result, permit regulations largely differ from one country to another. In the end, the general feeling was that the current debate should focus on how to balance the various interests while at the same time allowing

some flexibility in order to stimulate innovation and ensure that benefit-sharing mechanisms are in place and that benefits generated flow down to the communities.

- *Dealing with the issue of new utilisations:* When developing access provisions in national legislation, it was highlighted that the issue of new uses should be addressed. For example, the draft AU Guidelines clarify that there should be no new uses without establishing new PIC and MAT and propose to black list users that are utilising genetic resources previously accessed for new purposes (new uses) without due process. The draft Guidelines therefore suggest that those users that do not establish new PIC and MAT should be liable for sanctions.
- *Regulating access to genetic resources located in protected areas, access to shared resources and traditional knowledge, or endangered species:* Access to such resources adds another layer of complexity. Some countries indicated that they reached out to neighbouring countries when resources and/or traditional knowledge were shared in order to discuss how to deal with the situation. All countries highlighted the importance of obtaining the consent of traditional knowledge holders. Some participants suggested that documenting traditional knowledge may facilitate this process. With respect to genetic resources, it was observed that that are widely used, a regional and harmonised approach may simplify or provide a solution to the situation while fostering cooperation between the different States involved. With regard to access to genetic resources in protected areas or access to endangered species, additional international obligations and national requirements must be addressed. Finally, some participants highlighted that some countries do not regulate access on private lands.
- *Regulating access while promoting innovation and harnessing the potential of biodiversity at the same time:* Access regulations should not be a deterrent to do research. Restricting access for research purposes will not foster innovation. As most countries indicated that their overall aim was to promote access, utilisation and innovation, it is therefore necessary to develop ABS systems that facilitate this goal. It was highlighted that provider countries should therefore work towards developing such systems in order to unlock the potential of their biodiversity and, in so doing, support development through ABS. Although regulating access was seen as essential to negotiate any benefit-sharing or to have any potential recourse in case of non-compliance, some participants pointed out that protectionism was not a solution. In fact, they highlighted that too much control over the resources would kill access and any benefits ABS may generate.
- *The benefits of a regional regulatory approach to access:* Natural ecosystems and traditional knowledge systems are not confined to political boundaries. A regional approach to access could, among others, facilitate transboundary issues, prevent competition among countries sharing the same resources and/or associated traditional knowledge while fostering collaboration between States, increase the bargaining power of States in ABS negotiations, improve compliance and facilitate the sharing of information, technical cooperation and the circulation of expertise in the region. Overall, a regional regulatory approach, such as the one promoted through the draft AU Guidelines, could assist with the national implementation of the Nagoya Protocol by providing a harmonised approach to address critical issues such as access regulations while at the same time offering enough flexibility to take into account national circumstances.
- *The role of ABS National Focal Points:* Some participants highlighted that National Focal Points have an important role to play in ensuring that the information related to access and permit requirements was easily accessible to users and to the communities providing genetic resources and/or associated traditional knowledge, thereby contributing to compliance. They also pointed out that National Focal Points have a key role to play in the discussions and negotiations concerning shared genetic resources and/or associated traditional knowledge.

Benefit-Sharing

Introduction

The objective of this session was to discuss how to address benefit-sharing in practice. A short presentation provided a brief introductory overview of benefit-sharing related provisions under the Nagoya Protocol which can be found under Articles 5 and 9.

Examples of National Benefit-Sharing Provisions

The second part of this session aimed at presenting the experience of Malaysia, Ethiopia, and Brazil with respect to benefit-sharing.

Malaysian Experience

Malaysia is currently in the final stages of developing an ABS legislative framework as part of an overall strategy aimed at establishing an active biotechnology industry using genetic resources. An evidence-based study has been undertaken to assist in developing an ABS law that is both pragmatic and workable. The future legislation will apply to biological resources and their derivatives, including those accessed on private lands, associated traditional knowledge and their utilisation through research and development activities. No differentiation would be made between national or foreign applicants but provisions included in PIC would encourage foreign applicants to collaborate with nationals. Issues that have arisen while developing the draft ABS Law are the following:

- *Providers and the role of intermediaries*: Studies show that industries invariably access genetic resources through intermediaries. The draft law therefore takes into account the role of intermediaries in providing genetic resources.
- *Indigenous and Local Communities (ILCs)*: Development of 'protocols' after consultation with ILCs. Traditional knowledge must be accessed with the consent of all the communities holding the knowledge.
- *Researchers and simplified procedures for non-commercial research*: PIC and MAT procedures are in some cases impracticable. The current draft law is therefore to address the seamless movement of information from basic research to commercial use and the multiple exchanges of information between institutions and scientists.
- *Benefit-sharing*: Benefits will be shared with ILCs that have provided resources and associated traditional knowledge through a trust fund. The question currently under consideration is how to value genetic resources and associated traditional knowledge to be able to assess what is equitable and fair in terms of benefit-sharing?
- *Ex-situ collections*: The draft law covers *ex-situ* collections wherever they are located.
- *Genetic resources for food and agriculture*: The question currently under consideration is how to deal with the genetic resources that are not covered by the multilateral system under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and be consistent with the Nagoya Protocol.

Ethiopian Experience

Ethiopia's ABS regulatory framework was established before the adoption of the Nagoya Protocol. The ABS legislation includes three main principles. First, foreign researchers or applicants have to provide a letter of support from the relevant competent authority of their country. Second, access to genetic resources and associated traditional knowledge requires the PIC and the establishment of MAT with

concerned people or ILCs who hold the resource and/or associated traditional knowledge. Third, the exchange of genetic resources between ILCs is allowed. Negotiations for benefit-sharing between the competent national authority and the user take place after PIC has been obtained. The benefits negotiated include:

- Monetary benefits i.e. up-front payments, licence fees and royalties. The amount of the benefits differs according to the specifics/provisions of the contract agreement on a case by case basis;
- The benefits obtained from the company in relation to the use of genetic resources are shared between the State and the community. Fifty per cent of the money obtained is used for a project designed for conservation and sustainable use of biological diversity. The other fifty per cent goes to the community for development projects;
- The total monetary benefits obtained from access of traditional knowledge will go to the community custodian of the knowledge for community projects; and
- All money obtained from access to genetic resources and/or associated traditional knowledge is deposited in a special account called Access Fund and managed by the Access Fund Administration Committee established by the Ethiopian Institute of Biodiversity. The money is therefore not distributed to individuals.

Brazilian Experience

The 13 year old Brazilian ABS legal framework has provided a valuable leaning experience that overly bureaucratic requirements can be a disincentive for research and development and the generation of benefits from the use of biological diversity. To address the limitations of the current legislation and support benefit-sharing, Brazil initiated a complete reform of its ABS legislative framework. The new regulatory framework would, among others, encourage research and development, enable collaborative technology innovation, protect and enhance ILCs rights, focus on traceability and put in place a fair and easy way to operate the benefit-sharing regime. Furthermore, the new regime would minimise transaction costs for all parties while keeping the legal framework flexible enough so that revisions can be made where necessary. By simplifying procedures for access and MAT as well as ending private ownership of genetic resources, Brazil hopes to stimulate ABS related industries and economic development through innovative benefit-sharing agreements while at the same time promoting the conservation and sustainable use of biodiversity. Innovative benefit-sharing measures in the new draft ABS legislation include:

- Clarity regarding who must be involved in and decide on monetary or non-monetary benefit-sharing through sector-specific agreements;
- Monetary benefit-sharing through a soon to be established Benefit-Sharing Fund;
- The promotion of non-monetary benefit-sharing to users of genetic resources through an incentive system directed at the different industries users of genetic resources;
- Any monetary benefits arising from the use of traditional knowledge of non-identified origin are to be channelled through the Benefit-Sharing Fund;
- Any monetary benefits arising from the use of traditional knowledge of identified origin are to be directly and freely negotiated with at least one ILC holding that knowledge. Moreover, the user has to pay an extra percentage to the fund, that will channel the benefits to other ILCs holding the same knowledge; and
- A Benefit-Sharing Fund managed by the Federal Government and used for the implementation of the national benefit-sharing programme, biodiversity conservation and sustainable use projects. Benefits arising from the use of traditional knowledge will be exclusively used to

support ILCs in relation to any project on traditional knowledge. ILCs will directly participate in the decision-making of funds arising from the use of traditional knowledge.

Group Work

Participants were divided into 8 groups and invited to reflect on different aspects of benefit-sharing. Some highlights of the discussions are provided in the boxes below.

Who has the responsibility to share benefits along the value chain? What is the role of intermediaries?

(i) To establish the responsibility to share benefits, it is necessary to identify the relevant parties/persons in the value chain. This is often not possible since the resources are usually transferred many times along the value chain and the final user, through which a product is commercialised, may not be able to trace back the origin of a genetic resources used in the development of a product.

(ii) The role of intermediaries in the value chain differs considerably from case to case. It is difficult to ensure that intermediaries in the value chain share benefits as they are not always aware of the source of the genetic resources. Intermediaries may be traders who are not engaged in research and development. The value of the genetic resources and associated traditional knowledge is typically amplified by the time the final product is manufactured and marketed and so, ideally, the final producer should be largely responsible for sharing benefits with the providers of genetic resources and associated traditional knowledge. These manufacturers operate beyond the jurisdiction of the provider country in many instances, and the products are based on the genetic resources of other nations, often bio-resources sold to them as commodities.

(iii) Voluntary disclosure of genetic resources used for making the product, including their origin, to be included in the regulations.

(iv) The establishment of a biodiversity tax (1% of the profit) by companies to government and national/local biodiversity management authorities should be considered. The tax thus collected could be used for biodiversity restoration, conservation and to increase/improve livelihood of communities who protect biodiversity.

(v) National governments should share benefits of biodiversity more widely. Although a vast majority of nations have ratified the CBD over the past 20 years, some felt that Parties who have collected revenues from the biodiversity value-adding chain have not shared those benefits equitably with the providers of genetic resources and holders of traditional knowledge. The suggestion is that based on the extent of the biotrade/bioprospecting sector, monetary benefits should return to the providers of genetic resources, the holders of traditional knowledge and biodiversity conservation.

What types of benefit-sharing mechanisms are being considered (e.g. trust funds and what is the role of governments in establishing trust funds?)?

(i) Some suggested that non-monetary benefits should be preferred.

(ii) Where monetary benefits are agreed based on MAT, benefits should go to a national fund. The bulk of this fund up to 95% should go to benefit claimers directly where identified or to communities of the area from where the bio-resources have been sourced.

(iii) If monetary benefits, a State Biodiversity Board or similar entity should provide technical guidance and assistance.

With whom should the benefits be shared?

It is recommended that this question be approached this question by looking at two different aspects:

(i) Genetic resources accessed

a) Where a genetic resource is accessed, the benefits should flow to the provider of the resource.
b) Some percentage could be apportioned / allocated to conservation and sustainable use of biological diversity and managed by the State.

(ii) Associated traditional knowledge accessed.

a) Where the ILCs or individual(s) holders of traditional knowledge are identifiable, benefits should be shared with the identified ILCs or individual(s) – it could be more than one community/individual. There is an obligation on the applicant to carry out due diligence to ascertain whether associated traditional knowledge is also held by any other ILCs/individual(s). It is usually not practicable to identify all the traditional knowledge holders.
b) Where the ILCs or individual(s) holders of traditional knowledge are identifiable, PIC must be established with those ILCs or individual(s). Benefits must be shared with those ILCs or individual(s) only.
c) If no traditional knowledge holders can be identified or this specific traditional knowledge is widely spread, benefit-sharing should go to a fund managed by the State. Benefits have to be used for ILCs development projects and related conservation and sustainable use purposes.
d) If after PIC and MAT had been established, an ILC makes a claim that it also holds the same associated traditional knowledge, then a dispute resolution mechanism is triggered.
e) If the claimant ILC succeeds, they will enter in the benefits agreement established with the applicant.

When should the benefits be shared and what is fair and equitable (e.g. how is the amount of benefits established, should governments establish the level of % of benefit-sharing or should they be established in MAT/contract)?
(i) When should the benefits be shared? a) Milestones payments to communities / country of origin b) Time of signing the MAT c) Commercialisation of the end product placed on the market (ii) What is fair and equitable? a) Exchange of information and building the knowledge base b) Negotiate on sector specifics c) Involvement of the relevant stakeholders, including legal support for the communities d) Partnerships on product development e) Ministry approval of the benefit-sharing agreement to ensure that ILCs get a fair and equitable sharing of benefits where relevant f) Benefit-sharing – product specific g) State Board to facilitate the benefit-sharing negotiation.

Open Plenary Discussion

A number of issues were raised, including the following:

- *Information sharing:* Defining what is fair and equitable in terms of benefit-sharing is often difficult. For example, the draft AU Guidelines encourages African countries to share information that could help in determining what is fair and equitable.
- *Developing guidelines*: Clear guidelines on benefit-sharing alongside national legislation can assist in MAT negotiations.
- *Non-monetary benefits*: Improving technology in provider countries is essential. Therefore, in addition to monetary benefits arising from end products, it is crucial that benefit-sharing includes non-monetary benefits such as technology transfer during the bioprospecting and the research and development phases.
- *Understanding the value chain & business models*: Understanding where the value is added along the value chain and understanding business models is critical to establish benefit-sharing.
- *Genetic resources sourced from commodities*: Genetic resources may be sourced from commodities. However, ABS agreements are not always negotiated for such genetic resources. It is often unclear when activities cease to be sale of commodities and become utilisation of genetic resources. There is therefore no clarity on how this situation should be addressed.
- *Intermediaries*: It was stressed by some participants that access through intermediaries should be regulated in national law. Any user (individual or institution) that accesses genetic resources directly or through intermediaries must abide by the law of the country of origin. It was therefore suggested that rules about access to *ex situ* collections should be included in national law.

- *Awareness-raising:* It was suggested that application for commercial access should be published in an official gazette and/or in the media so that the public is aware of it.
- *Inefficiency of measures that are too bureaucratic and burdensome*: Learning from past experiences, and in order to stimulate innovation, some countries advocate simplified ABS measures for benefit-sharing. This includes establishing MAT and negotiating monetary benefits only once the end-product has reached the market.
- *Duration of benefit-sharing*: It was suggested that the duration of benefit-sharing should last as long as the end product is on the market. An inclusion of a provision for any cancellation of an ABS agreement is desirable.
- *Trust funds*: The use of trust funds was seen by many as a good solution to channel any financial benefits arising from the utilisation of genetic resources and associated traditional knowledge.

Compliance and Monitoring

Introduction

The objective of this session was to discuss how to address the implementation of the compliance and monitoring obligations of the Nagoya Protocol. As for the previous sessions, a short presentation provided a brief introductory overview of compliance related provisions included in the Nagoya Protocol in articles 15, 16, 17 and 18.

Development on an Internationally Recognised Certificate of Compliance

This presentation provided by the Secretariat of the CBD gave a detailed overview of developments regarding the establishment of the ABS Clearing-House. According to Article 14 of the Nagoya Protocol, this mechanism shall serve as a means for sharing information related to ABS. In particular, it shall provide access to information made available by each Party relevant to the implementation of the Protocol. The ABS Clearing-House Mechanism therefore aims at facilitating the use of common format to standardise information, the sharing of correct and relevant information and the monitoring of the utilisation of genetic resources. The presentation also elaborated on the main role of the internationally recognised certificate of compliance (IRCC) which is to provide evidence that genetic resource were acquired in accordance with PIC and MAT. The ABS Clearing-House will be fully operational and launched on 13th of October at COP-MOP 1, at which time modalities of implementation of the ABS Clearing-House will be further discussed.

Country Examples

Norwegian Experience: Status of Compliance and User Country Measures

In Norway, genetic resources are considered as a common resource belonging to Norwegian society as a whole. The state has therefore the responsibility to manage these resources on behalf of the people. The view is that genetic resources shall be utilised to the greatest possible benefit of the environment and human beings in both a national and an international context, also attaching importance to appropriate measures for sharing the benefits arising out of the utilisation of genetic material and in such a way as to safeguard the interests of indigenous peoples and local communities. The distinct feature of the Norwegian ABS law is that it contains conditions for import to ensure that users of genetic material in Norway comply with national regulations of provider countries. In the Nature Diversity Act, there is an obligation to disclose

the country of origin or the country from where the material is collected. If the provider country is a country other than the country of origin of the genetic material, the country of origin shall also be stated. In the Patents Act there are disclosure requirements regarding the country of origin/providing country, traditional knowledge and whether prior informed consent has been sought. The Act relating to the Plant Breeders Right has disclosure requirements similar to the Patents Act. When genetic material covered by the ITPGRFA is utilised in Norway for research or commercial purposes, it shall be accompanied by information to the effect that the material has been acquired in accordance with the Standard Material Transfer Agreement established under the treaty. Users in Norway have the obligation to follow the ABS legislative requirements of provider countries. However, this also means that provider country regulations should be simple, clear, efficient and user friendly in order for Norway to enforce them. Cooperation between providers and users is therefore viewed as essential. The legislation provides for a combination of monitoring measures such as control/inspection, investigation or duty to provide information; soft measures such as advisory services, guidance, information, notice of duty to comply or legal action and hard measures such as punitive or administrative measures. Regulations on user country measures regarding traditional knowledge associated with genetic material are currently being developed to fulfil the obligation under Article 5.5, 7 and 16 of the Nagoya Protocol. The Government is working on the designation of check points under Article 17.

Swiss Experience: Implementation of the Nagoya Protocol

Switzerland has a large number of biotech companies which use and/or supply genetic resources or trade commodities. This includes different types of access from provider countries, third party transfer, intermediaries or suppliers resulting in a lot of exchanges of genetic resources and the development of complex value chains. User measures aim to address to the different phases of this complex biotech value chain. Switzerland has amended its legislation (Federal Act on the Protection of Nature and Cultural Heritage) to align it to the Nagoya Protocol. Previous ABS measures were mainly based on the Bonn Guidelines and included disclosure of the source of genetic resources and traditional knowledge in patent applications (Federal Act on Patents for Inventions) and relevant measures to address the various obligations of the ITPGRFA. New ABS measures include (i) a due diligence obligation to ensure that access to genetic resources took place in accordance with ABS regulatory requirements of the provider countries and that MAT have been established, (ii) a notification obligation as compliance with the due diligence obligation must be notified to a centralised checkpoint (Federal Office for the Environment) by the time of market authorisation or commercialisation of products developed on the basis of utilised genetic resources, (iii) the possibility to transfer information to both the provider countries and the ABS Clearing-House, (iv) the possibility to regulate access to national genetic resources and to support their conservation and sustainable use and, (v) sanctions and administrative measures for non-compliance. These measures will only be applied at the entry into force of the Nagoya Protocol and will not be retroactive. They will also apply to traditional knowledge associated with genetic resources and only to Parties to the Nagoya Protocol. Further work still needs to be done such as, among others, developing and implementing regulation, updating the national ABS Clearing-House, raising awareness and developing

explanatory guidelines. The key challenge for further implementation of ABS user measures is to ensure the flow of relevant information throughout the biotech value chain and between users and providers of genetic resources and associated traditional knowledge without developing highly bureaucratic regulations.

Regional Experience: The Draft African Union Guidelines for a Coordinated Implementation of the Nagoya Protocol

The general approach taken by the draft AU Guidelines is to encourage cooperation across the region, to safeguard and enforce both the sovereign rights of States and ILCs rights. The draft Guidelines also clarify that PIC is required unless explicitly waived. More specifically, they make it easy to comply but make the consequences of non-compliance sufficiently onerous to be a serious deterrent. Overall, these Guidelines aim to strengthen the capacity of its member states in dealing with ABS. The ultimate aim is to change user behaviour. Among others, the draft AU Guidelines:

- Provide for information and reporting provisions to be included in MAT;
- Encourage information-sharing between national focal points, checkpoints, peers to peers and with AU database/clearing-house;
- Propose to blacklist non-compliant users in all African countries;
- Provide that access should be granted only to users domiciled in Parties to the Nagoya Protocol with adequate compliance measures in place;
- Prevent national actors and intermediaries from being used to circumvent PIC and MAT;
- Focus on access for utilisation and stipulate that PIC should also be required for utilisation of resources obtained from *ex situ* collections;
- Prohibit third party transfer if transfer of obligations/requirements are not complied with;
- Include a level of flexibility by adopting an "evolving "partnership" approach and establish agreement principles in initial MAT, including reservation of all rights when the transfer of genetic resources is not explicitly agreed. MAT is therefore regarded as a series of agreements;
- Require the disclosure of origin/source in all patents and intellectual property applications to be included in MAT;
- Stipulate that everything that is not explicitly agreed and permitted is prohibited;
- Provide for the option of using established African dispute resolution mechanism; and
- Provide for access to justice.

Group Work

Participants were divided into 4 groups and asked to put themselves in the shoes of a user country and discuss the following:

1) Measures:
   What would you do to ensure that researchers and companies in your country (be they domestic or foreign) respect ABS requirements of other countries where they have accessed genetic resources and any associated traditional knowledge? Measures can go from awareness raining up to legal measures to ensure compliance.

2) Checkpoints:
   a) Which institutions would you consider useful to establish as checkpoints in your country?

b) Which of the identified institutions would you prioritise to make the system work in practice?

Group A

Measures	Checkpoints
• Measures to prohibit the use of genetic resources and associated traditional knowledge unless PIC and MAT have been obtained. • When measures do not prohibit the use of genetic resources and associated traditional knowledge unless PIC and have been obtained, measures to impose a list of requirements that users must comply with such as due diligence obligations. • National legislation should encourage cooperation only with Parties to the Nagoya Protocol. In case of Non-Party, ensure that PIC and MAT have been obtained whether the provider country does or does not have an ABS law in place. • Sanctions could be put in place for non-compliance.	• Establish a central system linked to the Competent National Authority to verify if PIC and MAT have been obtained and which information will be provided to the provider country. • The process must involve patent offices, product approval bodies and those granting research funding. • The issuance of a permit is an additional checkpoint that can assist with ensuring compliance. • Develop a standardised permit which will become an internationally recognised certificate of compliance to facilitate the work done by the Secretariat of the CBD in relation to the ABS Clearing-House (strengthen the role of the ABS Clearing-House).

Group B

Measures	Checkpoints
ABS is a complex and challenging issue that requires implementing measures for: • Continued awareness • Capacity building • Education • Training • Networking of National Focal Points • Commodities used as genetic resources (with a certification for the purpose of import) • Strengthening existing ABS legal system • Harmonisation of ABS and other legal systems such as the ITPGRFA.	• Understand the role of checkpoint is essential – how could they be useful: certification? Documentation? Etc.? • Where: customs (sea, air, postal); registration of medical products (medical and pharmaceutical registries); patent offices, national ethic committees and other various checkpoints for microbes, plants, animals and agriculture. • Encourage national Focal Points interaction to exchange information and help the interpretation of compliance measures • Priorities: customs, patent office, registration of medical products and national ethic committees.

Group C

Measures	Checkpoints (and other measures to monitor compliance)
• Outlaw biopiracy – national user legislation provisions to include that ABS legislation of the provider country must be complied with. • To encourage compliance through capacity building and awareness-raising for stakeholders (e.g. academia) and research ethics. • To enforce compliance through penalties and sanctions, opportunity to remedy – loss of access, no publication, withdraw intellectual property license to operate, fines and imprisonment for persistent offenders.	• Checkpoint is one of the mechanisms to measure compliance. • Where (national, sub-national and local levels): National Focal Points and National Competent Authorities, research funding organisations, universities, research development organisations, academic publishers, sanitary and phyto-sanitary authorities, automated web searches, information exchange between National Competent Authorities, marketing and standards bodies, customs, custom declaration and searches (capacity building programmes for customs); crop and breed registration bodies, export permit offices, Intellectual Property offices, bilateral agreements (TRIPS+) should insist on compliance. • Priorities: National Focal Points and National Competent Authorities and Intellectual Property offices.

Group D

Measures	Checkpoints
• Clear regulation • Strong enforcement measures • Strong cooperation between countries • Exchange of information • ABS requirements as a prerequisite for funding research	• Patent offices • Customs • Plant breeders office • Public and private research institutions • Government offices • Food and Drug Administration or similar • Research councils

Open Plenary Discussion

The following highlights some key issues discussed by the participants:

- *Due diligence obligation*: A due diligence obligation is one approach to address Article 15 of the Nagoya Protocol. Some participants highlighted that it is a cost effective way to make users compliant. However, critics believe that an effective ABS system should go beyond due diligence to make sure that users are strictly compliant.

- *Retroactivity*: While many are of the view that new utilisations of genetic resources must not be allowed without a due process and the establishment of a new PIC and MAT, some countries have decided not to include such a provision in their national legislation.
- *Protecting the rights of providers in the user country*: Some participants pointed out that the adoption of measures in national legislation imposing an obligation on nationals to respect measures from other countries may be difficult to implement.
- *Dealing with non-parties or absence of ABS legislation:* Different scenarios can be visualised. For example, a situation where neither the provider country nor the user country is a party to the Nagoya Protocol; the absence of any ABS legislation in provider or user countries parties to the Protocol; a situation where one country is party to the CBD but not to the Nagoya Protocol, etc. The absence of an ABS system does not mean that resources can be accessed freely. Indeed, in the absence of any specific ABS legislation in provider countries, requirements relevant to access may be identified in various existing laws of the provider countries. Users will then have to comply with the procedures included in these different laws. The absence of legislation could also be overcome through the establishment of contracts. If some countries are not Parties to the Nagoya Protocol but are Parties to the CBD, they are committed to the ABS obligations of the CBD. Finally, it was suggested that countries could also refuse to issue a permit when the applicant is from a country that does not have compliance measures in place.
- *Managing checkpoints:* It was suggested that a checkpoint structure composed of one main checkpoint and sub-checkpoints could be an effective way to monitor the movement and use of genetic resources and associated traditional knowledge. Considering that border controls are already difficult to handle, establishing too many checkpoints could be difficult to manage, especially in terms of capacity building. Planning more awareness-raising and capacity building for check points was therefore considered a good investment to make.

Way Forward and Conclusion

This last session focussed on identifying priority issues for consideration in a future dialogue in order to achieve a coherent approach to the implementation of the Nagoya Protocol. Participants suggested the following:

- *Increase opportunities for South-South Dialogue*: Such dialogues support ABS in developing countries through exchange of experience, capacity, expertise, technology or information on a variety of issues.
- *Exchange of experience on specific issues*: Further in depth discussions on critical issues could support the implementation of the Nagoya Protocol. These issues include: compliance and monitoring, negotiation of ABS contractual agreements, access to *ex situ* collections, traditional knowledge, transboundary issues and benefit-sharing.
- *Include more countries*: A wider representation of countries in future dialogues could play a constructive role in developing effective ABS systems and strengthen cooperation between developed and developing countries.
- *Increase the involvement of users in these dialogues*: i.e. private sector, public or private research institutions, academia, intermediaries and bio-traders. Perspectives from users may assist in developing practical ABS legislation and vice versa and lead to fruitful partnerships contributing to development.

- *Invite ILCs and more members of government agencies to participate in dialogue*: Raising awareness of relevant government agencies/departments could be beneficial in finding some solutions to facilitate ABS national processes and make ABS systems more effective.
- *Use practical examples of ABS national implementation and concrete ABS case studies*: Strengths and weaknesses of existing ABS models and agreements, good or bad, could be analysed and discussed during dialogues and assist in the development of good practices and practical guidelines. It was suggested that participants could be invited to present actual case studies.
- *Explore new topics that are relevant to the national implementation of the Nagoya Protocol and the harmonisation of other international processes with the implementation of the Protocol*: For example, access to marine genetic resources in areas within national jurisdiction, access to genetic information, understanding the role of intermediaries/bio-traders and how to map out a country's bio-economy, the interface with the ITPGRFFA and the potential linkages with a potential new regime for marine genetic resources in areas beyond national jurisdiction and Antarctica.
- *Develop guidelines or manuals on different topics addressing different steps of ABS national implementation*: Topics suggested were, among others, criteria and processes for obtaining PIC, establishing MAT and negotiating benefit-sharing, understanding value chains, and establishing check-points.

Closure

Presentations

The full list of presentations made during the workshop is available here for download.

Day 1

Background and Key Outcomes of the First Dialogue on Practical Ways Forward for the Implementation of the Nagoya Protocol – Valérie Normand, ABS Capacity Development Initiative

Brazil - What Has Been Done to Implement the Nagoya Protocol? – Henry de Novion, Minitério do Meio Ambiente

ABS Mechanism in India: Preparing for Implementation of Nagoya Protocol – Hem Pande, Ministry of Environment, Forests and Climate Change

South Africa Approaches to Implement the Nagoya Protocol on ABS – Lactitia Tshitwamulomoni, Department of Environmental Affairs

Nagoya Protocol Provisions related to Access – Valérie Normand, ABS Capacity Development Initiative

Day 2

Nagoya Protocol Provisions related to Benefit-Sharing – Valérie Normand, ABS Capacity Development Initiative

National Benefit-Sharing Approach Adopted by Ethiopia in Relation to the Implementation of the Nagoya Protocol – Zeleke Ottoro W Tenssayat (PhD), Ethiopian Institute of Biodiversity

Brazil – Examples of National Benefit-Sharing Approaches – Henry de Novion, Ministério do Meio Ambiente

Nagoya Protocol Provisions on Compliance and Monitoring – Valérie Normand, ABS Capacity Development Initiative

The Access and Benefit-Sharing Clearing-House – Sarat Babu Gidda, Secretariat of the Convention on Biological Diversity

ABS Clearing-House Theatre – Sarat Babu Gidda, Secretariat of the Convention on Biological Diversity

Status on Compliance/User Country Measures in the 2009 Nature Diversity Act – Gaute Voigt-Hanssen, Royal Norwegian Ministry of Climate and Environment

The Implementation of the Nagoya Protocol in Switzerland – Marco d'Alessandro, Nagoya Protocol National Focal Point.

Annotated Agenda

Monday, 4 August

Time	Agenda
08.30	Registration
09.00	**Introduction to the Workshop**
	• Welcoming remarks from: Indo-German Biodiversity Programme National Biodiversity Authority • Brief overview of outcomes of the first dialogue (January 2014, Cape Town) • Objectives and agenda of this second dialogue • Getting to know each other
10.00	Official Opening by Minister of Environment, Forests and Climate Change, India
11.00	Coffee
11.30	**I. National Approaches to Implement the Nagoya Protocol**
	"What has been done to implement the Nagoya Protocol?" Panel discussion with Brazil, India, South Africa
13.00	Lunch
14.30	**II. Access**
	Overview of related provisions of the Nagoya Protocol
	"How to develop simple, clear, efficient and user-friendly national systems to foster innovation?" • Panel discussion with representatives from Kenya, Nepal, Indonesia, Mexico and the African Union <u>Indicative issues for discussion:</u> • What will national ABS legislation/regulations apply to? • How to address access to genetic information? • Procedures established for access for research vs. access for commercialisation purposes • From whom are genetic resources generally accessed (e.g. in situ, ex situ) and how is this addressed by national regulations? • Criteria/processes for obtaining the PIC of indigenous and local communities for access to genetic resources and/or traditional knowledge
16.00	Coffee
16.30	Exchange between panel and plenary
18.00	End

Tuesday, 5 August

Time	Agenda
08.30	**III. Benefit-Sharing**
	Overview of related provisions of the Nagoya Protocol
	Examples of national benefit sharing approaches • Brief introductory presentations by representatives from Brazil, Malaysia and Ethiopia
10.00	***"How to address benefit-sharing in practice?"*** • Exchange of experiences and views: group work <u>Indicative issues for discussion</u>: • Who has the responsibility to share benefits along the value chain? What is the role of intermediaries? • What types of benefit-sharing mechanisms are being considered (e.g. trust funds)? • With whom should the benefits be shared? • When should the benefits be shared and what is fair and equitable (e.g. how is the amount of benefits established)?
10.45	Coffee
11.15	• Group work continued • Report back to plenary
13.00	Lunch
14.30	**IV. Compliance and Monitoring**
	Overview of related provisions of the Nagoya Protocol
	Developments on an internationally recognised certificate of compliance • SCBD
	Examples of national legislation / regulations • Country examples: Norway, Switzerland • Regional example: African Union Guidelines
16.00	Coffee
16.30	Questions, answers and discussion • Panel with country / regional representatives
18.00	End

Wednesday, 6 August

Time	Agenda
08.30	**IV. Compliance and Monitoring (continued)**
	Introduction to group work
	"Addressing the challenges of compliance" • Exchange of experiences and views: group work <u>Indicative issues for discussion:</u> • What are different policy options for implementing articles 15-16-17 of the Nagoya Protocol on compliance? • What do compliance measures cover? • How to harmonise systems for issuing permits and monitoring the use of genetic resources? • Who has the responsibility for compliance in the value chain? What is the role of intermediaries?
10.30	Coffee
11.00	• Report back • Summary and conclusions from group results
12.30	Lunch
14.00	**V. Issues for Further Consideration**
	Identification of remaining issues for further consideration in order to achieve a coherent approach to implementation
15.00	**VI. Concluding Session**
	• Summary and next steps • Evaluation • Closing remarks
15.30	**End**

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Government of India

National Biodiversity Authority
Government of India

Indo-German Biodiversity Programme
GIZ India

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