

## **Meeting Report**

### **Brainstorming Session on “Developing Benefit Sharing Guidelines for Implementation on National Biodiversity Act and Rules”**

**19<sup>th</sup> December, 2007, New Delhi**

India's Biological Diversity Act, 2002 inter alia provides for the development of appropriate guidelines to ensure fair and equitable sharing of benefits arising from the use of bioresources. In the light of the global development and discussions on Access and Benefit Sharing (ABS), it is pertinent for provider countries rich in genetic resources such as India which already have legislation on ABS in place to develop guidelines that are sensitive to the genuine concerns of stakeholders. Given the current debates on the development of an international regime on ABS, the development of such guidelines is of relevance to the international processes also.

With this background, United Nations University – Institute of Advanced Studies (UNU-IAS) and the Ministry of Environment and Forests, Govt. of India co-organized a “Brainstorming Session” in collaboration with the National Biodiversity Authority (NBA) of India, to identify the elements of benefit sharing guidelines to be developed under the Biological Diversity Act, 2002. Various stakeholders representing government, policy makers, scientists, researchers, academicians, industries and civil society participated in the discussion.

The inaugural session was presided over by Mr.B.S.Parsheera, Additional Secretary, MoEF. Mr.G.Balachandhran, Joint Secretary, MoEF welcomed the gathering, followed by remarks by Dr.S.Kannaiyan, Chairman, NBA and Dr.Balakrishna Pisupati, UNEP. Mr.Parsheera in his presidential remarks called upon the participants to deliberate on the elements in order to have a framework for development towards the end of the meeting. Dr.Kannaiyan emphasized the sustainable use and conservation of genetic resources and outlined the provisions on ABS in Biodiversity Act, 2002 and Biodiversity Rules, 2004 and highlighted the national importance of developing the guidelines. Dr. Balakrishna Pisupati, UNEP, highlighted the international significance of the guidelines. Dr.K.Venkataraman, Member Secretary of NBA, proposed the vote of thanks at the end of inaugural session.

The meeting was divided into two sessions- the first comprised of presentations by speakers on various elements related to benefit sharing and the second was a roundtable brainstorming session on the principles and elements for the guidelines.

#### **Session 1**

The first session was chaired by Mr.G.Balachandhran, Joint Secretary, MoEF. Dr.Balakrishna Pisupati made the first presentation entitled '*Benefit Sharing: Issues, Options and Experiences*', in which he highlighted the importance of having a balanced policy on benefit sharing that gives due representation to the concerns of both users and providers. While sharing benefits, it is important to identify and define institutions through which benefits shall be routed and monitored. Type, timing, extent of benefits, and different sectors that need to be involved in the process may also be identified.

This was followed by a presentation by Dr. Biswajit Dhar entitled '*Reconciling the Agreement on TRIPS and the CBD*', in which he drew attention to the need to use the WTO Agreement on TRIPS as the machinery to counter misappropriations and ensure transparency in ABS processes. This is sought to be accomplished by amending or reaching an understanding within the TRIPS Agreement to include disclosure of country of origin/ source of genetic resource and/or traditional knowledge as a requirement while filing a patent application, in addition to providing evidence of having complied with national legislation of source countries including prior informed consent certificates. He added that while provider countries have asked for patent revocation in case of non-compliance or wrongful representation, countries such as Norway recommend that action should be taken outside the patent system. In addition, countries like Japan propose the development and adoption of a World Intellectual Property Organization (WIPO) based searchable database to establish prior art, he said.

Thereafter, Dr.V.K.Gupta highlighted the developments on protection of traditional knowledge (TK) within the WIPO system in his presentation entitled '*Updates on benefit sharing issues and other international instruments and agreements -WIPO*'. Apart from the Intergovernmental Committee on Genetic Resources, TK and Folklore that deliberates on measures to protect TK, WIPO also plays a role in the development of databases on TK to be included within the International Patent Classification (IPC) system. WIPO has enhanced its patent search capacity, and is in the process of enhancing its online portal for TK registries and databases. It has also increased the number of minimum periodicals searched for information on prior art. He concluded that to undertake effective benefit sharing it is essential to document and identify owners of knowledge who are associated with the access issue.

At the end of the session, Dr.K.Venkataraman, Member Secretary, NBA made a presentation entitled '*National Biodiversity Authority and Benefit Sharing- Provisions and Issues*' through which he highlighted the provisions within the Biological Diversity Act, 2002 and the Rules,2004 of India on benefit sharing. He said that the NBA is in the process of developing guidelines for which it needs to address various issues including scope, type, timing, volume of benefits and institutional procedures for routing them. He also raised the challenges faced by the NBA during scrutiny and approval of applications such as genetic resources being obtained from markets; question of extent of value addition that can be done to qualify for exemptions; difficulty in fixing extent of benefits to be shared when the genetic resources (GRs) form less than 2-3% of the total product.

Discussions in the morning session saw the participants raising concerns about how to identify beneficiaries, how should research products be handled, how to define what constitutes a fully Indian company and foreign entity, the adequacy of definitions within the law now, how to ensure payment of benefits and the necessity for the NBA to have stronger ties with patent offices.

Dr.Suneetha Subramanian, UNU-IAS, then summarized the discussions in her presentation entitled '*Applying Benefit Sharing Principles to India's National Biodiversity Act*'. She highlighted the various topics that need to be addressed while developing the guidelines. The topics were arranged thematically under Ownership over GRs and/or TK, by-products, benefit sharing, third party transfers and intellectual property rights.

## **Session 2**

In the afternoon the participants conducted a brainstorming exercise to identify areas within the guidelines that require definitions/elaboration; the principles within which the benefit sharing guidelines need to be developed; links to other processes that need to be considered while framing the guidelines and finally elements that should be included in the design of the BS guidelines.

The following is a set of points that emerged for further consideration and elaboration by the National Biodiversity Authority(NBA) for framing national benefit sharing guidelines.

### **1. Issues requiring definition/ elaboration within the Biological Diversity Act, 2002.**

1. Ownership
2. Derivatives
3. Synthetics/ Analogues
4. By-products – Unmodified and Modified
5. Humanitarian goods
6. Royalties (upfront, milestones, etc)
7. Research tools
8. Database
9. Value added products, including extracts
10. Exemptions
11. Third party transfers
12. Normally traded commodities
13. Company (India, non-India)- to reflect on Section 3 and 4- could use the Indian Companies Act as a reference
14. Forest species
15. Research use
16. Cultivated Vs Wild species (to involve State Biodiversity Boards and get in touch with different sectors for details)

17. Intellectual Property- Joint Ownership
18. Exemption to value added products, with respect to extracts/ derivatives (active ingredients to be defined- requires sector specific definition and to be designed for cases within and outside of India).

## **2. The principles of benefit sharing shall be based on:**

1. Prior Informed Consent (PIC)
2. Material Transfer Agreement (MTA)
3. Mutually Agreed Terms (MAT)
4. Traditional Knowledge + Genetic Resources
5. Fair and Equitable Sharing of Benefits
6. Local Development (Socio-economic)
7. Sustainable Use
8. Conservation
9. Source Country
10. Commercial Use
11. R&D
12. Case by case basis

Participants commented that each of the above form the principle for benefit sharing and further elaboration is needed on these that reflect the philosophy of ABS.

## **3. Links to other Processes**

While the participants agreed that Biological Diversity Act, 2002 forms the umbrella legislation to deal with ABS issues, they also opined that development of benefit sharing guidelines needs to consider discussions and developments under other related processes. Some of these national and international processes include:

1. Plant Variety Protection and Farmers' Rights Act, 2001
2. The Patent (Amendments) Act, 2002
3. The Geographical Indications of Goods (Registration and Protection) Act, 1999
4. The Seeds Act, 2004
5. Plant Quarantine Order, 2003
6. Discussions and decisions within WTO, WIPO, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), United Nations Convention on the Law of the Seas (UNCLOS), CBD and related multilateral processes
7. Other countries experiences and guidelines on benefit sharing

## **4. Designing BS Guidelines**

Participants deliberated on the elements of benefit sharing guidelines and came up with the following elements:

1. Benefits (define)
2. Who are the beneficiaries?
3. Who pays?
  - manufacturer
  - person invoicing the product
  - applicant
  - 3<sup>rd</sup> party transfer licensee-( a repository of licenses to be maintained)
4. Options to ensure payment
  - Royalty cess
  - % on gross sales
  - Based on the patent and life cycle of product, benefit sharing model can be decided.
  - Type of product planned to be indicated in access application, which is to be provided for as check boxes
  - Preferential treatment for government organization, e.g. CSIR
  - Indication in access application
  - Monetary/ Non-monetary
  - Milestones/ Royalties for development work

## **5. Possible Models for BS**

Considering the available experience and information available within India and outside, the participants came up with some possible models for benefit sharing that can be the basis for further discussion before finalizing the benefit sharing guidelines.

1. Own commercialization
2. Technology out-licensing (sub-licensing)
3. Public sector spin offs
4. Nominal fee at time of access licensing (agreement). A pilot case could be conducted to develop a template through a BS model between CSIR and NBA and a prospective licensee
5. Open source development (public domain- no BS)

In his closing remarks, Prof. Kannaiyan expressed satisfaction regarding the outcome of the session towards developing the guidelines on benefit sharing. A timeline to develop the guidelines was chalked out as follows:

- UNU-IAS will develop the next draft of the benefit sharing guidelines paper by February 2008.
- Based on the paper and further elaborations on this report, a side event will be organized during the CoP-9 to the CBD in May 2008, wherein

India will be invited to be on the panel for sharing her experiences in implementation of the Act.

- During August 2008, a national workshop will be held that will deliberate on the models suggested by the participants that will form the basis for finalizing the benefit sharing guidelines by November 2008.
- Legal support for further development of the guidelines will be identified.