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BUSINESS DIALOGUE ON ABS COMPLIANCE IN INDIA

ACCESS AND BENEFIT SHARING PARTNERSHIP PROJECT

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ACCESS AND BENEFIT SHARING (ABS) PARTNERSHIP PROJECT

The ABS Partnership project is commissioned by the Federal Ministry for Economic Cooperation and Development (BMZ) under the Indo-German Biodiversity Programme. The project is implemented inpartnership with the Ministry of Environment, Forest and Climate Change (MoEFCC), the National Biodiversity Authority, the State Biodiversity Boards of Maharashtra, Tamil Nadu and Uttarakhand and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH.

Objective

The ABS Partnership Project aims at strengthening the capacity of the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs), Biodiversity Management Committees (BMCs), as well as raising awareness amongst the commercial users of biological resources and traditional knowledge for the effective implementation of ABS mechanisms under the Biological Diversity Act 2002, in keeping with India's commitments under the Nagoya Protocol on ABS.

Approach

To achieve the objective, the project works on the following approaches:

- Awareness-raising, communication and stakeholder dialogues for creating better understanding of the Biological Diversity Act 2002, ABS Regulations and the Nagoya Protocol on ABS among different actors and stakeholder groups
- Development of good practices of benefit sharing of communities, based on utilisation of biological resources for commercial or research purposes
- Development of an IT-enabled ABS monitoring system for the National Biodiversity Authority for effective monitoring of the use of biological resources in ABS processes

The project is implemented at the national level in partnership with the NBA, at the state level, with the SBBs of Maharashtra, Uttarakhand and Tamil Nadu, and at local level with BMCs in three states.

EXECUTIVE SUMMARY

With the adoption of ABS Regulation in 2014, the implementation of ABS gained momentum in India. Since then, the National Biodiversity Authority (NBA) has progressively built on experience and established procedures to support effective implementation of ABS. It noteworthy to highlight an example of the notification on Normally Traded as Commodities, which has undergone two amendments since it was first notified in 2007 – with each amendment clear effort has been made to facilitate the access to many of the widely used biological resources to promote its trade and commercial use. Indisputably, goals of ABS cannot be fulfilled if there is no access provided to bio-resources.Thus,the NBA has been actively engaging with users to discuss the ABS issues and identify practical ways to strengthen implementation of ABS.

The National Biodiversity Authority with the support of Access and Benefit Sharing Partnership Project organised two business dialogues in Chennai and New Delhi to – (i) build a shared and common understanding of the ABS provisions among users (ii) identify the challenges faced by the users, (iii) obtain feedback from users particularly on ABS application procedure.

Majority of the companies opined that in absence of clear explanation on the provisions of Act, scope of ABS, illustrative examples of activities and bio-resources that come under the purview of the Biological Diversity Act, 2002, it becomes unreasonably cumbersome to fulfil on the ABS obligations. Participants also highlighted examples of differential interpretation of provisions of Act adopted by the State Biodiversity Boards. For instance, the Act exempts research carried out by Indians, however some states regulate research activities as well. Companies also emphasised the need to account for the differences in sectors, provide due consideration to scientific and technological methods employed by the companies to develop new products while executing ABS contracts.

I BACKGROUND

The Access and Benefit Sharing provisions of the Biological Diversity Act, 2002 in India came into force on 1 July 2004. Following which, in 2005 the National Biodiversity Authority in its third Authority meeting resolved to constitute an expert committee to deal with issues of access and benefit sharing (ABS) including material transfer agreements (MTA) involving biological resources. Implementation of ABS provisions has now considerably been streamlined, especially after the notification of "Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014" hereinafter "ABS Regulation 2014". The ABS Regulation, 2014 prescribes the procedure for access to biological resources and/or associated knowledge and benefit-sharing component for various regulated activities under the Biological Diversity Act, 2002.

The National Biodiversity Authority has been closely engaging with users including researchers and companies using biological resources in their research & development and commercial operations to address their concerns arising from the implementation of ABS regulations and to create awareness on the procedures to align various activities to fulfil the legal requirements.

II WHY DIALOGUE WITH BUSINESS ON ABS MATTERS?

To fully tap the economic incentives of ABS, active engagement with businesses is necessary to evolve a mechanism and establish a win-win ABS partnership. Access and benefit-sharing is a new and complex topic as it involves aspects of country's sovereignty over biological resources, legality of access, trade, Intellectual Property Rights and ethics. To top it all, there are considerable sector-specific variations with utilisation of biological resources and associated knowledge. Hence, legal or regulatory measures alone will not suffice to develop a coherent ABS system. The role of private actors such as researchers and commercial users is of paramount significance to address the gaps in the current ABS system.

The knowledge on principles, appropriate procedures and documentation to fulfil ABS requirements under national legislation needs to be strengthened among user groups. Supporting commercial users to comply with national legislation on ABS is one of the key activities under the ABS partnership project implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH under the Indo-German Biodiversity Programme.

III BUSINESS DIALOGUE ON ABS

The ABS Partnership Project organised the two-day business dialogues in Chennai and New Delhi in April 2018, brought together over 69business representatives, researchers and legal professionals, representatives of National Biodiversity Authority, State Biodiversity Boards and officials of Ministry of Environment, Forest and Climate Change (MoEFCC) to exchange experiences of ABS.

Aim of the dialogue was to :

- Provide guidance on legal compliance to fulfil obligations mandated under ABS provisions in India;
- Identify the challenges faced by the users;
- Sector-specific challenges arising due to ABS provisions;
- Gather specific suggestions from the companies on seamless operationalisation of ABS within the ambit of the Act.
- Sharing of ABS experience particularly on ABS application procedures and incorporation of compliance measures in sourcing of biological resources.

Opening Sessions :

In the opening session on day one, **Dr. Konrad Uebelhör,** Director of Indo-German Biodiversity Programme highlighted that India is among the first countries to establish a national legislation to fulfil obligations under Convention on Biological Diversity (CBD) as well as Nagoya Protocol. Countries around the world are looking to learn from India's experience in implementing ABS. He also explained the role of GIZ, it is the sole implementing agency for technical cooperation projects between India and Germany. The Access and Benefit Sharing Partnership Project under the Indo-German Biodiversity Programme is supporting the National Biodiversity Authority and State Biodiversity Boards in the states of Maharashtra, Tamil Nadu and Uttarakhand in strengthening the implementation of Access and benefit-sharing. Capacity building of commercial users and facilitating dialogue between regulators and users is one of the key steps towards achieving ABS compliance.

Mr. T. Rabikumar, Secretary of National Biodiversity Authority talked about NBA's efforts in streamlining the application process through holding regular meetings of Expert Committees and has recently launched facilities for e-filing of ABS applications. He also highlighted that the purpose of these dialogues was not only to provide a platform for users to get clarifications on application procedures and other ABS requirements, but also to flag issues and challenges arising due to access provisions.

Prof. R. S. Rana, former chair of NBPGR and Chair of Expert Committee on Agro-biodiversity at NBA was present at the dialogue in Delhi. He called on participants to flag issues and approach the topic with openness and interacted with participants during the Q&A session.

IV APPROACH

The business dialogue on ABS was moderated by Ms. Julia Maria Oliva from Union for Ethical BioTrade (UEBT). The ABS Partnership Project is collaborating with UEBT to develop case studies on good practices of ABS and facilitate dialogue between users and regulators.

A step-by-step approach was adopted to enhance understanding of ABS provisions among participants and moderate the discussions to identify challenges and possible solutions. Dialogue was facilitated through participatory tools such as input presentations on ABS, discussion on hypothetical case studies, group work and questions and answers with the regulators.

V INTRODUCTION OF ABS CONCEPTS

a. International context

Ms. Julia Maria Oliva gave an overview of key concepts and strategic implications for the countries and companies due to access regulations since the adoption of Convention on Biological Diversity (CBD) and Nagoya Protocol. While CBD has universal membership of having almost all countries being signatories to it, the Nagoya Protocol has over 70 countries, of which 38 have ABS procedure in place and 28 have clear access requirements. Considering that biodiversity is a source of innovation in many economic sectors, these numbers are set to rise in the near future.

While CBD recognised the sovereign rights over biodiversity, including genetic resources; its supplementary agreement Nagoya Protocol on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization" aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. Basic tenets of ABS while accessing genetic resources are:

- Prior informed consent (PIC) and mutually agreed terms (MAT), including fair and equitable benefit sharing are secured;
- Parties to ensure PIC and MAT for traditional knowledge held by indigenous peoples and local communities.

ABS in principle means "access to genetic resources and the fair and equitable sharing of benefits derived from their utilization". ABS is a new paradigm that not only recognises the growing value of biodiversity and knowledge of indigenous peoples and local communities who own genetic resources, but also its economic potential given the emergence of new technologies and intellectual property rights. ABS is looked upon as means to harness value for sustainable development.

Countries that are signatories to Nagoya Protocol are expected to establish legal and administrative measures to provide clarity and certainty for access to genetic resources and establish a mechanism to monitor R&D to ensure compliance with rules in provider countries. In order to facilitate exchange of information and support the countries in implementation of Nagoya Protocol, ABS-Clearing House (ABS-CH) mechanism has been established. ABS-CH hosts information on access requirements, including PIC and MAT and benefit-sharing obligations. Internationally recognized certificate of compliance (IRCC) generated through ABS-CH will assist the user countries monitor the flow of genetic resources along the value-chains.

A range of approaches have been established by the countries. The number of activities and extent to which they are regulated defines the scope and complexity of ABS implementation. It differs from country to country. For instance, in Brazil and South Africa, access regulation applies only to native species and in Columbia, only R&D requires compliance. South Africa requires permits for every single stage in supply-chain, whereas Brazil has single registration requirement for access. Involvement of multiple providers is challenging for coordination for benefit-sharing in South Africa. Single access point and benefit-sharing only for manufacturer of final product is challenge for traceability in Brazil.

Table 1: ABS around the world

No access requirements	Access requirements
No ABS-related restrictions – Netherlands, Germany, USA	**High complexity -** Brazil, India, Peru, South Africa
ABS requirements pending - China, Morocco, Mexico, Dominican Republic, Madagascar	**Medium complexity -** Colombia, France, Viet Nam, Kenya
Strategy and policy unclear - Paraguay, Indonesia, Bulgaria	**Low complexity -** Depends on strategy and experience

Source : Union for Ethical BioTrade

It is also important to recognise sector-specific variations for ABS implementation. For example, access and use of biological resources in the Ayurvedic sector differs from the plant breeding sector. Thus, development of sector-specific procedures and best practice may have far-reaching impacts in ABS implementation.

Ms. Julia also illustrated some ABS cases from around the world.

B. National context

Mr. T. Rabikumar focused his presentation on the India's national legislation on ABS and its scope. India become a Party to CBD in 1992 and established national framework to fulfil the commitments under CBD through enactment of the Biological Diversity Act in 2002. The objectives of the Biological Diversity Act, 2002 align with CBD and they are: 1. Conservation of biodiversity, 2. Sustainable use of its components and 3. Fair and equitable sharing of benefits arising out of the use of bio-resources.

The Biological Diversity Act, 2002 is being implemented throughout the country through decentralized institutional structures. They are: National Biodiversity Authority at the national-level, State Biodiversity Boards at State-level, and Biodiversity Management Committees at local-level.

He also explained the functions of National Biodiversity Authority, State Biodiversity Boards and Biodiversity Management Committees in fulfilling the objectives of the Act. He further explained the scope of ABS in India – ABS legal framework covers biological resources and/or associated knowledge and regulated activities are: research, commercial utilization, bio-survey and bio-utilization, Intellectual Property Rights (IPRs), transfer of research results, and third party transfer of accessed biological resources/associated knowledge or research results. The Act makes a distinction between access by NRI, non-Indian persons and non-Indian entities under Section 3, and Indians and Indian entities under Section 7. Access is regulated by National Biodiversity Authority and State Biodiversity Boards for these user groups, respectively.

Table 2: Scope of ABS Regulation in India

Provisions	Regulated activity	Regulated persons	Compliance
Section 3	Research, commercial utilisation Bio-survey Bio-utilisation	NRI, Non-Indians or non-Indian entities	Prior approval of NBA is required for access to biological resources or associated knowledge
Section 4	Transfer of research results involving biological resources to any non-Indians or non-Indian entities	Indians and non-Indians or non-Indian entities	Prior approval of NBA is required for transfer of research results
Section 6	Obtaining Intellectual property rights in or outside India for any invention based on any research or information on a biological resource obtained from India	Indians and non-Indians or non-Indian entities	Prior approval of NBA is required
Section 7	Commercial utilisation Bio-survey and Bio-utilisation for commercial utilisation	Indians	Prior intimation to be given to SBBs for access to biological resources
Section 24(2)	Not to carry out activities that are detrimental or contrary to conservation, sustainable use or fair and equitable sharing of benefits	Indians	

Mr. T. Rabikumar provided information certain exemptions of persons or activities from the purview of the Act, they are:

- Local people and communities for free access to use bio-resources within India (Section 7).
- Growers and cultivators, "vaids and hakims" (practitioners of traditional medicinal systems) to use bio-resources (Section 7).
- Biological resources normally traded as commodities as notified by the Central Government under Section 40 of the Act[1].
- Collaborative research through government-sponsored institutes subject to conformity with guidelines and approval of the Central / State Governments (Section 5).
- Access to value added products (Section 2p).
- Research carried out by Indians in India (ABS Regulation, 2014).
- Designated crop varieties listed in the Annex I of ITPGRFA by Department of Agriculture and Cooperation exempted from Sections 3 and 4. (MoEF&CC Notification dated 17th December 2014).

[1] This exemption is not applicable for research or IPR.

He also shared with participants that NBA has received over 2000 applications and 1200 approvals have been granted. Till date, over 700 ABS agreements have been signed. He also encouraged companies to submit form-1 though the online portal.

India has also generated 110 IRCCs, highest among all countries (ABS-CH has 174 IRCCs). He noted that, although companies can choose to keep majority of the sections in IRCC as confidential, it is advised to keep information of recipient as public to be able receive copy of IRCC. IRCC is an important document, especially for the multinational companies or companies that trade globally.

Mr. Rabikumar concluded his presentation by highlighting case studies on access to biological resources obtained for research, IPR and transfer of research results.

During the question and answer session, Mr. Rabikumar exchanged with participants various aspects of ABS including application procedures, whether the virus and other microorganisms isolated from humans come under the scope of ABS, how many bio-resources can be indicated in a single form-1 application, information to be furnished when source of collection is not known, bio-resources collected from markets, etc.

VI IN-DEPTH LOOK AT LEGAL INTERPRETATION AND PROCEDURE FOR ABS COMPLIANCE IN INDIA

In order to delve deeper into aspects of interpretation of the provisions of Biological Diversity Act, 2002, its scope, and application procedure, group work was moderated with four sector-specific hypothetical cases from–natural ingredients, plant breeding, bio-tech and consumer goods sectors. Participants were grouped based on their sector-specific interests and given a set of questions to debate and make recommendations.

VII KEY CONTEXTUAL CONSIDERATIONS — ISSUES AND CHALLENGES IDENTIFIED BY PARTICIPANTS

This section highlights various issues and challenges identified by the participants in business dialogues in Chennai and New Delhi.

a. Differential interpretation of the provisions of the Act and procedures and approach to ABS in SBBs

- Indians and Indian entities are required to give prior intimation to SBBs for access to biological resources (BR), bio-survey and bio-utilization for commercial utilization. Regulation 17 of ABS Regulation, 2014 provides exemption to Indians to carry out research in India. However, many SBBs still ask for intimation to be given while accessing BR for research.
- Scope of NTAC is not clear, only some SBBs have exempted NTACs such as ginger, turmeric from ABS requirements;
- Procedural delays in SBBs affects the manufacturing process of products which requires multiple bio-resources accessed from several states. There is no uniformity in form-1 application process – it may vary from one-time registration, application submission by the end of financial year to multiple times in a year
- Source of collection is not known, more often than not, bio-resource is collected from markets based in big cities or traders in towns. SBBs insist on the geographical information of intended collection to be furnished in form-1 applications
- Human genetic material is exempted from the purview of ABS. Does that also exclude viruses/microbial strains isolated from humans?

b. Definition and procedure

- Terminologies such as "conventional breeding" and "value-added product", "extract" and "by-products" are not defined in the Act.
- Examples of end uses of biological resources under definition of "commercial utilization" are required. Many times companies manufacture products as raw materials for another product or process. In this case, the final product may be considered under value-added product
- No clarity on what activities come under the scope of "common practices" in NTAC notification. A negative list of activities with explanatory notes may be helpful to comply with ABS provisions
- Companies that are incorporated in India and have only Indians in its management, but even with 1% of foreign share capital are considered as non-Indian company under Section 3(2) of the Act. It may be helpful to set a cut-off percentage to categorise the companies.
- Section 5 of the Act exempts collaborative research projects that are approved by and conform to policy guidelines issued by Central Government. However, there is no guidance on how to obtain such approvals.

- Companies make investments in cultivation of bio-resources to have adequate supply and sometimes to ensure no pesticide residue leach into plant materials. These cultivations are sometimes done on private lands owned by the companies themselves. Do they still need to pay ABS on such resources or products manufactured? Who gets the benefit-sharing amount?
- How many bio-resources can be accessed at a time? If access to 100 bio-resources is required, can the users submit only form-1 application?
- Provisions of the Biological Diversity Act, 2002 and the Protection of Plant Varieties and Farmer's Rights (PPVFR) Act, 2002 conflicting in case of access to varieties developed by breeders or researchers[2]
- The Biological Diversity Act, 2002 and PPVFR Act, 2002 both require benefit-sharing agreements.
- Although Act provides time lines, there are inordinate delays in processing of applications by NBA and SBBs. Time is a crucial factor in breeding sectors and severely impacts R&D.
- Nomenclature of microbes/viruses/bacteriophages used in R&D sometimes not established or cannot be determined at the beginning. In such cases, does the applicant have option of furnishing the details during the process of R&D rather than at the time of application?
- Do the microbial strains and mother culture obtained from MTCC or ATCC come under the scope of ABS?

[2] Detailed discussion is given the practical experience shared by Dr. Meenakshi Bharadwaj.

c. Benefit-sharing

- Regulation 3 of ABS Regulation 2014 prescribes benefit-sharing obligations for traders and manufacturers, at 1-3% and 3-5% on the purchase price of the biological resources respectively. Furthermore, stipulates ABS compliance for the supply-chain "where a buyer submits proof of benefit sharing by the immediate seller in the supply chain, the benefit sharing obligation on the buyer shall be applicable only on that portion of the purchase price for which the benefit has not been shared in the supply chain". Companies seldom procure bio-resources from one trader or location. Considering the complexity of the trade, it is impossible to establish a source location for a particular bio-resource;
- There are no convincing cases for ABS actually contributing to conservation or economic development of providers;
- Guidance or procedure for opting for non-monetary benefits is not given;

d. Online applications

- There is no option for uploading file on biological resources to be accessed from several locations across the country, each entry has to be made individually using drop down menu. Online portal also has time-out period and automatically logs out. This is challenging when information on hundreds of locations needs to be submitted.
- Some information to be furnished in online application is different from paper applications.

VIII PRACTICAL EXPERIENCE ON ABS IN INDIA

On day two, participants were invited to share their direct experience in complying with ABS provisions, including the application procedure, interpretation of the provisions of BD Act, 2002 and ABS.

A summary of presentations made by the participants in **Chennai** and response of regulator is provided below:

Submission of ABS application at NBA

Dr. D. Sreenivasa Rao from Laurus Labs Limited, Hyderabad shared his positive experience of application process. Laurus Labs specialises in synthesising natural ingredients for the food, pharma, cosmetics sectors etc. The company was approached by an international consumer for obtaining extracts from a bio-resource which cannot be synthesized in the lab. Although, the company has ensured compliance with good manufacturing practices and other regulatory practices, they were not aware about the Nagoya Protocol or India's Biodiversity Act. After examining available information on the internet, Laurus Labs approached the State Biodiversity Board in Hyderabad to enquire about the application procedures. They were advised to approach National Biodiversity Authority to submit form-1 to access bio-resources for the said purpose. They approached the National Biodiversity Authority in August 2016 and officials at NBA provided step-by-step guidance on application procedure, mandatory documents required, etc. They submitted the form-1 in December 2016 using e-filing option. In February 2017, technical officials at NBA asked for certain clarification on the application and also advised not to access the materials or carry out any activity before the approval was given. Laurus Labs provided some clarifications to the questions raised by the Expert Committee on ABS in May 2017. Following which they were informed about the ABS permit was granted and draft agreement on ABS was shared with them. NBA officials were supportive throughout the process and whole procedure was completed through emails and postal service. However, they had difficulty furnishing the details for IRCC, due to its language, which took about 3 months. Finally, the ABS agreement was signed in March 2018. The benefit-sharing paid separately for R&D and commercialisation. The entire process took about 1.5 years.

Mr. T. Rabikumar thanked Mr. Rao and informed that applicants have the option of keeping a part or all information to be furnished in IRCC as confidential. However, to receive a copy of IRCC it is advised keep information on recipient as open.

Plant breeding sectors

Dr. Meenakshi Bhardwaj Dow Dupont Pioneer highlighted some challenges in interpreting the ABS provisions of the Act in plant breeding sector.

1. The Act does not define conventional breeding or provide explanations on scope of what is covered or exempted. Seed companies undertake line development and hybrid development. These activities are commonly undertaken by the seed companies and necessary steps in any plant breeding. Seed companies consider these steps as conventional breeding. Seed industry associations approached Prof. Swapan Kumar Datta, DDG (Crop Science), ICAR and he communicated to NBA on vide letter no. F.No. CS/4/20/2013/Seed, dated 29th April 2013 that seed production is considered as "Traditional Practice" in agriculture. However, this definition has not been accepted by the NBA. Although, Section 2(f) provides exemption on conventional breeding both for Indian and non-Indian persons or entities, it is not clear whether the activity of seed production for food and agriculture come under the scope of ABS.
2. Section 3(1) covers the biological resources "occurring in India". Whether the exotic species used in breeding activity comes under the scope of the Act needs to be clarified.
3. PPVFRA Section 28(1) breeder is conferred with exclusive rights on a particular breed registered under the Act. This will enable the breeder to produce, sell, market distribute, import and export the variety.
4. PPVFRA also recognises Researcher's rights and certain exemptions given to researchers to develop a variety and for "the use of any variety registered under this Act by any person using such variety for conducting experiment or research; or the use of variety as an initial source of variety for the purpose of creating other varieties" called essentially derived varieties (EDV).[3]

This means, variety registered can be used privately for non-commercial, experimental purposes, and create other varieties. The researcher is required to obtain the authorisation of the breeder of registered variety. However, the National Biodiversity Authority requires plant breeders as well as researchers to obtain approval for access to carry out any research or breeding activities. Provisions of two Acts are conflicting and contradictory. A guidance on dealing with compliance issues is essential for seed companies carrying out R&D and commercial utilisation.

Furthermore, PPVFRA gives IP owners exclusive rights to import or export. When a company which has exclusive rights to a variety wants to export the variety, is the approval under the BD Act still required?

Benefit-sharing is mandated in PPVFRA as well as BD Act. PPVFRA requires benefit sharing to be shared at source of initial variety or landrace was accessed.

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[3] "Essentially derived variety", in respect of a variety (the initial variety), shall be said to be essentially derived from such initial variety when it–
(i) is predominantly derived from such initial variety, or from a variety that itself is predominantly derived from such initial variety, while retaining the expression of the essential characteristics that results from the genotype or combination of genotype of such initial variety;
(ii) is clearly distinguishable from such initial variety; and
(iii) conforms (except for the differences which result from the act of derivation) to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety

Dr. Bhardwaj appreciated efforts of NBAfor facilitating e-filing of form-1 applications. However, there are certain glitches. As an example, while e-filing form-1 for access to 20 insects to be accessed from 5-10 villages each in 20 districts spread over 10 states, the number of entries that needs to be made in online applications can run into thousands. Selecting from drop down menu is time consuming. Moreover, time-out in the online applications sometimes leads loss of all entries made. Hence, paper application is more practical. She suggested to NBA that online application should have option to upload the data through excel or any other external file will ease the process for applicants.

It was also clarifiedduring a follow-up discussion that, the opinion of Prof. Swapan Kumar Datta, DDG (Crop Science), ICAR on conventional breeding was not of ICAR's. Participants were sensitised to understand the intent of legislation in totality while interpreting the provisions of the Act. NBA is open to discuss with stakeholders in bringing out clarity on these issues.

With regard to exotics, there are instances when a company has brought the germplasm for testing in India and taken it back. They have the EC number assigned by the NBPGR[4]. When it is clearly proven that, the characteristics of the material brought remain same when it is taken out, NBA's approval is not required. However, if it is in India for many generations and adapted to Indian Agro-ecologies where they have developed distinctive properties, they are required to come to NBA. This is dealt with on a case-to-case basis. PPVFRA is more towards patent rights whereas the BDA is for regulation of access and its conservation.

Breeder's and Researcher's Rights versus provisions of BDA, needs to be understood in more details.

He also thanked Dr.Bharathwaj, for raising the issues regard to multiple entries in online applications and invited participants to inform NBA about such glitches faced while e-filing.

[4] Each germplasm accession is given an accession number. This number is pre-fixed in India, with either IC (Indigenous collection), EC (exotic collection). Every imported germplasm accession is assigned a national identifier number Exotic Collection number or EC number which remains unchanged. Every indigenously collected accession is assigned a national identifier number Indigenous Collection number or IC number which remains unchanged.

Natural ingredients

Dr. Arvind Saklani, Sami Labs, Bangalore focused his presentation on natural products. While industries support the principle of ABS, clarity on the stage at which a bio-resource becomes a value-added product is essential for carrying out R&D and commercial utilisation. Section 2(f) defines commercial utilization, it deals with "end uses" of biological resources. Any given resource, depending on the form, can be a biological resource, a value-added product, or both at the same time.

As per the definition of value- added agriculture of USDA[5], when a bio-resourceis processed, it changes its physical state and it becomes a value-added product (VAP). Once bio-resource is accessed, industries process the raw materials to make powder, then oleoresins, extracts, up to isolating phytochemical compounds. Can this be considered as a value-added product? Can this also be considered as end of use of the bio-resource? Sections 2(f) and 2(p), refers to commercial utilisation and VAP respectively. Value-added products are physically inseparable and unrecognizable. Extracts, oleoresins and phytochemical compounds fulfil these two criteria. There is also an argument that if it is only one bio-resource, then there cannot exist property of being physically inseparable.

When two definitions are read together, the examples for end uses of biological resources such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping;" implies that value-addition has already taken place and may qualify for VAP. Defining these terms and making a distinction between the two is a matter of crucial importance to the companies as they trade with many countries outside India. Oleoresins and extracts are made from company's IP and they invest heavily in developing technology.

With this regulation in place, for instance, the person sitting in the US is required to apply for access to NBA. It is impossible for industries to sustain this model. Importers in other countries may move other countries, as these resources are also widely available. These regulations will promote "jurisdiction shopping" and may affect the Indian business in the long run.

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[5] This definition of value-added agriculture is from the U.S. Department of Agriculture, Rural Business Development. Value-added products are defined as follows:
A change in the physical state or form of the product (such as milling wheat into flour or making strawberries into jam).

- The production of a product in a manner that enhances its value, as demonstrated through a business plan (such as organically produced products).
- The physical segregation of an agricultural commodity or product in a manner that results in the enhancement of the value of that commodity or product (such as an identity preserved marketing system).

As a result of the change in physical state or the manner in which the agricultural commodity or product is produced and segregated, the customer base for the commodity or product is expanded and a greater portion of revenue derived from the marketing, processing or physical segregation is made available to the producer of the commodity or product.

Other aspect is applicability of BS obligation of up to 5% for manufacturers. There has to be clarity on the BS at different stage, for example, turmeric is sourced from farmers, then to an intermediary company for making extracts. It changes several hands. Whether all involved should pay ABS? Since multiple players are involved, it is challenging for the final manufacturer to keep track of ABS that is already paid.

When companies promote cultivation, does that come under benefit-sharing? Cultivation actually fulfils the objective of Act, i.e. conservation. Companies invest in commissioning contract farming, from giving the materials to training the farmers. Sami Labs has been promoting cultivation of Coleus, currently around 10,000 farmers are involved. This activity itself may be considered as non-monetary BS. Aspects such as these need to be taken into consideration in ABS implementation.

Mr. T. Rabikumar in response to the queries raised by Mr. Saklani, explained that, the definition of a "product" in legal dictionary, means it is for the ultimate consumption. Anything going into production process is considered as a raw material. VAP cannot be a raw material for another production process. This needs to be dealt on a case-to-case basis. Extracts from oleoresin cannot be a VAP. Oleoresin is extracted from a bio-resource, it is an intermediary product and goes in as raw materials.

With regard to export, he explained that companies need not come to NBA for approval for every consignment basis. It can be for a specific period of time and NBA has previously given approvals to companies for a long period of time.

A summary of presentations made by the participants in **New Delhi** and response of regulator is provided below:

Non-monetary benefits under ABS

Ms. Gaura Verma, highlighted her company's efforts in promoting conservation of habitats, biological resources and wildlife. Dabur has been closely working with farmers in Himachal Pradesh to promote cultivation of some Section 38 species. As a part of company's CSR initiatives, various capacity building programmes for farmers and other stakeholders have been taken up. These established activities can also be expanded to fulfil the ABS obligations. Dabur is keen to work with the NBA to establish a mechanism for non-monetary benefits.

Mr. T. Rabikumar appreciated efforts of Dabur and informed that since system is already established under CSR, it may be difficult to carry out an evaluation of contribution of CSR versus ABS provisions. However, it is worth looking into.

Experience of ABS compliance in SBB

Dr. Ghanashyam Patel, Green Medic Solution. He is an Ayurvedic physician as well as a farmer from Gujarat. Mr. Patel informed that companies in Gujarat werenot aware of the Act until 2013. Upon receiving a legal notice from SBB to register using form-1, companies and associations learnt about obligations under ABS provisions. Association and company representatives approached the SBB and agreed to pay ABS every three years. Next instalment is due in 2017. However, following the notification of ABS Regulation 2014, the companies revisited the decision of paying ABS to SBBs as it was applicable from the date of notification. In Gujarat, more 90% of companies have less than 5 crores turn over. Authorities may consider setting certain cut-offs based on turn over to determine ABS payments. Companies support the principle of fair and equitable sharing; however, they also note that BMCs are not functioning in the state and 60 Lakhs of accrued benefits has not been shared with BMCs.

It is also challenging to ensure sustainability of wild medicinal plants as the extant trading structure is highly unregulated. He recommended that APMC model may be followed in case of medicinal plants, this will not only promote sustainability but also ensure a constant supply of raw materials without traders creating a market distortion. ABS compliant supply-chain is only possible when traders are also brought under the ambit of ABS provisions.

Need for continuous engagement with the regulators

Ms. Sangeeta Mendiratta, Bayer Crop Science began her presentation by acknowledging the National Biodiversity Authority's openness to have dialogue with companies and discuss the implementation issues. She also highlighted cooperation extended by the Authority during application process and time lag from application to obtaining approval has also become shorter.

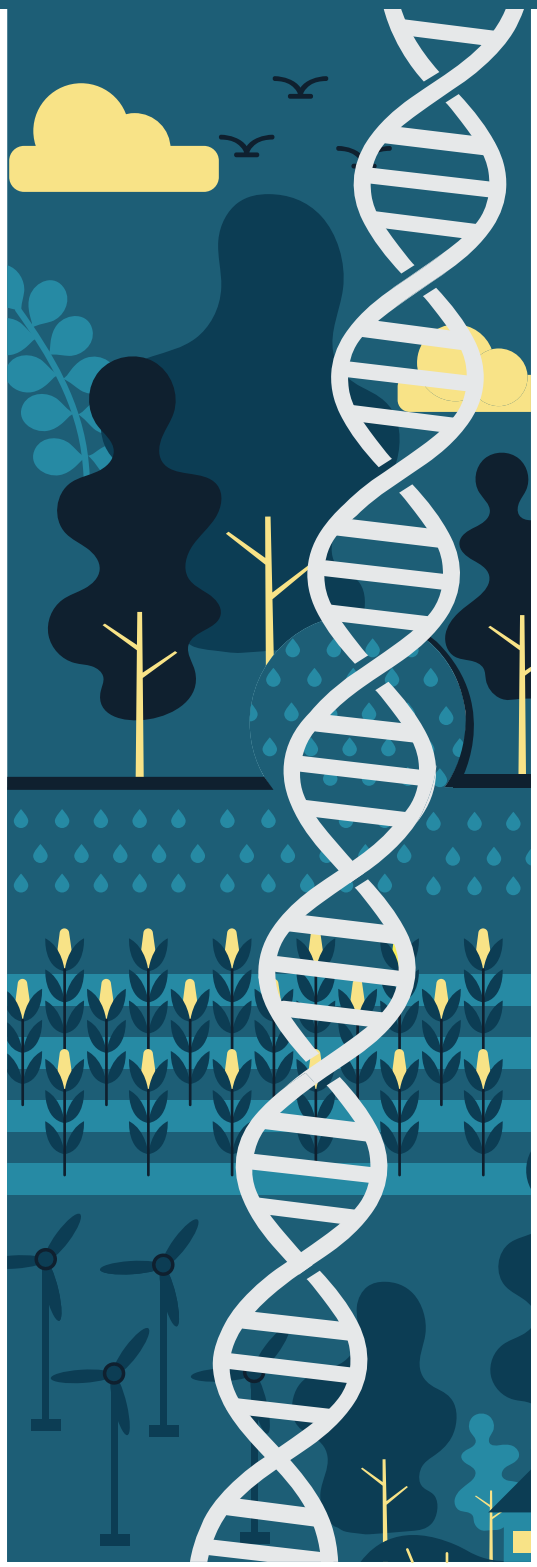
She also informed that issues of access to bio-resources in plant breeding sectors considerably differs from other sectors. Hence close collaboration with Ministry of Agriculture may help the industries as well as strengthen ABS implementation. There are still few aspects which remain unresolved such as exemption given for accessions under ITPGRFA, considering seed as normal traded as commodity, clarity on scope of exemption for conventional breeding, definition of Indian biological resource, etc.

IX RECOMMENDATIONS FROM PARTICIPANTS

End of day 2, **Dr. Sujata Arora,** Senior Adviser, Ministry of Environment, Forest and Climate Change joined the meeting in New Delhi thanked the participants for their participation and welcomed recommendations. Key recommendations from two-day dialogues held in Chennai and New Delhi are given below:

a. Technical aspects

- Provide explanatory notes on exemptions under the Act
- Explanatory notes on "end uses", "common practice" and "extracts"
- Definition of "conventional breeding" and "value-added products"
- Adopt sectoral approach in ABS implementation based on source of bio-resource, its use and intent of R&D or research
- Certain biological resources (e.g.: microbial strains) are used for testing or verification and not directly used for research and such bio-resource may be exempted. A guideline in this regard may be issued. For example: EU guidelines on bio-technology
- Document on Interplay of BDA and PPVFRA
- Engage with SBBs to establish uniform approach in ABS implementation
- Development of sector-specific SOPs



b. Operational aspects

- Advisory to Patent office to exclude biological resources sourced from outside India
- Advisory on access requirement for microbiology/ bacteriophage/ Technical help desk at NBA (e.g.: Biosafety Support Unit)
- Minutes of expert committee meeting to make available on NBA's website
- Transparency of usage of ABS amount collected by NBA and SBBs
- Less % of ABS payment may be levied in case of contract farming
- List of activities that can be considered under non-monetary benefits
- Coordination among related ministries and authorities
- Promote participation of other government departments in workshops on ABS
- Organise sector-specific workshops
- Organise region-wise workshops for companies, plant breeders and traders
- Publish newsletters on development of ABS regulation and case studies
- Publish good practice case studies to educate the companies

c. E-filing of ABS applications

- Workshop on e-filing of application
- Provisions for username and password for each company to access previously submitted data and Form-1
- Form-A to be made available on NBA's e-filing website
- Include option to upload excel files (instead of drop-down menu)
- Status of application made available to applicant through online portal (e.g.: visa application status is continually informed to applicants)

X RECOMMENDATIONS FROM THE NATIONAL BIODIVERSITY AUTHORITY

Mr. T. Rabikumar thanked all participations for participation in fruitful deliberations and he reiterated NBA's commitment to provide an enabling environment for users to discuss and bring forth issues of ABS implementation. He also proposed following recommendations.

- Adopt ABS practices in corporate policies
- Informal exchanges among companies on application procedures and other aspects of ABS
- Encouraged submission of online applications and provide feedback to improve the e-filing portal
- Share with NBA on success stories of ABS compliance
- Propose list of activities to be considered under non-monetary benefits with an evaluation of its value
- Provide information on source location of biological resources this will enable NBA and SBBs to channelise benefits to BMCs or benefit claimer in the region. However, in case the information not available, especially for the bio-resource access from traders, furnish the name and contact detail of traders or intermediaries.

XI CONCLUSIONS AND WAY FORWARD

The participants acknowledged increased understanding of ABS provisions which will enable them to navigate through the ABS procedure in NBA and SBBs. The dialogue also provided an opportunity to clarify interpretations of ABS provisions directly from the regulators. Deliberations held during these business dialogues puts the emphasis on need for promoting two-way communication between regulators and users to build trust and understand issues from perspectives of users and vice versa.

The National Biodiversity Authority with the support of the Access and Benefit Sharing Partnership Project will organise sector-specific workshops and engage with State Biodiversity Boards to create common understanding of the provisions of the Act.

XII FEEDBACK FROM PARTICIPANTS

Assessment of feedback given by participants in Chennai and New Delhi showed appreciation for the opportunity provided to discuss issues openly with authorities. They also acknowledge the openness of authorities to receive suggestions from the companies. Participants also appreciated the interactive and practical approach in which concepts were explained through group discussions and hypothetical case studies.

Participants also suggested to include following sessions in the next dialogue:

- Clarifications on various issues raised in the dialogue
- Session on amendments, notifications and procedural aspects at NBA and SBBs
- Workshop on scope of BDA, IPRs and PVPFRA
- Sector-specific considerations in ABS compliance

ANNEXURE 1 : LIST OF PARTICIPANTS
CHENNAI

SL. NO.	NAME	AFFILIATION
1	Ms. Aradhana Vipra	Gangagen Biotechnologies Pvt. Ltd., Bangalore
2	Dr. Arvind Saklani	Agri Biotech Sami Labs Ltd., Bangalore
3	Mr. A. Udhayan	Tamil Nadu Biodiversity Board
4	Dr. B. Meenashree	Asthagiri Herbal Research Foundation, Chennai
5	Mr. Balaji Kirupakaran	R.K. Dewan & Co., Chennai
6	Dr. D. Malathi Lakshmikumaran	Lakshmikumaran & Sridharan, Chennai
7	Mr. D. Sreenivasa Rao	Laurus Labs Ltd., Hyderabad
8	Mr. D Suresh Lingam	Yaazh Xenomics, Coimbatore
9	Mr. Dominic Arun Joseph	Varsha Bioscience and Technology India Pvt. Ltd., Hyderabad
10	Ms. Gaura Verma	Dabur India Ltd. New Delhi
11	Dr. Goutam Bhattacharya	K&S Partners, Chennai
12	Mr. J. Sankaran	Jasmine CE Pvt. Ltd., Chennai
13	Dr. Kripa Jalapathy	Gangagen Biotechnologies Pvt. Ltd., Bangalore
14	Mr. Krishna Chaitanya	The New Indian Express, Chennai
15	Ms. Maria Julia Oliva	Union for Ethical Bio-Trade, Netherlands
16	Dr. Meenakshi Bhardwaj	DuPont Pioneer, Hyderabad
17	Mr. N. Chidambaram	PhytoMycotus Pvt. Ltd., Mysore
18	Dr. P.Karnan	Rasi Seeds Project, Coimbatore
19	Mr. Onkar Singh	Bayer Bioscience Pvt. Ltd., Hyderabad
20	Mr. R. Sarathi Raja	Jasmine CE Pvt. Ltd., Chennai
21	Mr. S. Mohan Kumar	Senthil Papain & Food Products Pvt. Ltd., Coimbatore
22	Ms. Nithya Somasundaram	R.K. Dewan & Co., Chennai
23	Mr. S.M. Aravind	Kisankraft Ltd., Bangalore
24	Mr. Samarendra Sahoo	Kisankraft Ltd., Bangalore
25	Mr. Samrat Ganguly	K&S Partners, Chennai
26	Dr. Sanjay Nipanikar	Ari Healthcare Pvt. Ltd., Pune
27	Dr. Sanjay Tamoli	Abhinav Health Care Products Pvt. Ltd., Mumbai
28	Ms. Sathya Rani	ABTRI Biotech Private Ltd., Chennai
29	Mr. Selvaganapathy	Senthil Papain & Food Products Pvt. Ltd., Coimbatore
30	Mr. Tomal Dattaroy	Reliance Industries Ltd., Mumbai
31	Mr. T. Rabikumar	National Biodiversity Authority, Chennai
32	Ms. Vidya Vijayaraghavan	UNDP Global ABS Project, Chennai
33	Mr. Vignesh Murthy	Coromandel International Ltd., Cuddalore
34	Dr. Vijendra Prakash	The Himalaya, Bangalore

NEW DELHI

SL. NO.	NAME	AFFILIATION
1	Mr. Ashraf Arakkal	Maharashtra Biodiversity Board, Nagpur
2	Ms. Abhilasha P. Tripathi	APAC - Bayer Bioscience Pvt. Ltd., Gurgaon
3	Dr. Anjali Bose	Zytex Biotech Pvt. Ltd., Mumbai
4	Dr. Badari Narayan	Dabur India Ltd. New Delhi
5	Mr. Bhagirath Choudhary	South Asia Biotechnology Centre (SABC), New Delhi
6	Ms. Biba Jasmin	Federation of Indian Chambers of Commerce & Industry, New Delhi
7	Dr. C. Palpandi	Ministry of Environment, Forest and Climate Change, New Delhi
8	Mr. Chandra Mohan Verma	Patanjali Group, Haridwar
9	Ms. Dimple Wadher	Indfrag Biosciences Pvt. Ltd., Bangalore
10	Ms. Gaura Verma	Dabur India Ltd. New Delhi
11	Dr. Ghanashyam Patel	Green Medic Solution, Vadodara
12	Mr. Jitendra Jagota	AVON, Gurgaon
13	Mr. Kalyan Vadlamani	Federation of Indian Chambers of Commerce & Industry, New Delhi
14	Dr. M. Venkatachalam	Syngenta India Ltd., Pune
15	Mr. Manish Choudhary	United Nations Development Programme, New Delhi
16	Mr. Manish Deshpande	DuPont Pioneer, Gurgaon
17	Ms. Maria Julia Oliva	Union for Ethical Bio-Trade (UEBT), Netherlands
18	Ms. Namrata Singh	Centre for Agriculture and Bioscience International (CABI), New Delhi
19	Dr. Neeraj Kumar Tyagi	Savannah Seeds Pvt. Ltd., Gurgaon
20	Dr. Ninad Pandit	Zytex Biotech Pvt. Ltd., Mumbai
21	Mr. Nitin Joshi	Dow Agro Sciences India Pvt. Ltd., Mumbai
22	Dr. Pravir Deshmukh	India Business and Biodiversity Initiative (CII- IBBI), New Delhi
23	Ms. Purbitaa Mitra	Lakshmikumaran & Sridharan, Chennai
24	Mr. R. Vaithiyanathan	Syngenta India Ltd., Pune
25	Prof. R.S. Rana	National Biodiversity Authority
26	Ms. Rajani Jaiswal	Bioseed Research India, Hyderabad
27	Dr. Ranjeet Singh	MoEFCC (CS-III Division) Biodiversity, New Delhi
28	Dr. Rekha Chaturvedi	University of Delhi
29	Ms. Ruchi Pant	United Nations Development Programme, New Delhi
30	Mr. S. S. Rasaily	Uttarakhand Biodiversity Board, Dehra Dun
31	Dr. Sandhya Agarwal	Metahelix Life Sciences Ltd., Bangalore
32	Ms. Sangeeta Mendiratta	Bayer Crop Science Ltd., Gurgaon
33	Dr. Sanjeev Kalia	Bayer Crop Science Ltd., Gurgaon
34	Mr. Shivendra Bajaj	Agri Innovation, New Delhi
35	Mr. P. J. Suresh	Monsanto India Ltd., Hyderabad
36	Mr. R. Surya Rao	Syngenta India Ltd., Pune
37	Mr. Umesh Kathuria	AVON, Gurgaon
38	Ms. Vindhya S. Mani	Lakshmikumaran & Sridharan, Chennai
39	Mr. Vivek Vishal	Mahyco Seeds Ltd., New Delhi

GIZ TEAM

SL. NO.	NAME	AFFILIATION
1	Dr. Aeshita Mukherjee	ABS Partnership Project, Pune
2	Dr. Geetha Nayak	ABS Partnership Project, Chennai (NBA office)
3	Dr. Konrad Uebelhör	Indo-German Biodiversity Programme, New Delhi
4	Mr. Mithilesh Kandalkar	ABS Partnership Project, Pune
5	Ms. Patricia Dorn	Indo-German Biodiversity Programme, New Delhi
6	Dr. Poonam Pande	Private Business Action for Biodiversity, New Delhi
7	Ms. Priya Narayanan	ABS Partnership Project, Chennai (TNBB office)
8	Mr. Ravindra Singh	Indo-German Biodiversity Programme, New Delhi
9	Dr. Shameeka Rao	ABS Partnership Project, Chennai (NBA office)
10	Mr. Shreyas Bhartiya	ABS Partnership Project, Nagpur (MSBB office)

ANNEXURE 2 : FEEDBACK FROM THE PARTICIPANTS

What did you like most about the workshop?

- Practical interaction with regulators and functioning of NBA
- Interactive sessions and practical approach
- Design and participatory nature of the workshop
- Openness of authorities
- Openness to industry suggestions
- Group discussion and sharing experiences
- Case studies and practical, interactive sessions
- Logistical arrangements
- Opportunity for stakeholders to discuss their issues with the authorities
- NBA's willingness to respond queries from the participants
- Open house engagement
- Moderation and case studies
- Highly interactive
- Open discussion on interpretation of statutes
- Interactive and well-moderated
- Comprehensive introduction to ABS, helping to understand concepts
- Useful, informative and interactive
- Interactive discussions, practical exercises and legal provisions
- Structure of workshop and engagement
- Open discussion and transparency
- Case studies were interactive and fruitful
- Group activities and openness
- Willingness of authority to learn from stakeholders

Do you have any suggestions for improvement?

- Involve more participants fromuniversities, SBBs and other regulatory bodies
- Sessions on sector-specific issues in the workshop
- In-depth discussions on interpretation and scope of BD Act.
- Need to address definitions of "biological resources" and "value added products" and clarify Sections 3.2, 38 and 40
- Workshop focusing on legal aspects and e-filing
- Sessions on amendments and new notifications
- More clarity on ABS process and functioning of NBA
- More discussions on closed cases as well as pending applications
- Make standard operating procedure for all applications
- Share report and minutes of the meetings in NBA

- NBA should be open to suggestions and change
- Gather suggestions from industry on topics to be discussed
- Focus on research tools and use of pathogens
- Consider workshop recommendations for implementation
- Identify issues and recommendations to follow-up within certain timelines
- Involve more participants from sector other than plant science
- NBA should be open to suggestions and change

What other issues should future workshops address?

- Follow-up from workshop with FAQs
- Benefit sharing for manufacturing companies and traders
- Practical information for filling up NBA applications and e-filing
- Microbial products
- Sector-specific workshops
- Wider stakeholder participation including other government regulators
- More interactive sessions with additional stakeholders
- More information on implementation of ABS
- Interplay between BDA and other laws and regulations
- Scope of BDA, IPRs and PVPFRA
- Clarity on Normally Traded as Commodities (NTAC) and Value-added products (VAPs)
- ABS and research
- Short training courses conducted on ABS application procedure to reduce miscommunication
- ABS and germplasm exchange between Non-Profit Organisations and ICAR Institutes
- ABS and different breeding techniques
- Identifying top two or three issues and set a time line for resolution
- Priorities set by each of the groups

Any other comments or suggestions?

- BD Act as an instrument to address the issue of adulteration of raw materials by traders
- Include IP officials and State Biodiversity Boards, public research institutes and other governmental organisations in the workshop.
- Very well organised, extremely informative workshop.
- Excellent workshop, it added value to my understanding of NBA's functioning
- FAQs and minutes are important
- Periodical webinars, consultations via video conferences
- Please organise workshop on PVPFRA and BD Act.

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