

### 3-2. ワークショップ「遺伝資源へのアクセスと利益配分の実施におけるインドの経験」

2007年12月17～18日、インド政府環境森林省（Ministry of Environment and Forests、MoEF）主催、国連大学高等研究所（UNU/IAS）及びJBA協賛によるワークショップ（Workshop on “India’s Experiences on Access to Genetic Resources and Benefit Sharing”）がインド・ニューデリー（クラリッジス・ホテル）において開催された。JBAから炭田精造、藪崎義康が出席した。以下に概要を報告する。なお、資料2にUNU/IASによる報告書を掲載した。

#### ■ オープニング

主催・協賛組織を代表して、A. H. Zakri氏（Director、UNU/IAS）、S. Kannaiyan氏（Chairman、NBA）、炭田、B. S. Parsheera氏（Additional Secretary、MoEF）からそれぞれ挨拶があった。

生物多様性条約・アクセスと利益配分（CBD・ABS）に関する国際交渉が硬直化している状況下、日本とインドの2国間会合は2006年12月東京でのJBAワークショップ以来、2度目となる。インドは2002年に生物多様性法を制定し、関連する規則の整備・NBA（National Biodiversity Authority、国家生物多様性局）の設置等により、CBDの実施を進めてきた。一方、日本にとってインドは南アジア圏に位置する貿易相手国で、接触を希望する企業も多いが、ABSに関する規制状況が必ずしも明確になっていない。今回のワークショップが両国間の情報交換・交流のみならず、ABS国際交渉を別とした2国間の関係強化に資することが期待される。

#### ■ セッション1（座長：R. S. Rana – Former Director, National Bureau of Plant Genetic Resources）

本セッションでは、CBD・ABSの実施に当たり、締約国会議やABS作業グループ、関連国際機関での議論等、国際的制度（IR）の要否をめぐる国際交渉の現状が紹介された。

##### 1. Access and Benefit Sharing of Genetic Resources – Issues and Challenges from a Global Perspective : A. H. Zakri (Director, UNU/IAS, Tokyo)

20世紀後半のバイオ革命勃興から説き起こし、CBD・ABSは生物資源をめぐる環境・貿易問題のホット・イシューとなっており、COP決議114項目のうち55がABSと何らかの関係がある。ABSに関しては、提供国側が求めるもの（アクセス認可権、最終産物にまで及ぶ利益配分、特許出願時の出所開示、PIC証明）と利用国側が示す懸念（金銭的利益の割合、バイオパイラシー非難、知的財産権、各国制度の法的曖昧さ）があることを指摘した。また、利害関係者により科学技術能力に差があること、利益に対する要件が各国で異なること、製品開発コストが産業セクターごとに異なること、国際的に共通したABS実施政策がないこと、深海・南極等の遺伝資源の扱い等にも言及した。最後に、ABS実施に対する各国・地域の能力構築、

利用国と提供国の議論の加速、関係者の政策・科学的理解の向上が重要であるとした。

## **2. The International Regime – An Overview : Balakrishna Pisupati (UNEP, Nairobi)**

2002年のWSSDでの決議に基づき、COP7で「アクセスと利益配分に関するIR」について交渉することが決定された以降のABSに関する国際交渉の進捗状況をレビューした。また、CBDにおけるABS(第15条)と関連して、伝統的知識(第8条j項)、他の国際機関(WIPO/IGC、WTO/TRIPs、FAO/ITPGRFA、UPOV、UNCLOS等)での議論を紹介した。UNEPはCBDの実施を担う機関であるが、COPからの委託、加盟国の協力が必要であるとした。

## **3. Implementing the ABS Provisions - Importance of the International Certificate : Biswajit Dhar (Centre for WTO Studies, Indian Institute of Foreign Trade, New Delhi)**

ABS-IRとの関連で議論されている認証について発表した。彼の意見では、特許出願時における遺伝資源・伝統的知識の原産国等の認証は、PICの存在を確認するための有効かつ透明性のある手段であるとした。

### **■ セッション2 (座長:S. Kannaiyan – Chairman, National Biodiversity Authority)**

本セッションでは、インド政府におけるCBDの実施に関して、生物多様性法及び関連した規則、また、NBAの役割について紹介された。NBAがチェンナイに存在し、中央政府と離れていることから、インド国内におけるCBD関連施策の関係省庁間の連携や一般普及がまだまだ不十分であるとの印象を受けた。

## **4. Historical Overview on Development of ABS Legislation and Protection of Traditional Knowledge in India : Sujata Arora (Additional Director, Ministry of Environment and Forests, New Delhi)**

1970年代における生物多様性の保全への関心の高まりからCBDの締結に至った経緯、CBD発効後のインドにおける条約実施の取り組み、特に生物多様性法(BDA、2002)、同規則(2004)の発効と他の関連法令(特許法改正、植物品種・農民権利保護法)に焦点を当てて概説した。改正特許法では遺伝資源・伝統的知識の出所開示を義務付けており、違反の場合には特許無効となる。植物品種・農民権利保護法(PVP&FR、2001)でも新品種開発に用いられる植物品種に対する利益配分を規定している。一方、BDA策定に至る課題として、国内産業における利用、研究開発と学術研究でのアクセス、輸出用コモディティの扱い等が議論された。また、BDAに基づくインド国内の行政体制(NBA:政府レベル、SBB:州レベル(State Biodiversity Board)、BMC:地域レベル(Biodiversity Management Committee))についても紹介した。

**5. Implementation of National Biodiversity Act and the Rules – Issues and Experiences :  
K. Venkataraman (Member Secretary, National Biodiversity Authority, Chennai)**

政府レベルの ABS 許認可機関である NBA から、BDA の概要及び主要条項、アクセス手続きの詳細が説明された。特に、国外からの遺伝資源アクセス、希少・絶滅危機資源の使用制限、共同研究に関する規則、一般貿易用コモディティー等について紹介された。

コモディティーについては、2007年11月23日開催の NBA 本部会合で、専門委員会 (Expert Committee on Normally Traded Commodities) 2007年10月10日会合の議事録が承認されており、ここにリスト化されている<sup>1</sup>。

**6. Links between Biodiversity Act and Plant Variety Protection Act : D. S. Raj Ganesh  
(Legal Adviser, Protection of Plant Variety and Farmers' Rights Authority, New Delhi)**

BDA と密接に関連する植物品種・農民権利保護法 (PVP&FR) について紹介した。PVP&FR でも利益配分を規定しており、両法は相補的關係にある。PVP&FR に基づくアクセス申請は BDA から除外される。

**■ セッション 3 (座長:P. Pushpangadan – Director General, Amity Institute for Herbal and Biotech Products Development)**

**7. Japan's ABS Guidelines and Experiences : Seizo Sumida (Director General, JBA, Tokyo)**

CBD 及び ABS に関するボン・ガイドライン実施・普及に関する日本政府 (経済産業省) の取組み、及び普及活動における JBA の役割・貢献について講演した。特に、利用者向け「異伝資源へのアクセス手引」の作成、相談窓口等の国内利用者に対する対応を紹介するとともに、2 国間の関係構築の重要性を強調した。

**8. Future Dimensions on ABS : Balakrishna Pisupati (UNEP, Nairobi)**

ABS に関する IR の国際交渉の状況、IR の目的、範囲、要素等、及び COP10 に至るまでの交渉プロセスを紹介した。

**9. V. K. Gupta (Head, IT Division, Council of Scientific and Industrial Research, New Delhi)**

遺伝資源と伝統的知識との関連について紹介し、不正使用は遺伝資源と伝統的知識の境界領域で起こりうることから、伝統的知識を保護する必要性を強調した。インド政府は伝統的知識

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<sup>1</sup> 資料編 (13) 参照。

を保護するために、CSIRにおいて「伝統的知識デジタル・ライブラリー」(TKDL)を作成し、各国へ提供している。インドはこのTKDLをデファクト標準とする。

■ セッション 4 (座長:A. H. Zakri – Director, UNU/IAS)

**10. Global Experience with ABS – Emerging Evidence from India and South Africa : Sachin Chaturvedi (Research and Information System for Developing Countries, New Delhi)**

ABSの事例として、インド・カニ族(CBD発効以前から)と南アフリカ・サン族の事例を紹介した。両ケースとも当初は地域的な共同研究から開始されたが、商業化の可能性が生じた後には、開発が国外の企業の手に移り、利益配分は国際的な課題となった。事例からの教訓として、プロセスの透明性が指摘された。

資料 1 ワークショップ出席者

Affiliation	Name	Title
Government of India, Ministry of Environment and Forests	Mr. Bir Singh Parsheera	Additional Secretary
	Mr. R. K. Rai	Additional Director (CS: BIO DIV)
	Dr. Sujata Arora	Additional Director ( MEGA DIVERSE C.SECTT.)
	Mr. G. Balachandhran	Joint Secretary
	Dr. Shruti Rai	
United Nations Environment Programme (UNEP) Division for Environmental Law and Conventions	Dr. Balakrishna Pisupati	
United Nations University Institute of Advanced Studies (UNU/IAS)	Prof. A. H. Zakri	Director
	Dr. M. S. Suneetha	JSPS-UNU Post Doc Fellow
	Ms. Yumiko Usui	Programme Associate
Japan Bioindustry Association (JBA)	Dr. Seizo Sumida	Director General
	Dr. Yoshiyasu Yabusaki	Director, Bioindustry Development
Indian Institute of Foreign Trade Centre for WTO Studies	Dr. Biswajit Dhar	Professor and Head
	Mr. Reji K. Joseph	
Government of India, Ministry of Agriculture, Department of Agriculture and Co-operation, Protection of Plant Varieties and Farmer's Rights Authority	Mr. D.S. Raj Ganesh	Legal Advisor
Indian Drug Manufacturer's Association	Mr. Gajanan Wakankar	Executive Director
National Biodiversity Authority (NBA)	Dr. S. Kannaiyan	Chairperson
	Dr. K. Venkataraman	Secretary
Bio-Links	Dr. R. S. Rana	Chair
Research and Information System for Developing Countries (RIS)	Dr. Sachin Chaturvedi	Fellow
	Mr. Ramesh	
	Dr. Mohanty	
Government of India, Ministry of Finance	Dr. Sanjay Kumar	Commissioner of Income Tax
JNU (Jawaharlal Nehru University)	Mr. Deepu M.	
Amity Institute for Herbal and Biotech Products Development	Prof. P. Pushpangadan	Director General
Council of Scientific and Industrial Research (CSIR)	Dr. V. K. Gupta	Head, IT Division
WWF-India Secretariat	Dr. Rajesh Sehgal	Senior Law & Policy Officer, Centre for Environmental Law
IUCN India Office	Dr. J. S. Rawat	
	Ms. Lindy Thompson	
	Mr. Michal Zrust	
Ashoka Trust for Research in Ecology & the Environment	Ms. Ankila Hiremath	
	Mr. K. S. Murali	Programme Officer
	Dr. Yogesh Gokhale	

**Report on the Workshop on “India’s Experiences in implementing Access and Benefit Sharing”**

**17-18 December, 2007, New Delhi**

Intergovernmental negotiations to develop an international regime on access and benefit sharing (ABS) within the framework of the Convention on Biodiversity (CBD) are ongoing aspiring to finalise negotiations for the regime by 2010. These negotiations are difficult given the various positions assumed by different countries, depending on their broad status as users or providers of genetic resources.

Bilateral discussions between India and Japan on ABS began in 2006 with the visit of a delegation from India to Japan to share experiences on how India and Japan are dealing with issues of access and benefit sharing (ABS). In continuation of this dialogue, a joint workshop between India and Japan (through Ministry of Environment and Forests, Government of India and the Japan Bioindustry Association) was organized in New Delhi, India supported by United Nations University-Institute of Advanced Studies (UNU-IAS). It sought to provide a platform to flag meaningful bilateral interactions between India and Japan on ABS issues that will eventually provide guidance to the international processes. India has passed the National Biological Diversity Act (2002), and is in the process of implementing the provisions of the Act. The Workshop focused on the experiences of India in this process, and a sharing of thoughts and concerns between India and Japan on various issues related to the implementation.

The Workshop commenced with a brief inaugural ceremony. Prof. A. H. Zakri, Director, UNU-IAS welcomed the delegates remarking on importance of the meeting within the global context. Dr. Seizo Sumida, Director-General, Research Inst. of Biol Resources, JBA, then addressed the gathering indicating the importance Japan placed on India from cultural to trade angles. He emphasized the importance of mutual understanding of issues in domestic situations by both the users and providers of genetic resources. Prof. S Kannaiyan, Chairman, National Biodiversity Authority (NBA) of India, then addressed the gathering about the role of NBA as the implementing agency for India’s ABS provisions. Mr. B.S. Parsheera, Additional Secretary, MoEF, India then launched a publication of the National Biodiversity Authority (NBA) of India titled “Implementation of Biological Diversity Act 2002”, which provides a useful guide to the status of implementation of the Biodiversity Act of India. In his presidential remarks, Mr. Parsheera highlighted the importance of the meeting in the light of global and regional developments and hoped the discussions will be gainful for not India and Japan alone but to the global community as well.

### **Session 1:**

The morning session was chaired by Dr. R.S.Rana, former Director, National Bureau of Plant Genetic Resources, India. The session was flagged off by Prof. A.H.Zakri, who in his presentation titled '*Access and Benefit Sharing of Genetic Resources-Issues and Challenges from a Global Perspective*', identified the various issues and challenges related to ABS. He listed the different concerns related to Access and Benefit Sharing of genetic resource providing countries (Providers) and countries that use genetic resources for commercial and other end-uses (Users). In addition he pointed out that the technological and scientific capacities of different stakeholders vary; awareness levels are different; benefit requirements vary between countries; costs of product development vary with sector and there is still lack of a uniform coherent global implementing policy. In addition to these issues that need to be resolved within territorial jurisdictions of countries, there are also issues of accessing genetic resources from areas beyond national jurisdiction, such as accessing deep sea bed genetic resources and bioprospecting in Antarctica. These various issues will have to be addressed while developing the international regime framework, and in negotiations between co-operating nations.

Following this, Dr. Balakrishna Pisupati, UNEP, Nairobi in his presentation titled '*The International Regime- An Overview*', drew attention to the various discussions ongoing in global forums on the development of the international regime on ABS (IR). He pointed out that negotiations were currently underway to decide on the nature, scope and elements of the IR with emphasis on disclosure requirements during filing of patent application, provision of certificates of origin and of having taken prior informed consent during patent applications and defining adequately the development of derivatives from genetic resources. He also identified other outstanding issues including intellectual property protection of traditional knowledge and issues related to terms of benefit sharing. In order to address the ABS discussions and for this purpose, UNEP is engaged in discussions with the co-chairs of the ABS Working Group of the CBD and is considering holding meetings with regional groups and develop a strategy between 2008 and 2010 for the purpose of development of the IR. However, for this UNEP would require mandate and support of the Parties to the CBD.

This was followed by a presentation by Dr. Biswajit Dhar, Head, WTO Division, Indian Institute of Foreign Trade, on '*Implementing the ABS Provisions: Importance of the International Certificate*'. In his talk, Dr. Dhar clarified that an international certificate of origin of genetic resource and/or traditional knowledge submitted at the time of applying for patents will make the whole process of accessing genetic resources transparent. It will indicate compliance with national laws and will enable in tracking the use of genetic resources and related traditional knowledge. It would serve as a commercial measure to tackle an ethical issue. He added that some of the issues that will have to be addressed include

affordability of implementation of this measure, competence of countries to provide such certificates and the compatibility of such a system with other processes such as FAO's International Treaty on Plant Genetic Resources (ITPGR) and the WTO Agreements, especially on issues related to transboundary movement of resources/ derivatives.

Discussions focused on the data intensive nature of the certification process and if alliances between countries could help to address such data insufficiency. Concerns were also raised about cross - boundary issues of origin. A need to strengthen databases and fill knowledge gaps was expressed. It was also expressed that these issues should be addressed while implementing the certificate of origin and take the 'early harvest' and wait for the developments.

Deliberating on capacity development of countries on various issues related to ABS, it was agreed that there should be a process to educate parliamentarians (the decision makers) on these issues. Also, capacity development is needed at individual, institutional and systemic (societal) levels. It was also felt useful to get regional groups into preparatory meetings before international meetings. The issue of ABS as a market failure issue was identified as the one that needed attention.

## **Session 2:**

The afternoon session on Day 1 was chaired by Dr. S. Kannaiyan, Chairman, National Biodiversity Authority. Dr. Sujata Arora, MoEF presented on '*Historical development of development of ABS legislation and protection of traditional knowledge in India*'. During this presentation, Dr. Arora gave the background to the development of ABS discussions globally and the national action called for implementation of these provisions within the CBD. She then provided details on the development process and enactment of the National Biological Diversity Act of India (2002). The provisions of the Act are well complemented by other national legislations, such as the Patent Amendment Act, which makes it compulsory for declaration of source and geographical origin of genetic resource and traditional knowledge, non-compliance with which could result in revocation of patent. The Plant Variety Protection and Farmers' Rights Act (PVP & FR) also provides for systems of benefit sharing while using native varieties for crop development purposes. She also mentioned the challenges faced while developing the Biodiversity Act of India, some of which include regular use of genetic resources by domestic industries, local population and communities for product development, everyday purposes and trade purposes (as non-timber products) respectively and export of large quantities of primary 'bioresource' commodities from the country.

The second part of the presentation highlighted the various institutional provisions within the



Biodiversity Act including its three-tiered structure to deal with national, regional and village level resources and stakeholders. It also threw light on the various related measures within the country to protect genetic resources and related traditional knowledge.

Dr. S.Kannaiyan presented on '*Biodiversity Act and Rules-Elements and Provisions*', in which he highlighted in detail the nature, scope and elements of the Act. In a chapter wise narration, Dr. Kannaiyan elaborated the administrative, institutional and operational aspects of the Act including details about the National Biodiversity Authority (for central decisions and on matters related to foreigners), State Biodiversity Boards (SBBs at State/ Province level) and Biodiversity Management Committees (BMCs at village level).

Dr. K.Venkataraman, Member Secretary, NBA, presented on '*Implementation of National Biodiversity Act and the Rules- Issues and Experiences*', in which he provided adequate details on the processes and procedures involved in implementing the Biodiversity Act of India. He highlighted the procedures to be followed for foreign nationals to access genetic resources within India, use restrictions, exemptions for research collaborations, normally traded commodities and value added products and related guidelines issues so far; benefit sharing norms expected to be followed by the users; efforts taken by the NBA to protect traditional knowledge (TK) and genetic resources through Plant Biodiversity Registers (Databases at village levels), provision of unique indigenous collection or accession numbers to specimens, restrictions on taking a material outside the country for identification, restrictions on access to endangered species, regulations on filing IPR claims.

Following this, Mr. D.S.Raj Ganesh from the Protection of Plant Variety and Farmers' Rights Authority presented on the '*Links between the Biodiversity Act and Plant Variety Protection Act*'. He highlighted the similarities in approach to recognizing local knowledge between the two legislations, and the inter-relatedness of the Acts in dealing with resources that fall in either Act's purviews. Both Acts provide for benefit sharing measures while accessing related resources.

Discussions focused on the issue of normally traded commodities and their implications for benefit sharing and how far into the value addition chain will the inclusion of such commodities be considered for benefit claims. NBA's position was that such commodities are meant only for consumption and not for further research and development. It was felt that the notification of the list should be done in consultation with the Ministry of Commerce and Industry.

**Day 2: 18<sup>th</sup> Dec, 2007**

### Session 3:

The morning session on Day 2 was chaired by Dr. P.Pushpangadan, Director General, Amity Institute for Herbal and Biotech Products Development. The first presentation was made by Dr. Seizo Sumida, JBA on '*Japan's ABS Guidelines and Experiences*'. Dr. Sumida highlighted the role played by JBA as the implementing body for ABS under CBD provisions in Japan for the Ministry of Economy, Trade and Industry (METI) that is a competent national authority for ABS issues. Identifying that users of genetic resources require more clear-cut and user-specific guidelines to complement the Bonn Guidelines on ABS, JBA and METI developed '*The Guidelines for ABS for Users in Japan*' (2005). These Guidelines provide a step by step guide to Industry and Academia on the process of accessing and using genetic resources from provider countries- starting from understanding provider's policy situation, establishing contact with concerned authorities and stakeholders, establishing contracts and terms associated including need to obtain prior informed consent, arriving at mutually agreed terms, and execution of contracts. A number of activities are supported by JBA-METI through services such as providing information, obtaining relevant information through fact finding missions and bilateral workshops and dissemination of the information through a helpdesk. From their experience in implementing ABS provisions, JBA-METI understands that national compulsions are different which is reflected in policies and regulatory systems. Hence, JBA seeks to establish collaborative models with providing countries to develop jointly practical and effective procedures that will generate benefits, reduce risks and ensure equity.

Dr. Balakrishna Pisupati then made a presentation on '*Future Dimensions on ABS*', in which he highlighted that the pragmatic way to take ABS discussions forward would be to reach compromises without sacrificing user and provider interests. This is possible if ABS is looked at from a trade or market perspective and considered as a 'you pay' (BS) for what 'you get' (access). To make these operational, inputs from people in the fields of economics, commerce and law are required. For the regime to be effective certainty of source of material, insurance of rights and obligations of providers and users, raising the capacities of all countries to a common level of understanding and development of a mechanism for dispute settlement will have to be provided for.

This was followed by a presentation by Dr. VK Gupta on '*Considerations for Traditional Knowledge linkages in dealing with ABS provisions*'. Dr. Gupta highlighted the interrelationship between traditional knowledge (TK) and genetic resources stating that it has been noted within the CBD provisions also. Misappropriation issues are common in the interface between GRs and TK, calling for efforts to protect TK. An initiative of the Council for Scientific and Industrial Research (CSIR), Government of India, to ensure defensive protection of TK has been the development of the Traditional Knowledge Digital Library (TKDL). The TKDL is a database of medicinal plants from texts from traditional systems of

medicine such as Ayurveda, Siddha, Unani. It has been introduced into the International Patent Classification (IPC) system in various categories and is available in 5 languages.

Discussions centered on Japan's approach to ABS and it was clarified that the criterion for benefit sharing in Japan was the extent of contribution to the results achieved. The participants also appreciated the efforts taken by Japan through the JBA to understand and be sensitive to policy scenarios of individual countries.

In addition, discussions also called for the need to develop a global search tool for all databases- including Patent and Non- patent databases, access to which needs to be regulated.

#### **Session 4**

The final session was chaired by Dr. A. H. Zakri. Dr. Sachin Chaturvedi, Research and Information System for Developing Countries (RIS), made a presentation on '*Global Experience with ABS: Emerging evidence from India and South Africa*'. In his presentation, he highlighted two case studies related to ABS that were first implemented before CBD negotiations on ABS took place- the Kani case study (India) and the San tribe case study (South Africa). He narrated the evolution of access to a genetic resource and related traditional knowledge by domestic research institutes in both cases. In both cases, the product that was later developed was commercialized, and the benefits accrued shared with the communities. However, the processes involved in the benefit sharing exercise varied with a higher degree of conflict and arbitration required in the San case study for recognition of the San tribe's right to benefits.

Elaborating on the lessons to be learnt from both the case studies, Dr. Chaturvedi mentioned that some of the key issues that emerge clearly include: clear and transparent process to obtain consent from community; if not dealt sensitively, the process could increase the vulnerability of tribal communities by conflicting with their extant cultures; and it is important that national measures are suitably complemented by international processes to mitigate any misappropriation beyond national territories.

The final discussions of the meeting looked at how to improve India's implementation of the Biodiversity Act and on how best to carry forward the dialogue between India and Japan.

For India, it was felt that the NBA should participate in regional discussions on ABS, and perhaps even convene a regional consultation at least in South Asia on ABS. It was also suggested that NBA could chalk out a programmatic link on ABS with UNU-IAS and UNEP. The MoEF could be involved in regional consultations and in regional capacity building and benefit sharing discussions. It could also get involved in second track diplomacy in science-policy dialogues to arrive at meaningful arrangements

with users.

The JBA could look at developing perspectives on benefit sharing in its next phases of MoU with UNU-IAS that could include a technical support programme to further define benefit sharing principles at national level, convening side meetings, expanding bilateral dialogues (such as the current one) into multilateral ones. JBA-MOEF joint programme on ABS was also suggested as a possibility.