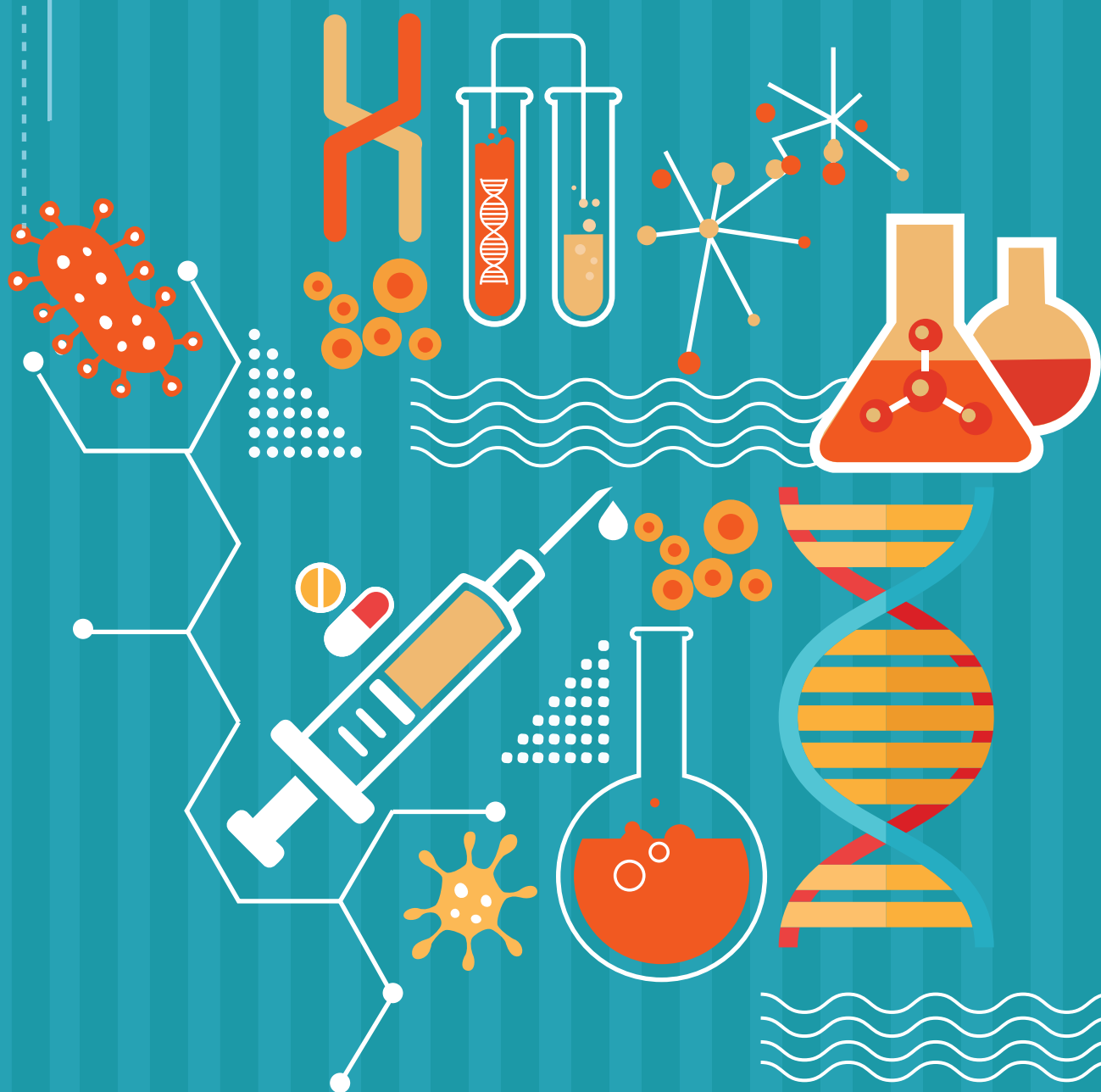




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BUSINESS DIALOGUE ON ABS COMPLIANCE IN INDIA
BIOTECH SECTOR
ACCESS AND BENEFIT SHARING
PARTNERSHIP PROJECT

2019

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BUSINESS DIALOGUE ON ABS COMPLIANCE IN INDIA: BIOTECH SECTOR

ACCESS AND BENEFIT SHARING PARTNERSHIP PROJECT

21 January 2019 | Hyderabad

23 January 2019 | Chennai

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ACCESS AND BENEFIT SHARING 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 in partnership 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 employs 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

The topic of “fair and equitable benefit sharing” also known as “Access and Benefit Sharing” or in short, ABS has garnered national interest following the Uttarakhand High Court’s judgement on Divya Pharmacy case in December 2018. The Court concluded that the petitioner (Divya Pharmacy) being the user of biological resources for commercial purposes is bound pay the ABS amount as per the provisions of the Biological Diversity Act, 2002 to the State Biodiversity Board.

India has well established legal instruments for the implementation of ABS since 2004. However, lack of understanding of its scope, applicability and legal principle have delayed its implementation. The ABS Partnership Project—implemented by National Biodiversity Authority (NBA), Chennai, Ministry of Environment, Forest and Climate Change (MoEFCC), New Delhi and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, New Delhi—has been proactively engaging with users of biological resources since 2018, through workshops and dialogues to strengthen the understanding of ABS compliance in India among commercial users of biological resource and knowledge associated with it.

The National Biodiversity Authority (NBA) with the support of Access and Benefit Sharing Partnership Project organised business dialogues with the bio-tech sector to – (i) identify the scope of ABS on sector-specific activities and user obligations, (ii) identify challenges for the biotech sector and identify joint solutions to fulfil the obligations mandated under the ABS provisions of the Biological Diversity Act, 2002.

The participants informed the regulators about the various ways in which the biological resources are used in biotech sector that does not amount to “utilisation” as defined in the Biological Diversity Act, 2002. For example, biological resources used as diagnostic/testing tools to fulfil statutory/regulatory requirements to test against another biological material or disease or germplasm exchanged as a part of core business practice among sister companies. It may be considered to exempt these activities from the purview of the Act. The participants expressed the need for the Guidance Documents for ABS compliance that guide the applicants on the scope of activities, applicable definitions and application process.



I BACKGROUND

The ABS Partnership Project—implemented by National Biodiversity Authority (NBA), Chennai, Ministry of Environment, Forest and Climate Change (MoEFCC), New Delhi and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, New Delhi—has been proactively engaging with users of biological resources since 2018, through workshops and dialogues. Based on the outcome of the dialogues held in April 2018, a second round of dialogues with users and regulators was held in January 2019. These dialogues focused mainly on sector-specific issues involving biotechnology and agri-biotechnology companies. Specifically, the dialogue focused on: (i) identifying the scope of ABS on sector-specific activities and user obligations, (ii) identify challenges for the biotech sector and identify joint solutions to fulfil the obligations mandated under the ABS provisions of the Biological Diversity Act, 2002.

II BUSINESS DIALOGUE WITH BIOTECHNOLOGY SECTOR

The dialogues were held on 21 January 2019 at Hyderabad and 23 January 2019 at Chennai; and were moderated by Ms. Maria Julia Oliva, Deputy Director, Union for Ethical BioTrade, The Netherlands.

Hyderabad

Dr. Konrad Uebelhör, Director, Indo-German Biodiversity Programme, GIZ, India welcomed Dr. Achalender Reddy and other members of State Biodiversity Boards and company representatives. He mentioned that during the two workshops held in Chennai and New Delhi in 2018, it was suggested by the participants to organize sector-specific workshops to discuss specific aspects of ABS implementation for the biotechnology sector. Biotechnology is a fast-emerging sector that requires additional attention concerning ABS compliance. Industrial biotechnology, which includes chemicals, plastics, cosmetics, textiles, bioprocessing, bioenergy, etc. presents unique conditions, and it is essential to note that nature is often the source for raw materials in the sector. Industrial products reach markets within 2–5 years, which is faster than the pharmaceutical industry, and implementing the Nagoya Protocol in these situations is more challenging. When CBD was adopted in 1992, many biotech activities did not exist. The development of legislative frameworks cannot keep pace with the speed of technological advancement, and awareness of the applicability of ABS is low, despite increased demand for IRCC when trading with the European Union.

Dr. Uebelhör also highlighted that India receives a lot of international attention regarding ABS as it is one of the first countries to establish national legislation. GIZ is proud to support the National Biodiversity Authority and three State Biodiversity Boards of Maharashtra, Tamil Nadu, and Uttarakhand in strengthening the ABS implementation through the Access and Benefit Sharing Partnership Project. GIZ has also been supporting countries from Asia, Africa, to the Americas. GIZ is wholly owned by the federal republic of Germany and supports the development policy of the German Government, especially in achieving Sustainable Development Goals around the world. GIZ provides technical cooperation, whereas sister organization KfW supports through financial cooperation.

He wished deliberations to contribute towards ABS implementation.



Dr. Achalender Reddy, IFS, PCCF, and Director, Centre for Innovations in Public Systems (CIPS) in his inaugural address, talked about the progress made by the National Biodiversity Authority in streamlining the ABS implementation through various notifications and joint actions with the Patent office. Creating awareness on ABS among multiple stakeholders is crucial at this stage to speed up the implementation. He complimented NBA and GIZ India for providing a forum for businesses to interact with regulators. He encouraged the company representatives to propose solutions that are admissible within the boundaries of the law.

Chennai



Mr. T. Rabikumar, Secretary, NBA, welcomed the participants. In this address, he thanked GIZ India and noted that this is the fourth in series of business dialogues held since 2018 under the Access and Benefit Sharing Partnership Project. He also said that it was encouraging to see the participation of the companies in these business dialogues. The National Biodiversity Authority is keen to understand the ABS experience of users and obtain feedback from all stakeholders. These business dialogues will specifically focus on compliance requirements and application procedure in practice in the biotech sector. The National Biodiversity Authority is committed to facilitating the dialogue with companies to achieve the objectives of ABS. He also encouraged companies to include ABS as a part of their corporate policy. Since the adoption of the Nagoya Protocol, many countries have put in place a system to monitor the import of biological resources, and companies are beginning to realize that compliance with ABS also promotes their brand images. Although there may not be practical solutions to address all challenges of compliance, the NBA remains committed to facilitating compliance through dialogues. The dialogue is not intended to provide the participants with defined solutions to the challenges arising due to ABS implementation. However, the approach of the National Biodiversity Authority on dealing with ABS applications.



Dr. Konrad Uebelhör, Director, Indo-German Biodiversity Programme, GIZ, India welcomed Mr. T. Rabikumar, Dr. A. Ashraf, Member Secretary, Maharashtra Biodiversity Boards, Mr. A. Udhayan, Secretary, Tamil Nadu Biodiversity Board, and company representatives. He also acknowledged that it was befitting to have the dialogue on Access and Benefit Sharing hosted in MS. Swaminathan Research Foundation in Chennai.



Professor M.S. Swaminathan addressed the participants in Chennai. He recounted that the first draft of the PPVFRA was drafted in this Foundation (M. S. Swaminathan Research Foundation, Chennai). Most farmers in India are small marginal farmers, and their capacity to buy seeds every year is low. Hence, the traditional variety of seeds need to be maintained to support farmers. He also acknowledged the role of women in biodiversity conservation and emphasized benefit sharing is rewards for primary conservers. Many countries look to India to ensure equity in access, which is more important with gene modification. He complimented the National Biodiversity Authority and companies for engaging in a dialogue on ABS implementation.

Dr. B. Meenakumari, Chairperson, National Biodiversity Authority, **Dr. Sujata Arora**, Advisor, MoEFCC, and **Ms. Amarjeet Ahuja**, IAS (Rtd) were also in attendance.



III OVERVIEW OF THE DIALOGUE ON ABS

1. India as both provider and user of genetic/bio-resources



Dr. Geetha Nayak, Team Leader, Access and Benefit Sharing Partnership Project, GIZ India, in her presentation, provided an overview of the framework for ABS implementation in India. The ABS framework in India¹ is guided by the following:

- The Biological Diversity Act, 2002
- The Biological Diversity Rules, 2004
- Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 (with effect from 21 November 2014)
- Notification on Normally Traded As Commodities under Section 40 (with effect from 4 April 2016)
- Notification to exempt Annex I of ITPGFRA (with effect from 17 December 2014)
- The Patent (Amendment) Act, 2002

CBD and Nagoya Protocol distinguishes two types of countries- Provider and User countries. Most countries are both user and provider of genetic resources and associated knowledge. User countries have to designate checkpoints to monitor the utilization of genetic resources, and users who obtain genetic resources from other countries have to exercise “due diligence” and are obliged to declare compliance with the law of the country from where genetic resources have been obtained. India is both a user and a provider country. While India has access requirements enshrined in the law, checkpoint(s) to monitor the utilization of genetic/bio-resources are yet to be designated. With the designation of checkpoint(s), it becomes increasingly crucial for the companies to be transparent. The Act mandates consultation with the community before the access approvals provided by the National Biodiversity Authority or the State Biodiversity Boards. Dr. Nayak also urged companies to trace the supply chain of the resources they access and provide information on the geographical location of the collection in form-1 to enable the NBA and the respective SBB to disburse the benefits to providers of the resources appropriately. This will help regulators to implement ABS in both letter and spirit.



¹ States have its own Biodiversity Rules. Please consult website of National Biodiversity Authority for a complete list of Rules and notifications.

2. Access and Benefit-sharing – key concepts and principles



Ms. Maria Julia Oliva, Deputy Director, Union for Ethical Bio-Trade, presented a talk on key concepts and principles of ABS. The core principles of ABS are guided by the Nagoya Protocol, which was adopted in 2010, entered into force in 2014, and currently has over 110 countries party to it. While its scope is defined by CBD, Nagoya Protocol clarifies and builds on concepts and requirements.

The three pillars of ABS – **Access** is subject to Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), **Benefit sharing** is decided on a case to case basis, many countries have established some parameters for determination of benefit sharing and **Compliance** is the obligation of the countries to monitor biodiversity utilization in their countries.

She also highlighted that principles of CBD and Nagoya Protocol are not directly applicable, but it provides the framework for the establishment of national legislation for ABS. Currently, there are 54 countries with access requirements, and this number is set to increase in the coming years.

The scope of Access and benefit-sharing requirements differ from country to country (Annexure I). This presents significant challenges to the business operations of companies, especially when it is dependent on bio-resources from many countries. Limited awareness of applicability, lack of mechanisms to establish traceability, and complexity of interactions between various stakeholders has led to slow progress in ABS implementation. She highlighted the need for dialogues between regulators, providers, and users to identify joint solutions.

IV PRACTICAL EXPERIENCE FROM COMPANIES ON ABS COMPLIANCE IN INDIA

Biotechnology companies in India are centered mainly on pharmaceutical R&D, Agri-biotech (seed variety development, crop protection), and other biologicals (diagnostics, vaccines and biotherapeutics, DNA technology, genomics, etc.). There are also wide range of institutions from gene banks, laboratories operational under Govt. of India, agencies, institutions such as Council of Scientific and Industrial Research (CSIR), the Indian Council of Agricultural Research (ICAR), the Department of Science and Technology and the Department of Biotechnology, the Indian Council of Medical Research (ICMR), etc., to private companies both of Indian and multinational origin are all contributing to the growth of biotech sectors in India. Cross collaboration for R&D and the exchange of germplasm takes place as a matter of routine practice among public and private actors. However, following the adoption of the legal framework on ABS in India, there have been uncertainties, especially concerning access procedures for germplasm and “biological resources,” and a range of regulated activities such as transfer of research results, third party transfer of biological resources and IPRs. Participants deliberated on various issues arising out of a lack of clarity on the definitions, the scope of ABS, regulated activities under ABS, etc.

A summary of the discussions and recommendations is presented below:

a) Definitions & scope of ABS provisions

- What is a biological resource in context of bio-tech sector?
- The Act broadly classifies biological resources in Section 2(c), however, in biotechnology sector the companies develop their own inputs materials through a patented process of characterization and evaluation to bring the genetic materials into a usable form
- Microbial cultures are grown in solution/medium of living or chemical forms. Cultures can be consortia of microorganisms.
- Mother cultures (formulations) are most often developed by companies and hold proprietorship
- Antigen is produced by the virus in the blood. For an applicant, is the access application to be filed, for the antigen or the blood sample? Does it come under the definition of biological resource (BR)?
- Imported bio-resource as a screening or testing tool.
- Germplasm exchange is a part of core business and regular practice in biotech sectors
- Recombinant genes
- Biological resources used as diagnostic/testing tools to fulfill statutory/regulatory requirements
- Seeds as a bio-resources – does the company need approval for its cultivation? Commercial utilization case of seed is considered as commodity trade under a different law.
- A human genetic resource is exempt from ABS provisions. However, the pathogens extracted from the blood sample is currently being considered as a biological resource.
- Accessing human fecal samples/skin to study pathogens
- Is the crude extract of microorganisms exempted, or does it fall under the definition of value-added product?

Recommendations from the participants:

- Development of explanatory notes along with illustrative examples to guide what falls under the definition of biological resources
- Examples of value-added products
- The exemption given to biological resources when used as a testing tool to fulfill statutory/regulatory requirements
- Conditional approvals to be granted for accessing specific “biological resources,” which are used for testing, characterization, etc.
- Clarity on whether seeds considered as bio-resource or commodity is needed.

b) What activities are regulated?

- The biotechnology involves characterization, evaluation, formulation, extraction, purification, testing, and clonal propagation, gene technology to be carried as a matter of routine activity. Do these activities come under the definition of research² or bio-survey and bio-utilization?³

² Section 2 (m) “research” means study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use;

³ Section 2(d) “bio-survey and bio-utilization” means survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterisation, inventorisation and bioassay;

- Germplasm/microbial cultures/mother cultures have been developed over decades and exist within industry collections. Does the company need to obtain prior approval of the NBA to conduct any activity?
- Each company or research institution rely on biological resources in distinct ways and carry out R&D activities, most often require the use of end product⁴ developed by an entity as input materials for a different R&D project altogether. Does this come under the purview of the Act?
- Bio-resources are used as research tools to either test products or as a regulatory requirement (tested against another biological material or disease). E.g., a plant is used to develop a hybrid and then check the product against pests and diseases currently distinguished as two activities.
- Testing of molecules on bio-resources. Tests for regulatory approvals not required in some countries (maybe exempted)
- Check “variety seeds” are not used for breeding. However, it requires prior approval for Section 3(2) entities.
- Formulations and extraction processes are currently considered as research under the Act.
- Germplasm was originally Indian but is now stored abroad in seed banks. Does the company require the permission of the NBA to be able to carry out R&D activities on such germplasm?

Recommendation from participants

- Define a clear scope for activities by considering sector-specific needs. Explanatory notes are required in this regard.
- Bio-resources are used as research tools to either test products or as a regulatory requirement may be given exemption
- Development of sector-specific SOPs to guide what comes under regulated activity and how benefits are shared
- The development of a hybrid and subsequent testing against pests and diseases are considered two activities and require the approval of the NBA twice. Options to apply once may be allowed and appropriate changes to be made in the Form-1.

c) Timelines, access and application procedure

- Applicability of ABS provisions for the materials accessed before the enactment of BD Act
- A lot of investment and time is required to turn genetic resources into usable resources in biotech sectors. Shortening the time needed gives companies a pricing advantage. However, due to delay in obtaining approvals will disrupt business operations and incur significant losses to companies.
- The biotechnology sector is driven by the use-value of certain traits rather than genetic materials per se and requires time and huge investment to characterize and evaluate and test the traits and establish the use-value.

⁴ Section 2(f) “commercial utilization” means end uses of biological resources for commercial utilization 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;

- The process of plant breeding involves selection, then breeding with several germplasm (genetic lines), resulting in the development of a new variety. Since the enactment of the Biological Diversity Act, 2002, it mandates obtaining prior approval for accessing BR. However, the PPVFRA doesn't require any approval in case of the desired variety.
- Clarity on whether the NBA exempts the desired variety if it is bred through conventional breeding.
- Clarity on whether NBA exempts the desired variety if all parental lines (germplasm) used in the development of said variety sourced from outside India
- It is unclear whether the permission required in case seed variety developed using germplasm (accessions) exempted under ITPGFRA
- Whether permission is required for a variety expired under PPVFRA exemptions.
- For companies to maintain a competitive edge, it requires varieties to be changed more frequently to maintain resistance to pests and diseases. Timelines determine business operations.

Recommendations from participants:

- Explanatory notes/FAQs addressing temporal scope of ABS provisions
- Due consideration while negotiating ABS amount – by accounting for the capital as well as time investment in turning genetic resources them into usable resources
- Regularise and provide an exemption for germplasm exchange as a matter of routine practice
- Regular meetings and dialogue with regulators to discuss the emerging trends and developments in biotech sectors
- Some material will cease to exist after a period of time, such as diseases that occur suddenly and exist a short duration. Consider providing conditional/tatkaal approvals for the development of a vaccine to deal with emergencies.
- Establish a procedure to claim an exemption under conventional breeding and value-added products
- Explanatory notes on provisions of Act for the benefit of companies (not as an academic exercise)
- Sector-specific/technology-specific guidelines and Guidance Document issued by the NBA to guide on the scope and application procedure
- Benefit-sharing under the Biological Diversity Act, 2002, maybe exempted when done under PPVFRA.
- NBA to establish a roster of ABS experts for companies to seek guidance.
- Since there are wide specific variations, it may help to include industry representatives in expert committees in an advisory capacity.

d) Online applications

Participants also provided feedback on the online portal for submitting access applications. Participants acknowledged that the online process had eased the application process, but the process should be dynamic. Following suggestions made by the participants:

- Provision to upload an excel file rather than fill it one by one
- Payment gateways are not smooth
- Make it easy for uploading data
- Increase bandwidth as the site gets clogged up
- Online application status (as in any visa applications)
- Provisions for uploading additional documents

V SUGGESTIONS FROM THE REGULATORS

Mr. T. Rabikumar addressed participants in Hyderabad via Skype and answered questions related to the application procedure and scope of ABS. He participated in business dialogue in Chennai and interacted with participants. He also reiterated the commitment of the NBA to continue to address concerns raised by the participants in Hyderabad as well as Chennai. He made the following suggestions to companies:

- Conduct focussed group discussions on arriving at a consensus on a definition of terms such as conventional breeding, value-added products and provide recommendations to NBA
- Companies to actively take part in stakeholder meetings and awareness workshops.
- Create awareness on ABS aspects among other companies and industry associations
- He also thanked participants for their recommendations. He highlighted efforts of the NBA to refine the functionality of the online portal to provide real-time online status. He also accepted the request of companies to conduct a workshop on the e-filing of applications.

Mr. T. Rabikumar thanked GIZ for organizing two business dialogues, and he also thanked Prof Swaminathan, MSSRF, Dr. Konrad Uebelhör, and Ms. Maria Julia Oliva.



VI CONCLUSIONS AND WAY FORWARD

Fast and emerging technological advancement in a sector such as biotech requires both regulators and users to promote joint actions to facilitate the objectives of ABS. This calls for more frequent direct engagement and trust-building exercises. The procedure for compliance should be flexible, to be able to adapt and serve to fulfil the objectives of ABS quickly. It may be worthwhile to consider developing sector-specific guidance documents – which serves as a guide for the capacity development of regulators to understand nuances of the sector and vice versa. It was also agreed to conduct a workshop on e-filing of ABS application in Feb 2020. The workshops served as a platform for companies to strengthen their understanding of requirements and procedures under the Biological Diversity Act, its Rules and Guidelines, as well as learn and draw suggestions for improvement from the practical experiences of businesses in navigating the legislation. The workshops engaged over 90 participants at Hyderabad and Chennai representing different companies working in India.



ANNEXURE I: ACCESS REQUIREMENTS AND DIFFERENT APPROACHES

Access requirements?	<ul style="list-style-type: none"> Germany, Netherlands no access requirements France, Brazil, South Africa, India regulate access
Which resources ?	<ul style="list-style-type: none"> Only indigenous Or native Also exotic with unique properties 'Occurring in the country' Wild or cultivated
Which activities ?	<ul style="list-style-type: none"> Certain or all types of R&D Formulation or product development Trade or commercialization
Which stakeholders ?	<ul style="list-style-type: none"> One-stop shop Various authorities PIC and MAT with local actors
Which benefit sharing ?	<ul style="list-style-type: none"> Pre-established parameters Case-by-case Non-negotiable percentages

	ABS in France	ABS in Brazil
Which resources?	<ul style="list-style-type: none"> Wild and native Not Annex I FAO Treaty Possible system for cultivated, not yet pursued Traditional knowledge associated to genetic resources – only if not widely disseminated 	<ul style="list-style-type: none"> Native or introduced if distinctive properties Not Annex I FAO treaty Specific approach for food and agriculture Traditional knowledge associated to genetic heritage – even if widely disseminated
Which activities?	<ul style="list-style-type: none"> Access for utilisation of genetic resources New utilization 'Valorization' = Subsequent applications? Study and valorization of TK 	<ul style="list-style-type: none"> Research or technological development Information for traceability Access to TK – even through secondary sources
Which stakeholders?	<ul style="list-style-type: none"> Ministry of Foreign Affairs Ministry of Environment Management authorities Local authorities Local communities 	<ul style="list-style-type: none"> Electronic Registration System (SisGen) Council for Management of Genetic Heritage National Benefit Sharing Fund Indigenous peoples and local communities
Which procedures?	<ul style="list-style-type: none"> Application Consultation Agreement Authorization 	<ul style="list-style-type: none"> Registration Notification Benefit sharing agreement Payments into fund

ANNEXURE II: LIST OF PARTICIPANTS

HYDERABAD

SL. NO.	NAME	AFFILIATION
1	Dr. Achalender Reddy	Centre for Innovations in Public Systems, Hyderabad
2	Ms. Anamika Dalui	International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Hyderabad
3	Ms. Anamika Dass	Bharat Biotech International Ltd., Hyderabad
4	Ms. Anitha Chowdary Doddala	Valagro Biosciences Ltd., Hyderabad
5	Ms. Anuradha Verma	Metahelix Life Sciences Ltd., Bangalore
6	Ms. Aruna Nadipilli	Kaveri Seed Company Ltd., Secunderabad
7	Mr. A.S.P. Ranga Prasad	CSIR-Indian Institute of Chemical Technology, Hyderabad
8	Mr. Bhagirath Choudhary	South Asia Biotechnology Centre (SABC), New Delhi
9	Dr. Brajesh Barse	International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi
10	Dr. Chiranjit Maity	Advanced Enzymes Technologies, Thane
11	Dr. Deepti Sood	Advanced Enzymes Technologies, Thane
12	Mr. G. Babul Reddy	SOM Phytopharma (India) Ltd., Hyderabad
13	Mr. G. Sailu	Telengana State Biodiversity Board, Hyderabad
14	Dr. Hampaiah Ralladoddi	Andhra Pradesh Biodiversity Board
15	Mr. Harish Gandhi	Independent consultant
16	Dr. Keerthi Kiran Bandru	Humboldt University, Berlin
17	Ms. Kotha Laxman Prasad	Laurus Labs Ltd., Hyderabad
18	Mr. Manish Kumar	Bharat Biotech International Ltd., Hyderabad
19	Ms. Maria Julia Oliva	Union for Ethical Bio-Trade, Netherlands
20	Mr. Onkar Singh	Bayer Bioscience Pvt. Ltd., Hyderabad
21	Mr. Parag Agarwal	VNR Seeds Pvt. Ltd., Raipur
22	Mr. Phani Kumar	DuPont, Hyderabad
23	Ms. Prabha Nair	Freelance consultant
24	Ms. Rajani Jaiswal	Bioseed Research India- D.C.M. Shriram Ltd., Hyderabad
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26	Mr. Rajesh Sivipally	National Biodiversity Authority
27	Dr. Rama Rao	HM. Clause India Pvt. Ltd., Hyderabad
28	Ms. Rohini Wayal	Godavari Biorefineries Ltd., Mumbai
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36	Mr. Shaklain Khurshid	Biological E Ltd., Hyderabad
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SL. NO.	NAME	AFFILIATION
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40	Mr. Sukumar Karuganti	AgrLife, Hyderabad
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47	Dr. Vinod Kumar Yadav	Bisco Biosciences Pvt. Ltd., Secunderabad
48	Mr. Virender Singh	Karnataka Biodiversity Board, Bengaluru
49	Mr. Vishwanath Patil	HM. Clause India Pvt Ltd., Hyderabad
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9	Mr. Shreyas Bhartiya	ABS Partnership Project, Nagpur
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ANNEXURE III: FEEDBACK FROM THE PARTICIPANTS

What did you like most about the workshop?

- Interactive approach, productive and useful.
- Structure of the workshop
- Opportunity to share various perspectives and concerns of the industry with NBA and participants from diverse sectors
- Willingness of NBA to address each query transparently and engage in a discussion.
- Interaction on problems faced in application process
- Commendable effort to bridge gaps between authorities and stakeholders
- Concept of ABS
- Clarity provided on the Biodiversity Act
- Q&A session

Do you have any suggestions for improvement?

- Organize similar workshop in New Delhi
- Include successful ABS cases
- Share agenda and background information in advance
- More information about how industry in other countries are dealing with ABS
- Active participation of policymakers and NBA
- Sector-specific workshops
- More time for Q&A
- Clarification of “bio-resource” and “value added product” by giving examples
- More clarity on filling-up applications
- Clarity on ABS regulations
- Bring in BMC to explain how it addresses ABS
- Collect specific questions in advance to streamline discussions
- Include panel discussions led by subject matter experts
- NBA should be open to suggestions for change
- Use case studies
- Start with summary of outcomes of previous workshops
- Share information on approach and considerations taken by Committee making decisions on applications
- Organise events at different levels – from beginner to expert
- Workshops focused on specific technology areas
- Clarify what happens to questions and suggestions posed during the workshop
- Concrete examples of how ABS process has contributed to biodiversity conservation
- Suggestions on process for manufacturing companies to address ABS
- Arrange meetings among traders
- Organise workshops in local language

Some participants interpreted the question as referring to suggestions on ABS requirements and procedures. They mentioned suggestions such as:

- Creating helpdesk on NBA processes
- Guidance on interpretation of terms
- Consistent interpretations of Biodiversity Act
- Develop sectoral guidelines on ABS
- Improve time required for approvals
- Include FAQs in NBA website
- NBA should address stakeholders concern and support changes in Biodiversity Act
- Simplification of ABS process

What other issues should future workshops address?

- Online application platform
- Include more government officials
- Follow-up from previous workshops specifically questions and action plans
- NBA basic information and materials
- How to make application process shorter and more user-friendly
- NBA processes and communication
- Issues for university researchers
- Benefit sharing guidelines
- Plant genetic resources for food and agriculture
- Exceptions in Biodiversity Act
- Definitions and their interpretation
- Provide clarity on “conventional plant breeding” in context of the Biodiversity Act
- Information dissemination
- Plant genetic resources for food and agriculture
- ABS implications for seed sector
- More clarity on NTACs and which species to include in it
- Addressing ABS within company policies and procedures
- Non-monetary benefit sharing
- Addressing practical difficulties with traceability
- Taking example and to go through the whole application process with participants
- Longer (2-3 days) workshops

Any other comments or suggestions?

- Well-structured programme. Discussions are informative.
- Workshops like this are important to understand stakeholders' perspectives and improve implementation
- Develop online platform for anonymous discussion of these issues
- Organise such workshops periodically to maintain awareness
- For seed sector, need to have two-day workshops for training and awareness at least twice a year
- Proceedings should be formalised and communicated to participants and regulators

- Action points should be captured and communicated
- Involve more companies working with raw materials
- More, regular meetings like this are needed
- It would be good to have NBA certificates for participants
- Formalize proceedings and send action taken by NBA within 6-8 months
- Bring more international experts to share comparative experiences
- Consider role of private sector in conserving biodiversity
- Participation of industry associations should be mandatory
- Provide participants with update on follow-up before convening next workshop

ANNEXURE IV: FOLLOW UP WORKSHOPS ON E-FILING OF ABS APPLICATIONS HELD AT CHENNAI IN FEBRUARY 2019

The National Biodiversity Authority (NBA) launched an online portal in 2017 for submitting applications to access biological resources. Since then NBA has received over 600 e-applications from companies and researchers. During the business dialogues held in Hyderabad and Chennai in January 2019, participants requested the ABS Partnership Project to organise a workshop on e-filing process, particularly on the information to be furnished for different types of access and related documents.

The Access and Benefit Sharing Partnership Project in collaboration with National Biodiversity Authority, Chennai organised two half-day workshops on 14th February 2019 at the National Biodiversity Authority, Chennai.

Mr. T. Rabikumar IFS, Secretary, National Biodiversity Authority, Chennai addressed the participants in these workshops. He invited participants to share their experience and highlight the challenges they face while submitting applications through the online portal, in order to improve its functionality. He stated that applicants will soon be able to check the status of their applications through the NBA website.

Dr. K.P. Raghuram, Technical Officer – Benefit Sharing, National Biodiversity Authority provided a brief introduction into the Biological Diversity Act, 2002 and its ABS provisions. He provided step-by-step guidance on the application process for filing various applications, i.e. Form-I, II, III and IV through the online portal. A mock e-application form was initiated, and the participants were provided with opportunities to clarify their queries throughout the session. He also highlighted the need for providing appropriate attachments as requested in the forms.

The workshops were attended by 28 participants from various entities accessing biological resources from India. The participants provided several suggestions for improving the functionality of the online portal for filing access applications. Participants illustrated an example—when the biological resources are accessed from multiple locations or sources. Currently, the online portal has only the option of selecting each location from a drop-down menu rather an option to upload a file with all the required information. Participants mentioned that these entries sometimes run up to thousands. The suggestions and feedback received from the participants were noted by the officials from National Biodiversity Authority to maintain a user-friendly e-filing process.





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