

Ministry of Environment, Forest and Climate Change Government of India





Regulation of Access to Biological Resources and Benefit Sharing in India

An Analytical Study

Gayathri Shanbhag N, B. Meenakumari & Rai S. Rana Centre for Biodiversity Policy and Law (CEBPOL) National Biodiversity Authority, Chennai











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Fig. 1 India's ten bio-geographic regions: Rich in bioresources, and associated traditional knowledge, reflecting India's bio-wealth.

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Captions for photographs on the cover page:

- 1. National Gene bank (underground) for long-term storage of crop genetic resources at the NBPGR, New Delhi.
- 2. Genetic variability in size and shape of brinjal (aubergine), native to Indian region.
- 3. Orange lichen from Madhya Pradesh, potential source for developing anti-cancer drugs.
- 4. Vechur cow, native to Kerala state, valuable for genetic adaptation to climate change.

Executive Summary

Access to biological resources (bioresources) and benefit sharing are regulated in India under the Biological Diversity Act, 2002 (BD Act). Its implementing mechanism involves a 3-tier system comprising the Central Government and National Biodiversity Authority (NBA) at the national level, State Biodiversity Boards (SBBs) constituted by the State Governments and Biodiversity Management Committees (BMCs) established at the village level. Their roles are well defined and non-overlapping. This Analytical Study Report, prepared under the CEBPOL project, deals primarily with implementation of the BD Act's Sections 3, 4 and 6 by the NBA until 1st October, 2017, its 15th Foundation Day.

Applications received by the NBA during this period have been analysed with a view to developing comparative information on the users of bioresources and associated traditional knowledge on the one hand and it's systematic study across major user sectors on the other. The work done during this study involves scrutiny of all the applications, tabulation and analysis of the data submitted by the applicants seeking NBA's approval.

The NBA Secretariat has received and processed 1,853 applications during the period under this study. Out of these, 1,168 have been approved (63%) on a case by case basis, leading to signing of 554 benefit sharing agreements (30%) by the applicants with the NBA on mutually agreed terms.

Results have been presented in tabular form and also depicted graphically for easy comprehension. This study provides an insight into NBA's accomplishments in regulating the four activities mandated to it.

The study shows that Indian applicants form over 74% of the total number while the rest comprise foreign citizens/entities, non-resident Indians and Indian companies/ organisations having foreign participation in their share capital or management. It further reveals that the applications in Form III (seeking IPR over products/processes based on research conducted on Indian bioresources and associated traditional knowledge) make up nearly 73% of the total number of applications. This category is

followed by Form I (Access to Indian bioresources by foreigners) with 20%, Form IV (third party transfer) with 4% and Form II (transfer of research results to foreigners) with just 3%. A major factor contributing to the skewed distribution appears to be the Indian Patents Office's requirement for disclosure of the origin of bioresources used in developing the product seeking IPR and the legal need for obtaining NBA 's prior approval where Indian bioresources have been used.

Among the six major sectors using bioresources under study, pharmaceuticals led with 55% of all applications, research sector had 19% share, nutraceutical products 15% while the rest together had 11% share of the total number.

The authors expect that this Study Report, presented in easy-to-comprehend graphic form, may help the decision makers in appreciating the information on key features of implementation of the BD Act by NBA during 14 years after its establishment. It may also assist the concerned authorities in re-orienting implementation of the present ABS Regulatory System in tune with the emerging new policies of the Government of India and align it to the primary objective of the BD Act, namely, conservation of biodiversity through sustainable use of its components at the grass-root level. It may also form a part of the reference materials required for training and capacity building programmes planned under the CEBPOL Project.

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Global Scenario

The legally binding UN Convention on Biological Diversity, 1992 was the first major step taken by humankind for promoting conservation of bioresouces, their sustainable use and fair and equitable sharing of benefits arising from their commercial utilization. This International Treaty, having 196 Contracting Parties including India, stands as a turning point in many ways. Firstly, it recognized sovereign rights of nation states over their naturally occurring bioresources and also on determining terms of access to them with benefit sharing subject to their national legislation. Secondly, it sought to balance the rights of providers of bioresources (their primary conservers and developers) with those of the innovators and breeders seeking IPR on products developed from conducting research on bioresources. Thirdly, it provided that each Contracting Party shall respect, preserve and maintain knowledge, innovations and practices of local communities relevant for the conservation and sustainable use of bioresources subject to its national legislation. Fourthly, it encouraged the Parties to develop national strategies and plans for the conservation and sustainable use of biodiversity reflecting the measures set out in this Convention and also to integrate these considerations into relevant sectoral and cross-sectoral plans, programmes and policies. The CBD is, however, a framework treaty and it has added three Protocols under it to further strengthen the effective implementation of its broad principles and commitments. The legally binding 2010 Nagoya Protocol, presently ratified by 111 Contracting Parties including India, has provided an effective mechanism for implementing the ABS objective of the CBD.

The Indian Scene

India has rich heritage of biological diversity and associated traditional knowledge. It is recognized as a mega-diverse country in view of its spectacular biological diversity adapted to a wide range of environments available in its ten distinct bio-geographic zones. It is also one of the eight Vavilovian Centres of Origin of Crop Plants. Respect for all living organisms and conservation of biodiversity have been a way of life in India since ancient times as reflected in its spiritual texts, sacred groves, cultural practices, local traditions and religious rituals. In recent years, laws like the 1972 Wildlife (Protection) Act and the 1980 Forest Conservation Act were enacted to further strengthen the protection of wildlife and biodiversity-rich forest areas.

Under the CBD, the authority to determine access to biological resources along with benefit sharing terms (ABS) rests with national governments and it is subject to their national legislation. The Biological Diversity Act, 2002 (BD Act), was enacted in India in response to this requirement. It also provides suitable linkage to the provision for patenting of products and processes/ technologies, based on the use of bioresources and associated traditional knowledge under Section 10 (4) of the Patents (Amendment) Act, 2002.

I. National ABS Legislation in India

The BD Act has adopted a common but differentiated approach [Sections 3 and 19] under which the Indian citizens/entities are permitted free access to bioresources for research and apply to seek approvals from the SBBs for their commercial utilization but the following categories of persons/ body corporate / associations/ organizations are required to obtain prior approval of NBA for seeking access to India's bio-resources (and associated TK) for research and commercial use or engaging in bio-survey and bio-utilization activities:

"A person who is not a citizen of India; a citizen of India, who is non-resident; a body corporate, association or organization – not incorporated or registered in India; or incorporated or registered in India but having any non-Indian participation in its share

capital or management". On having obtained access to Indian bioreources, they also cannot pass them on to a third party without approval of NBA.

All users of bioresources are also required to seek prior approval of NBA for transferring results of research on bioresources to users of the above defined category of foreign persons/entities and for applying to obtain IPR over products of research on bioresources (occurring in India) by submitting applications in specified formats and after payment of prescribed fee for each of the above mentioned four purposes.

Access of Indian citizens to bio-resources for research is not restricted. However, Section 7 under the Act states that no person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial use except after giving prior intimation to the concerned State Biodiversity Board implying that a benefit sharing agreement may have to be signed before access is granted.

II. Implementing Mechanism for the Biological Diversity Act

A 3-tier system for implementing the BD Act has been adopted comprising the Union Ministry of Environment, Forest & Climate Change (MoEF&CC) and National Biodiversity Authority (NBA) (established by the central government) at the national level, State Biodiversity Boards (SBB) at the state level (constituted by state governments) and Biodiversity Management Committees (BMC) at the local level (constituted by the local bodies). Their roles are non-overlapping and well defined under the Act. SBBs have been constituted by all the 29 states and over 72,000 BMCs have also been established at the village level across the country.

Established by the Central Government on 1st October, 2003, the NBA comprises the Chairperson, 10 ex-officio members representing union ministries/departments, having jurisdiction over different components of biodiversity, and 5 experts with specialization in subjects relevant to biodiversity (nominated by the Central Government). Thus, the NBA is essentially an inter-ministerial body assisted by five technical experts (See Box 1). Funds and grants accruing to these three partners in implementing the Act are operated under the National, State and Local Biodiversity Funds. The mechanism for passing on the monetary benefits from the National and State Biodiversity Funds to BMCs and benefit claimers, where identified, is explained in the Guidelines on ABS Regulations notified in November, 2014.

III. The National Biodiversity Authority

In exercise of the powers conferred by Sub-Section (1) (4) of Section 8 of the BD Act, 2002 (No.18 of 2003), the Central Government established an autonomous body called the National Biodiversity Authority (NBA) on 1st October, 2003. The main functions of this Authority are:

- To lay down procedures and guidelines to govern the activities provided under Section 3, 4 and 6 (Permission to foreigners/non-resident Indians and foreign companies).
- To regulate activities and advise the government of India on research/ commercial use of bioresources, bio-survey and bio-utilization.

To grant approval under Section 3, 4 and 6 based on the following considerations:

Certain persons/ entities not to undertake biodiversity related activities without approval of NBA u/s 3 (Access to bioresources/ associated TK).

Results of research not to be transferred to certain persons/ entities without approval of NBA u/s 4 (Transfer of Research Results).

Applications for seeking IPR rights not to be made without prior approval of NBA u/s 6.

- To grant approval to certain persons/ entities seeking transfer of already accessed biological resource/ associated TK u/s 20 (Third Party Transfer).
- 4) To determine and impose terms of benefit sharing, arising out of the use of accessed biological resources and associated traditional knowledge u/s 21.

- 5) To advise the State Governments in the selection of areas of biodiversity importance to be notified u/s 37 (1) as heritage sites and on measures for their management.
- 6) To take any measure, on behalf of the Central Government, necessary to oppose the grant of IPR in any country outside India on any bioresource (or associated TK) occurring in or obtained from India.

Box 1

Constitution of NBA u/s 8(4), a statutory and an autonomous body under the MoEF&CC

- a) Chairperson [an eminent person having adequate knowledge and experience in conservation and sustainable use of biological diversity and in matters relating to equitable benefit sharing, to be appointed by the Central Government; tenure: 3 years]
- b) Three *ex officio* members to be appointed by the Central Government, One representing the Ministry of Tribal Affairs and two from the MoEF&CC
- c) Seven *ex officio* members to be appointed by the Central Government to represent the following Ministries/Departments of the Central Government:
 - (i) Agricultural Research and Education
 - (ii) Biotechnology
 - (iii) Ocean Development
 - (iv) Agriculture & Cooperation
 - (v) Indian Systems of Medicine & Homeopathy
 - (vi) Science and Technology
 - (vii) Scientific & Industrial Research
- d) Five non-official members to be appointed by the Central Government from among specialists and scientists [Tenure: 3 years]

The Present Study

I. Objective

This Analytical Study Report, prepared under the CEBPOL project, deals primarily with implementation of the BD Act's Sections 3, 4 and 6 (read with Sections 19, 20 and by the NBA from October, 2003 to October, 2017. Objective of the CEBPOL project, under implementation by NBA, is to collect, collate, analyse, research and disseminate information relating to biodiversity, policy and law to help in developing India as a regional and international resource center for training and capacity building programme.

One of the thematic areas identified in this program is 'Access and Benefit Sharing', under which this activity has been taken up on analysis of applications received by NBA with a view to developing comparative information on the users of bioresources and associated traditional knowledge on the one hand and its systematic study across major sectors on the other. Scope of this study extends over identifying, classifying and analyzing the data submitted by applicants seeking NBA's approval for the intended purposes across different sectors and also biodiversity components sought to be accessed.

Since its establishment on 1st October 2003, NBA has received 1853 ABS applications (complete in all respects), approved 1080 out of them and 554 benefit sharing agreements have been signed up to 1st October, 2017. This study is set to analyse the information contained in these applications, submitted in four formats specified for different purposes for seeking NBA's approvals, and show the tabulated results graphically for clarity and easy comprehension. This analysis provides an opportunity for assessing the accomplishments of NBA in implementing the BD Act as gleaned from regulatory activities related to Sections 3, 4 and 6 read with Sections 19, 20 and 21.

Box 2 Approved Formats for Submission of Applications and specified Fees

Application Forms	Purpose of Application	Who should apply	Application Fee
FORMI	Access of biological resources occurring in or obtained from India and/or associated traditional knowledge for research, commercial utilization, biosurvey or bio-utilization	Non-Indian, NRI, Foreign entity or Indian entity having non-Indian participation in share capital or management	INR 10,000/-
FORM II	Transfer the results of research	Any Indian / nonIndian or entity to any non-Indian, NRI, foreign entity or Indian entity having non-Indian participation in share capital or management	INR 5,000/
FORM III	Applying for Intellectual Property Rights for inventions based on any research or information on a biological resource obtained from India	Any Indian/ Non- Indian or entity	INR 500/-
FORM IV	Transfer of biological resources / knowledge already accessed, to a third party	Any person who obtained approval of NBA in Form I, to Indians / non-Indians or entities	INR 10,000/-

II. Study design:

Considering the need to have ready-to access information on the approved uses and users of biological resources occurring in India, this study attempts to collate the information contained in applications placed before the Expert Committee on ABS for scrutiny on a case by case basis and making suitable recommendations to the Authority for their approval or stating reasons for possible rejection while also suggesting terms and conditions for benefit sharing. Information on the parameters considered for evaluation of applications by the EC has been used for creation of a comprehensive database for analysis from different perspectives including the categories of bioresources used by the applicants across user sectors and comparisons among the applications received in the four formats for approval and also their relative contributions to the National Biodiversity Fund. Based on the analysis undertaken, this study is also expected to lead to some specific suggestions for making the implementation process of the BD Act simpler and more effective in addition to project the NBA's achievements in implementing the ABS regulatory legal framework.

III. Process of Approval of Applications by the Authority

The applications, seeking approvals u/s 3, 4 and 6 read with sections 19, 20 and 21, are received by the NBA Secretariat and placed before the Expert Committee (EC) on ABS which assesses each application on a case by case basis, based on the information provided by the applicants, and gives its recommendations for approval (or otherwise) along with terms and conditions for benefit sharing based on the Guidelines on ABS Regulations that were notified in November, 2014. A schematic presentation of the approval process has been presented below in Fig.2.

Fig 2 Schematic Presentation of Processing of Applications under Biological Diversity Act, 2002 and Rules 2004



* For details please go through Biological Diversity Act, 2002 & Rules, 2004

Contents of individual applications contain useful information providing an opportunity to conduct a comprehensive study of the categories of applicants, uses and users of different types of bioresources as reflected from the four specified formats of application forms. The present study has tabulated the data assembled from application forms, analysed them in various ways and present the results graphically for easy comprehension and ready comparison among users of bioresources, biodiversity components used and also the user sectors. Relative contributions by different categories of users and user sectors to the National Biodiversity Fund have also been compared.

IV. Data collection, Analysis and Interpretation:

Primarily the data were collected from the applications placed before the ABS expert committee and the information so obtained was collated as these were the applications that were complete in all respects and were ready to be granted approval by the authority, after the applications were scrutinized and benefit sharing was fixed by the expert committee.

Following the primary data collection, all the applications were checked for their eligibility and accuracy. Those applications, which were incomplete or lacked in required clarity, were not considered for further analysis. The database, developed from the applications submitted to the NBA, is now available in a ready-to-use data set containing all the information provided by the applicants to the NBA. Topics on which information is available include unique application identity number, status of the applications, category of application form linked to the intended purpose of access, nature of requested bioresource, its geographical location and quantity requested, consent of the concerned SBB, proposed use of bioresource and its purpose, conservation status of the requested bioresource and recommendations of the EC. The data are presented in both tabular and graphical forms for easy grasp and quick comparison by the readers.

Results

NBA has received 1853 applications in Forms I to IV from 1st October, 2003 to 30th September, 2017 seeking approval for different purposes and these have been duly filed and processed by the ABS Facilitation Desk at the Secretariat. Information provided by the users in these applications has been compiled, collated and analysed based on several criteria chosen for this study. Results obtained from organising these enormous data into distinct categories and analysing them user group-wise, also resource use-wise and sector-wise, are presented here in both tabular and graphic forms for instant comparison and easy comprehension along with inferences drawn from different perspectives. Main objective was to assess the accomplishment of tasks mandated to NBA [vide Sections 3, 4 and 6 read with 19, 20 and 21] as well as to suggest improvements where such scope was indicated by this study.

a) Year-wise pattern of applications received in Forms I to IV

Out of 1853 applications received by NBA during the past 15 years, 368 applications have been received in Form I requesting for access to biological resource and/or associated knowledge, 56 applications in form II seeking transfer of results of research conducted on bioresources, 1353 applications in Form III seeking IPR on products/ processes based on bioresources/TK associated with them while 76 applications have been received in Form IV intending to transfer of already-accessed biological resources/associated knowledge to third party. Year-wise data on applications received in these four categories are presented below in Table 1 and Fig. 3. Years represent Indian financial years beginning from 1st April of any year and ending on 31st March of the following year. Figures for the year 2017-2018 are, however, up to 30th September, 2017 when the NBA completed 14 years after its establishment.

Year-wise distribution of applications received in four categories of Forms					
Year	Form I	Form II	Form III	Form IV	Total
2003-2004	1	0	0	0	1
2004-2005	4	1	1	2	8
2005-2006	7	3	0	3	13
2006-2007	14	1	94	3	112
2007-2008	22	1	174	10	207
2008-2009	15	7	58	2	82
2009-2010	22	11	97	11	141
2010-2011	13	12	15	8	48
2011-2012	11	0	35	14	60
2012-2013	25	0	63	11	99
2013-2014	21	4	62	6	93
2014-2015	32	4	74	2	112
2015-2016	66	4	148	3	221
2016-2017	64	7	364	1	436
2017-2018	51	1	168	0	220
Total	368	56	1353	76	1853

Table 1



Fig. 3: Trends in number of applications received in four categories of application Forms

Total number of applications crossing 1850 is commendable as it reflects growing acceptability of the role played by the NBA among the users of bioresources across all sectors. The presented data also show a gradual overall increase in number of applications received by NBA from October 2003 until October 2017. It is noteworthy that the number of applications submitted in Form III (dealing with IPR) dominates the overall pattern but the number of applications received in Form II (requesting transfer of results of research to foreign entities) and Form IV (for Third Party transfer) are relatively low.

b) Status of Applications received in Forms I to IV

NBA has received 1853 applications in four categories (Form I-368, Form II-56, Form III-1353 and Form IV-76) and these have been filed and processed by its ABS Facilitation Desk at the Secretariat. The analyzed data are presented in Table 2 and Fig. 4. Incomplete applications were sent back to the applicants requesting them to provide the required information to facilitate NBA's scrutiny process. Applications, that were complete in all details, were placed before the Expert Committee (EC) on ABS for the purpose of making its recommendation for approval and the benefit sharing terms on a case by case basis. The

Authority deliberated the EC's recommendations and granted approval for 1080 applications specifying the terms for benefit sharing for the applicants.

These 1080 applicants comprised 160 applications in Form I requesting for access to biological resources and/or associated knowledge, 26 applications in Form II seeking transfer of results of research conducted on bioresources, 863 applications in Form III seeking IPR on products/process based on bioresources/TK associated with them and 31 applications in Form IV for transfer of already accessed biological resources/associated knowledge to third party. These 1080 applications were intimated about the approval of their applications and requested to enter into a benefit sharing agreement with the NBA. Out of 1080 approvals, 554 applicants signed the benefit sharing agreement with NBA in various categories (Form I – 119, Form II

- 18, Form III - 389, Form IV - 28). Furthermore, 491 applications under different categories (Form I - 134, Form II- 25, Form III 297 and Form IV-35) were closed due to various reasons 1.

- b) obtaining necessary document, as appropriate, without referring to the Expert Committee / Authority]
- c) Where the applicants do not fulfill the conditions stipulated under the Biological Diversity Act and Rules and queries from the NBA Secretariat despite issue of two reminders / notices for compliance by giving 30 days each.

a) ¹Where the applicants choose to withdraw the application on their own, if requested by the applicant unconditionally and when there is no adverse implication on granting such withdrawal. [Provided that the applicant chooses to withdraw his application in the event of patent application abandoned / refused to grant / dropped in the patent office, in or outside India, the NBA secretariat may close the Form III application after Where the NBA directs execution of an agreement and the applicant does not execute such an agreement within 60 days.

In addition, 156 applications are still under process awaiting recommendations of the EC (Form I – 50, Form II – 2, Form III – 103 and Form IV - 1). A careful scrutiny by the EC also revealed that 126 applicants appeared to have already accessed the biological resources under various categories (Form I - 24, Form II - 3, Form III - 90, Form IV - 9) without prior approval of NBA and were thus in violation of the Act.

SI. No.	Application Status	Form I	Form II	Form III	Form IV	Grand Total
i.	Received	368	56	1353	76	1853
ii.	Approved	160	26	863	31	1080
iii.	Agreement signed	119	18	389	28	554
iv.	Closed *	134	25	297	35	491
۷.	Under process	50	2	103	1	156
vi.	Violations	24	3	90	9	126

Table 2Status of applications submitted in Forms I to IV



Received Approved Agreement Signed Closed Under Process Violation

Fig. 4: Status of applications received in Form I to Form IV

Further analysis showed that 73% of the applications received by NBA were in Form III for obtaining patent in India or abroad on products based on research on bioresources occurring in or obtained from India, 20% were in Form I for accessing bioresources for research by foreigners or commercial utilisation through export by Indians and 4% is Form IV for transfer of already accessed bioresources to third party while only 3% were in Form II for seeking approval for transfer of results of research to foreign citizens/ entities as defined u/s 3 (2). Results of this analysis are presented below in Fig. 5.



Fig. 5: Analysis of Application Forms category-wise

c) Analysis of the status of applications

All applications seeking NBA's approvals, submitted by foreign citizens/entities or nonresident Indians are received by the NBA Secretariat for their processing for approval by the Authority u/s 3, 4 and 6 read with sections 19, 20 and 21. Indian citizens/entities seeking patents over products based on research on bioresources are also required to obtain NBA's prior approval by applying in Form III. An analysis of all the 1853 applications showed that 1375 applications of them were submitted by Indian citizens/entities, 268 applications were received from foreign citizens/entities,

186 applications received from Indian companies having non-Indian participation in their share capital or management and 24 applications received from Non- resident Indians. Results of this analysis are presented below in Fig. 6.



Fig. 6: Applicants' status



Indian Non-Indian Indian entity NRI

Fig. 7: Analysis of the Status of Applicants

The results shown diagrammatically in Fig. 7 reveal that 74 % of all the applicants are Indian citizens. This is so because all persons seeking patents in India on products based on bioresources are required to obtain clearance from NBA by applying in Form III and most of them happen to be Indian citizens/entities. The non-Indian applicants (15%) are largely the individuals/institutions seeking approval for accessing biological resource for carrying out research or commercial utilization. In recent years, number of applicants in the Form I category has increased owing largely to greater awareness about the Act and bioresource users' obligations to comply with the BD Act at the international level. While the Indian entities having foreign share in their capital or management constitute 10% of all the applicants, the non-resident Indians make up just 1% of the total.

d) Analysis of Form I applicatios

Form I applications are classified based on the status of the applicant using the biological resources and associated TK occurring in India into 4 different types (Non-Indian, Indian entity having Non-Indian participation in share capital or management and NRI). Out of 368 Form I applications; 236 applications are applied by NonIndian applicants, 108 are Indian entity having Non-Indian participation in share capital or management and 24 applications are submitted by the NRI. Results are presented graphically in Fig.8.





e) Analysis of Applications based on Purpose of Access

As the Biological Diversity Act (2002) and Rules (2004) are in place, all users of Indian Biological resources have obligations to comply with the Act's provisions and seek approval from the NBA before obtaining any biological resources or associated traditional knowledge thereto for different purposes like research, commercial utilization, bio-survey & bio-utilization, transfer of results of research conducted on bioresources and seeking patents on products derived from or based on bioresources.

Out of the 368 applications received by NBA in Form I, 243 applications were for research purpose, 111 applications for commercial purpose and 14 applications were for bio-survey and bio-utilization purpose. Results are presented graphically in Fig. 9.



Fig. 9: Purpose of Accessing Bioresources

f) Analysis of Applications based on Nature of bioresources used

As per the BD Act, all living organisms; plants, animals and microorganisms excepting human beings are biological resources used for various purposes (research, commercial utilisation, biosurvey & bioutilisation) in view of their actual or potential value. These bioresources are utilised for developing a wide range of products (including medicines, aromatics and cosmetics) and provide numerous services for human benefits. These biological resources are procured from the naturally occurring wild species (growing in situ) or their domesticated or cultivated forms or procured from markets and collection centres such as botanical gardens, gene banks, seed banks and microbial culture collections (*ex situ collections*).

Out of 1853 ABS applications received by NBA, 1398 applications were for accessing plants, 324 applications for microorganism, 128 applications for animals and 3 applications seeking access traditional knowledge associated with bioresources as presented graphically in Fig. 10.



Fig. 10: Nature of Bioresources accessed by the Applicants

Out of the bioresources accessed, plants comprise the dominant group with 75% applications since plants and plant extracts have a huge market as it is used widely for research and development because of their valuable compounds and physical characteristics. Most of the industries (particularly *Pharma and Ayurveda*) depend on plants as the bioresource for production of drugs, chemicals and cosmetics. Plants are also used extensively for extracting chemical compounds and metabolites.

Microorganisms, the next group with 18 % applications, are used in industries for research and development activities as well as for commercial utilisation and production of various biotechnology goods and applications. Microorganisms are also used for fermentation and bio-remediation purposes as well. Animal species have been accessed by 7% of the applicants for various purposes. Applications for accessing wild

plants and animals occurring in protected areas have to be submitted to the concerned Chief Wildlife Warden as provided under the Indian Wildlife (Protection) Act, 1970. Results of this analysis are presented in Fig. 11.



Fig. 11: Nature of Bioresources used

g) Sector wise Analysis of applications received by NBA

Different types of biological resources (Plants, animals, microorganisms) are used by different types of users (academic, industries, export etc.), for different purposes (research, commercial, biosurvey /bioutilisation, seeking IPR, transfer of technology), across a range of sectors (Pharmaceuticals, cosmetics, research etc.). This study has grouped users of biological resources into 6 different sectors, viz., pharmaceuticals, nutraceuticals, research, environmental bioremediation, cosmetics and export based on their broad objectives of using bioresources. The activity varies from exporting raw bioresources, conducting basic research on them to development of value added products in these 6 sectors. Pharmaceutical industries, cosmetics, perfumery, food production & processing enterprises have turned out to be main user groups. Results are presented in Fig. 12.



Fig. 12: Sector-wise Analysis of Applications

The sector-wise classification was done on all the 1853 ABS applications received by NBA until October 2017. Out of these, 1010 applications were grouped under pharmaceutical sector, 351 applications under research sector, 280 applications under nutraceutical sector, 100 applications under export sector, 64 applications under environmental bioremediation sector, and 48 applications under cosmetic sector. The pharma sector turned out to be the dominant user sector followed by the research, nutraceutical and export sectors in descending order. In recent years, users in cosmetic/perfumery sectors have grown considerably due to the increasing market for the herbal products. In addition, export of bioresources like neem, sea weed, cattle embryo and red sanders has shown remarkable increase.

These results are also presented pictorially for easy comparison in Fig. 13 showing the proportionate number of applicants coming from the chosen six sectors.



The pharmaceutical sector represents 55% of all the applications received by NBA, followed by the institutional research sector with 19% share, the nutraceutical and food processing sector with 15% share, the export sector with 5 % share while the cosmetic and environmental bioremediation sectors had just 3 % share each.

Sector-wise analysis of applicants within each Form category

I. Form I applications

Out of 368 applications submitted in Form I, 200 applications were from research sector, 79 applications from export sector, 50 applications from nutraceutical sector, 23 applications from pharmaceutical sector, 9 applications from cosmetic sector and 7 applications from environmental bioremediation sector. Results are presented in Fig. 14.



Fig. 14: Sectoral Analysis of Form I Applications

Applicants submitting their applications in Form I comprise non-Indians, Indian entities having foreign share capital or management and non-resident Indians interested mostly in conducting research for developing products for direct commercial utilization or seeking patents over them for exclusive marketing rights. In this analysis of Form I applicants, the research sector comes out as the largest user of bioresources followed by the export sector meant for commercial utilization.

II. Form II applications

Indian researchers are required u/s 4 of the BD Act to obtain prior approval of NBA for transferring results of research conducted on bioresources to persons/entities defined u/s 3(2) by submitting their applications in Form II. Out of 56 Form II applicants, 48 applications were from the research sector, 5 applications from pharmaceutical sector and 3 applications from nutraceutical sector. Results are presented in Fig. 15 showing that foreign persons/entities were looking for making full use of the research conducted by their Indian counterparts for developing value added products for commercial utilization in the global market.



Fig. 15: Sectoral Analysis of Form II Applications

III. Form III applications

All persons/entities seeking patents on products/processes based on bioresouces are required to get clearance from the NBA by submitting their applications in Form III. This category is outstandingly dominant over the other three Form categories. Out of 1353 Form III applications, 980 applications from pharmaceutical sector, 222 applications from nutraceutical sector, 57 applications from environmental bioremediation sector, 55 applications were from research sector and 39 applications from cosmetic sector. Results, presented in Fig. 16, reveal that the largest number of applicants come from the pharma sector, followed by the nutraceuticals and food processing sector.



Fig. 16: Sectoral Analysis of Form III Applications

IV. Form IV applications

Foreign persons/entities and non-resident Indians, as defined u/s 3(2) of the BD Act intending to transfer the already accessed bioresources occurring in India to third party are required to obtain prior approval of NBA by submitting their applications in Form IV.



Fig. 17: Sectoral Analysis of Form IV Applications

Out of 76 Form IV applications received by NBA, 49 were from the research sector, 20 applications from the export sector, 5 applications from the nutraceutical sector, and 2 application from the pharmaceutical sector. This analysis shows that bioresources accessed by foreign persons/entities in India are largely transferred by them to third parties for conducting advanced research over them for developing more value added products. The results are presented in Fig. 17.

Status of applications received in different User Sectors

I. Pharmaceutical Sector

Pharmaceutical sector is the largest sector using bioresources in India for manufacturing of herbal healthcare drugs and formulations used in different systems of indigenous medicine systems including the ayurvedic and unani traditional systems. NBA received 980 applications from this sector in Form III. Out of these, applications by 632 applications were approved and 312 of them entered into a benefit sharing agreement with NBA on mutually agreed terms.



Fig. 18: Pharmaceutical Sector

Results of the analysis are presented in Fig. 18. While 210 applications got closed, 78 of them appeared to be in violation of the BD Act and these are under further scrutiny.

II. Nutraceutical Sector

After pharmaceutical sector, the nutraceutical sector has grown remarkably over the years based primarily on agricultural and food products. This sector has contributed 222 applications in Form III and 50 applications in Form I. Out of these, 152 applications received approval in Form III and 18 applications in Form I while 50 applications with Form III and 14 applications with Form I signed benefit sharing agreements with NBA. Results are presented in Fig. 19.



Fig. 19: Nutracetutical Sector

III. Research Sector

Foreign persons/ entities apply to NBA for access to bioresources primarily for research and biosurvey & bioutilisation. The research sector contributed 200 applications in Form I and 65 of them received Authority's approval. From the applicants receiving approvals, only 38 applications entered into benefit sharing agreement with NBA. The results are presented in Fig. 20.



IV. Environmental Bioremediation Sector

This sector has applied for access to microbes for their use largely in biodegradation and environmental bioremediation. NBA has received 57 Form III applications in this sector. While 40 of them got approved, only 9 applications entered into a benefit sharing agreement with NBA. In addition, 7 applications were received in form I. Two of them got approved and one applicant entered into benefit sharing agreement with NBA. The results are presented in Fig. 21.



Fig. 21: Environmental Bioremediation Sector

V. Cosmetic sector

Herbal cosmetic industry has grown considerably in recent years. This sector contributed to 39 applications in Form III and 9 in Form I. While 23 applications in Form III and 5 applications in Form I received approvals out of them, only 11 applicants in Form III and 5 applicants in Form I signed benefit sharing agreements with NBA. Results are presented in Fig. 22.



Fig. 22: Cosmetic Sector

VI. Export Sector

Biological resources especially like red sanders, sea weed algae, cattle embryos have been exported for commercial utilization. NBA has received 79 applications in Form I and approved 59 of them while 55 of these applicants have entered into benefit sharing agreements with NBA on mutually agreed terms. In addition, 20 applications have also been received in Form IV for transfer of the accessed bioresources to a third party in export sector. Six of these applications were approved and all 6 applicants have signed benefit sharing agreements with NBA in monetary mode. The results are presented in fig. 23.



Fig. 23: Export Sector

Major Findings

1) Analysis of Applicants

Four activities related to biological resources, occurring in India, are regulated by the NBA. The users are required to obtain prior approval for accessing them by submitting applications in any of the four types of application forms, relevant to their intended purpose, along with paying the specified fee. Applicants, whose applications get approved by the Authority, are also required to enter into benefit sharing agreements on mutually agreed terms. A total of 1853 duly filled applications have been received by the NBA up to 30th September, 2017 since its establishment in October, 2003. These include 368 applications in Form I (19.8%), 56 applications in Form II (3%), 1353 applications in Form III (73%) and 76 applications in Form IV (4%). Out of them, 1080 applications were approved (58%) by the authority and 554 applicants have signed benefit sharing agreements with NBA (30%). While 156 applications are under processing, 126 appear to be in violation of the BD Act's provisions and these are under investigation.

This study also revealed that 55% of applications were from pharmaceutical sector, 19% applications were from academic research sector, 15% applications were from nutraceutical sector, 5% applications were from export sector and 3% applications were each from environmental bioremediation and cosmetic sectors. Access was sought for plant materials (75%), animal species (7%) and also microbes (15%). Among the applicants, 74% were Indians (seeking patents or engaging in commercial utilization activities) and the rest were foreign citizens/entities (15%), Indian companies having non-Indian participation in their share capital or management (10%) and non-resident Indians (1%).

2) Analysis of Application Forms

Analysis of applications submitted in Forms I to IV revealed the following pattern:

Out of 368 applications applying for access to bioresources in Form I, 200 applications were from the research sector (54%), 79 applications were from the export sector (21%), 50 applications were

from nutraceuticals (14%), 23 applications received from pharmaceutical sector (6%), 9 applications from cosmetic sector (2.4%) and 7 applications were received from the environmental bioremediation sector (2%).

Out of 56 **Form II** applications for transfer of research results by Indians to a non-Indian or Indian entity having foreign share capital or management or to an NRI; 48 applications were from research sector, 5 applications were from pharmaceutical sector and 3 applications were from nutraceutical sector.

Out of 1353 **Form III** applications seeking approval for obtaining patent on the bioresource-based products; 980 applications were from pharmaceutical sector (72%), 222 applications were from nutraceutical sector (16%), 57 applications were from environmental bioremediation sector, 55 applications were from research sector and 39 applications were from cosmetic sector.

Out of 76 **Form IV** applications seeking approval for transfer of the biological resources to third party; 49 applications were from research sectors, 20 applications were from export sectors, 5 applications were

from nutraceutical sector, and only 2 were from pharmaceutical sector.

3) Sector-wise Analysis

Comparative study on sector-wise use of the biological resources showed the following pattern:

- (i) Pharmaceutical sector received 980 applications in Form III. Out of which 632 applications were approved (64%) and 312 of them entered into benefit sharing agreement with NBA (49%).
- (ii) Nutraceutical sector received 222 applications in Form III and 50 applications in Form I. Out of these 272 applications, 170 applications were approved (63%): 152 applications in Form III (56%) and 18 applications in Form I while 64 of them entered into benefit sharing agreements (38%): 50 applications in Form III and 14 applications in Form I.

- (iii) Research sector received 200 applications in Form I and 65 of them were approved (33%). Benefit sharing agreements were signed by 38 applicants in this sector (58%).
- (iv) Environmental bioremediation sector received 57 applications in Form III and 7 applications in Form I. Out of them, 40 applications in Form III and 2 applications in Form I received approval. Benefit sharing agreements were signed with NBA by 9 applicants in Form III and one applicant in Form I.
- (v) Cosmetic sector received 39 applications in Form III and 9 aplications in Form I. Out of these, 23 applications in Form III and 5 applications in Form I were approved. Benefit sharing agreements with NBA were signed by 11 applicants in Form III and 5 applicants in Form I.
- (vi) Export sector received 99 applications: 79 applications in Form I and 20 applications in Form IV. Out of these, 59 applications got approval in Form I (75%) and 6 applications in Form IV (30%). While benefit sharing agreements with NBA were signed by 55 applicants in Form I (93%), all the six applicants in Form IV entered into benefit sharing agreements with NBA (100%).
- 4) Effectiveness of Implementation

In order to assess the effectiveness of the BD Act's implementation by the NBA, the results of this analysis need to be linked to the Act's primary objectives which focus on conservation of India's biological resources by promoting their sustainable use and encouraging fair and equitable sharing of benefits arising from their commercial utilization. In other words, the benefit sharing should reach the conservers and primary beneficiaries enabling them to continue their conservation and sustainable use practices. This, in turn, requires adequate capability and capacity building to receive and fully utilize the accruing benefits at the ground level.

At present, only 27% of the total number of BMCs have been established and it is obvious that the number of BMCs must increase substantially and in addition the existing ones need to be properly equipped and strengthened. However, it is noteworthy that the NBA has made a good beginning by transferring some of the accrued monetary benefits to several SBBs and BMCs and the effort is on to learn from such experiences and develop good practices in this context.

This Study has also revealed that nearly 95% of the National Biodiversity Fund has been realized from the auction of seized stocks of smuggled Red Sanders wood and export of embryos of three cattle breeds to Brazil. It shows that realization of monetary benefits from 'access to bioresources' and IPR routes leaves much to be achieved by way of monitoring and follow up.

Discussion

Interpretation of the observed patterns and trends

a) Overall Pattern

Overall pattern emerging from this Study shows that 58.3% of the applicants were granted approvals by the authorities for various activities but only 29.9% of them entered into benefit sharing agreements with the NBA on mutually agreed terms. Considering that processing of applications and granting of approvals involves a lot of work in the Secretariat, including the time spent by the Expert Committee on ABS and the Authority Members, there is an urgent need to understand the underlying causes of the seemingly low level of approvals and even lower level of signing the benefit sharing agreements by the applicants.

Since approvals are granted on a case by case basis keeping in view a set of criteria developed for this purpose, the observed low level of granting approvals points to a gap in communication between the authorities and the perceptions about the interpretation of the BD Act's provisions by the users of bioresources. Creating more awareness among the stakeholders about compliance to the BD Act and developing sector-specific guidelines about the users' obligations require urgent attention. In addition, liberal interpretation of the terms defined under the BD Act (like commercial utilization, value added products and conventional breeding) may improve the situation by following the guiding principle of conservation of bioresources with a focus on promoting sustainable use of bioresources, rather than imposing excessive restrictions. This will also result in generating more benefits that will flow to the National Biodiversity Fund and support conservation at the local community level.

There is also a need to further simplify the approval process. NBA is already engaged in this direction. For example, recommendation of an Expert Committee was accepted to do away with the requirement of consulting the SBBs before granting clearance to Form II applicants intending to transfer results of research on bioresources to foreign persons/entities and also to Form III applicants seeking patents over bioresource-based products. This step alone saved a lot of time that was spent earlier in such consultations. Another helpful recommendation accepted by the Authority was doing away with the requirement of submission of reference samples to Designated Repositories by the Form II and Form III applicants in normal situations.

b) Applications received by NBA until 30th September, 2017 [Table 1 and Fig. 1]

Increased number of applications received in 2012 onwards, more so after 2014, may be explained largely by the following developments:

- Increasing level of awareness among the users of bioresources about the provisions of the BD Act and Rules and also their growing realization that compliance to these provisions makes better business sense and doing so does not make their companies/business houses less competitive in the market.
- 2) Wide media coverage of the negotiations in 11th meeting of the CBD-COP, held in Hyderabad, and their outcome appreciating some outstanding features of the Indian ABS legislation, including its focus on conservation of bioresources through sustainable use.
- Ratification of the Nagoya Protocol on ABS by India in October, 2012 and several positive steps taken during India's Presidency of the CBD-COP and COP-MOP of the Nagoya Protocol on ABS.
- 4) Entry into force of the Nagoya Protocol on ABS in October, 2014 setting out obligations on the Contracting Parties to take legal and administrative measures for compliance to national laws and rules of the providing countries governing access to genetic resources and benefit-sharing terms.
- 5) Decision to treat the export of bioresources through the Director General of Foreign Trade as commercial utilization of bioresources through export and, hence, requiring prior clearance by NBA for this purpose and this, in turn, making the exporters of bioresources to comply with the benefit sharing provisions of the BD Act and Rules.
- 6) Issuance of guidelines for patent filing by the Indian Patent Office requiring disclosure of origin of bioresources used in developing products and also mandatory requirement of prior approval by NBA for this purpose in Form III in case those bioresources are obtained from India.

- 7) Notification of Guidelines on ABS Regulations on 21 November, 2014 providing clarity, transparency and consistency in India's national legal mechanism for implementing ABS obligations as a Provider Country under the Nagoya Protocol and having the lowest rates for benefit sharing in monetary mode at the regional and global levels.
- 8) Launching of online filing of applications to save the time taken for processing applications in direct communication with the applicants and offering online guidance in filling the applications.
- 9) Revising benefit sharing formats in response to feedback received from the applicants. The improved formats for signing the agreements and the fixed benefit sharing component specified in the access and benefit sharing guidelines have helped in speeding up the application processing at the Secretariat, NBA.
- 10)
 - 10)Impact of well planned awareness workshops, conducted by NBA in several states in partnership with various government departments on ABS Guidelines, biannual India Biodiversity Awards and well publicized celebration of International day on biological diversity.
 - 11)Implementation by NBA of several bilateral and globally funded projects (including those granted by UNEP-GEF, CEBPOL, BIOFIN, and GIZ), in partnership with more than a dozen SBBs, with a focus on capacity building and creating awareness about the provisions of the BD Act and ABS Guidelines.
 - c) Sector-wise Analysis

Among the six sectors under study, the pharmaceuticals had a share of 55% of the total number of applications, followed by the research (19%) and nutraceutical sectors (15%). Sectors, using bioresources in bulk, need to be provided sector-specific guidelines. Applying on-line with the guidance provided by the Secretariat is a welcome step in this context.

This Study also revealed a lot of variation among the applicants in the four Form categories and also the six user-sectors regarding the grant of approvals received as well as in signing the benefit sharing agreements by the applicants whose applications had been granted approvals. This aspect needs to be looked into carefully as it indicates a lot of scope in increasing both

efficiency and effectiveness of the implementing mechanism. Making available sector-specific guidelines may help in improving the current situation. Confidence-building consultations on a regular basis with the usersectors and promptly addressing their concerns received from the feedback may also help in clearing the prevailing apprehensions among the users.

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Recommendations

Some suggestions are being offered in this section with a view to improving the efficiency and effectiveness of implementing the BD Act by NBA and also to harmonise this implementation with the present policies, plans and programmes of the Government of India.

- 1. Different user groups (both public and private) inside and outside the country need legal certainty, procedural clarity and transparency in domestic ABS legislation and regulatory requirements to carry on their activities smoothly. This requirement under the Nagoya Protocol has been largely met with the notification of ABS Guidelines Regulations in November, 2014. Sector-specific guidance is still required to enable the bioresource-users to exercise due diligence in complying with provisions of the BD Act. In addition, the Rules framed by the State Governments for implementing this Act need to be harmonized with the ABS Guidelines notified by the Central Government.
- 2. There is need to develop a regular consultation process with different stakeholders to identify issues of concern and address effectively by balancing the users' concerns with the conservation and sustainable use considerations. In-house discussions with key partners, like SBBs, BMCs and Line- Departments of Central and State governments are also essential for the BD Act's effective implementation.
- It will be helpful to develop case studies for different user-groups, highlighting good practices being followed. It may help for this purpose to extend the scope of the on-going National Biodiversity Awards by including this aspect.
- 4. In cases where bulk bioresources are being exploited, there is a need to monitor the quantum of bioresources used and location as well as timing of their collection with a view to developing a national database for reference and monitoring. This information is essential towards promoting sustainable use of bioresources.
- 5. Institutional mechanisms involved in implementing the ABS provisions play a pivotal role and require to be strengthened at different levels of operations.

- 6. Developing suitable mechanism for more effective coordination and greater understanding among the concerned government departments is essential for the effective implementation of the BD Act. A more liberal interpretation of the BD Act's provisions is required to support the 'Ease of Doing Business" policy of the government and to help the BD Act-compliance companies and business houses to remain market-competitive.
- 7. There is also a need to hold more sensitisation programs, workshops, seminars and disseminate information on the Biological Diversity Act and compliance procedures to diverse stakeholders. This step will reduce the number of un-intended violations of the Act.
- 8. More concerted effort is required to promote the non-monetary mode of benefit sharing among the bioresource users after duly standardizing elements of this approach. It is equally important to mind the existing gap in effective linking of funds accruing in the National Biodiversity Fund to conservation of bioresources at the ground level.
- India should notify Users' Obligations as required under the Nagoya Protocol on ABS and make full use of the potential offered by its ABS Clearing House in realizing benefit sharing in other user countries who are Parties to this Protocol as shown in Box 3.

Box-3

Tracking use of bioresources through ABS-CH in countries parties to the Nagoya Protocol on ABS

Steps to be taken for realization of benefit sharing through the Checkpoint System under the Nagoya Protocol on ABS: 1. User to find Provider Country Rules via ABS-CH 2. User follows process of PIC & MAT with Provider Country CNA 3. CNA issues a Permit after entering into BS agreement 4. CNA submits Permit to ABS-CH who generates IRCC with unique Id 5. User submits IRCC to User Country Checkpoint (s) 6. Checkpoint submits such information to ABS-CH who alerts NFP and CNA of the Provider Country for action as required - ABS Clearing House in the Secretariat ABS-CH PIC - Prior Informed Consent MAT - Mutually Agreed Terms - Competent National Authority CNA IRCC - Internationally Recognized Certificate of Compliance - National Focal Point NFP

- 10. Greater use needs to be made of granting exemption from provisions of the BD Act u/s 40 to assist export of bioresources as commodities.
- 11. Increasing demand for redefining the provision u/s 3(2) by replacing "any foreign share in their capital or management" by "more than 50% foreign share in their capital or management" to define foreign companies/entities, needs to be discussed at the highest levels to resolve this prickly issue.
- 12. Acknowledging the useful contributions made by the externally funded projects granted under GEF, UNDP and UNEP, under implementation in 15 states, and also bilateral projects under technical cooperation programme, there is need to develop more such ABS-related projects to cover all the remaining States. Considering that the term of Indo-Norway CEBPOL project is nearing completion, there is need for the government of India to adopt this Centre with full funding commitment and integrating it with the NBA Secretariat.

The Way Forward

Implementation of the BD Act has gained the much awaited momentum by now with the number of applications crossing the mark of 2,250 and signing of benefit sharing agreements reaching 1,850 by October, 2018. The way forward for more effective implementation of this law appears to be paved with expanding the process of dialogues with major user sectors and conducting more consultation workshops with all stakeholders. It is equally important to continue addressing the concerns of user industries and make pavailable sector -specific guidelines for exercising due diligence for compliance of the regulations. The twin process of holding consultations with stakeholders and learning from experince has yielded good results so far and needs to be continued.

Commendable progress already made in this direction notwithstanding, there is still a large scope for improving the regulatory system's efficiency and effectiveness as reflected by the magnitude of huge variations observed in percentages of approvals granted among the four categories of Application Forms and also in signing of benefit sharing agreements across the six sectors under study.

There is still need for creating more awareness about the user's obligations under the BD Act and accelerating the pace of capacity building at all levels. Recent effort by the NBA to access new technologies for monitoring the use of Indian bio-resources in other countries, under the Indo- German Technical Cooperation Programme, is a welcome step in this direction.

Capacity building activities undertaken in 15 SBBs under UNDP, UNEP and GIZ funding are also commendable and more such projects need to be developed on a priority basis. In this context, the Indo-Norwegian CEBPOL Project has also contributed significantly to NBA 's capacity building efforts and needs to be developed into a regional and international training centre.

About CEBPOL

Government of India in collaboration with the Norwegian Government has established "Centre for Biodiversity Policy and Law (CEBPOL)" at the National Biodiversity Authority (NBA), an autonomous and statutory body of the Ministry of Environment Forest and Climate Change towards strengthening of expertise in Biodiversity Policy and Law in India. This programme is executed by the NBA in collaboration with Norwegian Environment Agency through the Royal Norwegian Embassy, New Delhi, India.

The Centre aims to provide advice and support to the Government of India and Norway on Biodiversity Policy and Law related issues including complex negotiations on Access and Benefit Sharing and Traditional knowledge as well as governance issues relating to biodiversity at the National and International level. The Centre proposes to help NBA in the effective implementation of International agreements on conservation, sustainable use and the associated access and benefit sharing components of it.

CEBPOL is set up as a specialized Centre of Excellence in Biodiversity Policy and Law to network, organize and consolidate expertise on issues of Biodiversity Policy and Law in India and Norway. The Centre, located at NBA, would function as an independent think tank on Biodiversity Policy and Law. In addition, CEBPOL aims to contribute to the effective implementation of the Biological Diversity Act 2002 and Rules 2004.

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Centre for Biodiversity Policy and Law (CEBPOL)