

THE **ABS**  
CAPACITY  
DEVELOPMENT  
INITIATIVE



L'INITIATIVE DE  
RENFORCEMENT  
DES CAPACITES  
POUR L'**APA**

## National Study on ABS Implementation in **India**

Commissioned by

the **ABS Capacity Development Initiative**

in collaboration with

the **Government of India**

Carried out by



**Research and Information System for Developing Countries**

**India Habitat Centre**

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**The ABS Capacity Development Initiative, in collaboration with the Governments of Brazil, India and South Africa, commissioned national studies to review each country's experiences with Access and Benefit Sharing. Lessons learned from these experiences will inform the global implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from its Utilization (Nagoya Protocol). These studies were prepared to provide background information in preparation for the first Dialogue on Practical Ways Forward for the Implementation of the Nagoya Protocol, hosted by the Government of South Africa on 30-31 January 2014 in Cape Town, South Africa and the second Dialogue on the same topic, co-organized with the Ministry of Environment and Forests of India, from 4-6 August 2014 in Goa, India.**

**The national study on ABS implementation on ABS was carried out by Research and Information System for Developing Countries (RIS): Biswajit Dhar (Director, General), T.C. James (Consultant), Vinayak Pandey (Research Associate).**

## List of Abbreviations

ABS	Access and Benefit Sharing
AK	Associated Knowledge
BD	Biological Diversity
BDA	Biological Diversity Act, 2002
BDR	Biological Diversity Rules, 2004
BHS	Biodiversity Heritage Site
BMC	Biodiversity Management Committee
BR	Biological Resources
BS	Benefit Sharing
CBD	Convention on Biological Diversity
CG	Central Government
CSIR	Council of Scientific and Industrial Research
FoB	Free on Board
GR	Genetic Resources
IPR	Intellectual Property Rights
LBF	Local Biodiversity Fund
MAT	Mutually Agreed Terms
NBA	National Biodiversity Authority
NBF	National Biodiversity Fund
NRI	Non-Resident Indian
PIC	Prior Informed Consent
SBB	State Biodiversity Board]
SG	State Government
TK	Traditional Knowledge

## Background

India enacted the Biological Diversity Act, (BDA) 2002 to fulfil its obligations under the United Nations Convention on Biological Diversity (CBD), 1992. The BDA became operational after the Biological Diversity Rules (BDRs) were adopted in 2004. The BDA delineates the conditions under which persons, commercial firms and other institutions can access biological resources (BR<sup>1</sup>) occurring in India and the knowledge associated with the BR, for research or for commercial utilization or for bio-survey and bio-utilization. These conditions of access are instituted to ensure conservation of biological diversity (BD), sustainable use of its components and fair and equitable sharing of the benefits arising out of the commercial utilization of BR and associated knowledge (AK).

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<sup>1</sup> The BDA covers biological resources and associated knowledge. Hence, the expression 'BR' is used in this document to include biological resources and associated knowledge as well as all genetic resources but excluding human genetic material.

## The National framework

### Who are the competent national authorities?

The BDA established a three-tiered structure for the implementation of its various provisions. The National Biodiversity Authority (NBA),<sup>2</sup> the State Biodiversity Boards (SBBs)<sup>3</sup> and Biodiversity Management Committees (BMCs)<sup>4</sup> are respectively the national, state and local level institutions for the implementation the Act and the Rules. All these institutions are statutory, autonomous bodies. The NBA<sup>5</sup> and the SBBs<sup>6</sup> are body corporates. In case of disputes between the SBBs, the Central Government (CG) is to refer them to the NBA<sup>7</sup>, which while adjudicating the dispute, is to be guided by the principle of natural justice and procedures prescribed by the CG.<sup>8</sup> In case of dispute between the NBA and SBBs, an appeal may be made before the CG.<sup>9</sup>

There is no overlap in the functions of NBA and SBBs on the issues of access and benefit sharing (ABS). Foreign individuals, companies or institutions, and non-resident Indians (NRIs)<sup>10</sup> are required to seek prior approval of the NBA to obtain any BR and AK occurring in India. Further, prior authorisation of the NBA is required to transfer the results of any research relating to any BR occurring in, or obtained from, India to any foreign individual, company or institution,<sup>11</sup> and also for applying for Intellectual Property Rights (IPRs) for any invention based on any research or information on a BR obtained from India<sup>12</sup>. Indian citizens or firms registered in India can obtain any BR for commercial utilization or bio survey and bio utilization for commercial utilization after giving prior intimation to the State SBB only<sup>13</sup>. However, the benefit sharing (BS) guidelines are to be issued by NBA.<sup>14</sup> NBA may take any measure necessary to oppose the grant of IPRs in any country on any BR or AK obtained from India, on behalf of the CG.<sup>15</sup>

### Is there one or more?

As of October 2013, 28 states of India have established SBBs, and 32,221 BMCs have been set up at the local level. There is significant unevenness in the number of BMCs across states. Almost three-fourths of these BMCs have been set up in Madhya Pradesh (23743). The number of BMCs in Karnataka and Kerala are 4374 and 1043 respectively. Uttarakhand, Maharashtra Andhra Pradesh and Mizoram have 598, 340, 222 and 221 BMCs in that order. All other states, barring Haryana, Orissa and Sikkim, where BMCs are yet to be established, have less than 100 BMCs.<sup>16</sup>

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<sup>2</sup> Section 8 of the BDA 2002, (herein after BDA)

<sup>3</sup> Section 22 of the BDA

<sup>4</sup> Section 41 of the BDA

<sup>5</sup> Section 8 (2) of the BDA

<sup>6</sup> Section 22 (3) of the BDA

<sup>7</sup> Section 50 (4) of the BDA

<sup>8</sup> Section 50 (5) of the BDA

<sup>9</sup> Section 50 (1) of the BDA

<sup>10</sup> Section 3 of the BDA

<sup>11</sup> Section 4 of the BDA

<sup>12</sup> Section 6 of the BDA

<sup>13</sup> Section 7 of the BDA

<sup>14</sup> Section 21 (2) of the BDA

<sup>15</sup> Section 18(4) of the BDA

<sup>16</sup> <http://nbaindia.org/content/20/35/1/bmc.html>

### **How were they established?**

The NBA was established by the CG for the implementation of the BDA and the BDR.<sup>17</sup> It is also reconstituted from time to time by the CG. Similarly, as envisaged in the BDA, the SBBs are established by the State governments (SGs) by,<sup>18</sup> and the BMCs are constituted by the local body<sup>19</sup> of that area.<sup>20</sup>

The composition of the NBA is as under:

- (i) A Chairperson, who is an eminent person having adequate knowledge and experience in the conservation and sustainable use of BR and in matters relating to equitable sharing of benefits
- (ii) Three ex-officio members, one representing the Ministry dealing with Tribal Affairs and two representing the Ministry dealing with Environment and Forests of whom one is the Director General of Forests or the Additional Director General of Forests
- (iii) Seven ex-officio members to represent respectively the Ministries dealing with Agricultural Research and Education; Biotechnology; Ocean Development; Agriculture and Cooperation; Indian Systems of Medicine and Homeopathy; Science and Technology; and Scientific and Industrial Research.
- (iv) Five non-official members appointed from amongst specialists and scientists having special knowledge of, or experience in, matters relating to conservation of BD, sustainable use of BR and equitable sharing of benefits arising out of the use of BR, representatives of industry, conservers, creators and knowledge-holders of BR.

The SBBs are established with a Chairperson, five ex-officio members representing the departments concerned and five members appointed from experts in matters relating to conservation of BD, sustainable use of BR and equitable sharing of benefits arising out of the use of BR. The BMCs are to be constituted by the local bodies. The *Guidelines for Operationalisation of BMCs* issued by the NBA state that the BMCs may be constituted with members of the participating forest/ natural resources management committees, horticulturists, *vaids* (traditional healers), foot botanists and tribal heads based on local conditions. The SBBs should issue suggestive list of persons to be included in the BMCs but there should be flexibilities to meet local requirements.<sup>21</sup> The following States have also passed Rules regarding setting up of SBBs, BMCs and conditions for access to BR and AK, in line with the provisions of the BDA: Andhra Pradesh, Arunachal Pradesh, Assam, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Manipur, Meghalaya, Mizoram, Rajasthan, Tripura, Sikkim, West Bengal, and UP<sup>22</sup>.

### **What is the scope of the measures in place?**

The BDA was enacted to address the issues of conservation of BD, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of BR and AK. The Act regulates access to BR by foreign<sup>23</sup> and Indian,<sup>24</sup> both natural and legal persons, for research and commercial utilization. It also covers issues relating to granting of no objection certificates for obtaining IPRs,<sup>25</sup> ABS

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<sup>17</sup> Section 8 (1) of the BDA

<sup>18</sup> Section 22 (1) of the BDA

<sup>19</sup> The term “local bodies” defined in Section 2 (h) of the BDA. It means local self government institutions such as Panchayati Raj and Municipal institutions.

<sup>20</sup> Section 41 (1) of the BDA

<sup>21</sup> <http://nbaindia.org/uploaded/pdf/Guidelines%20for%20BMC.pdf>

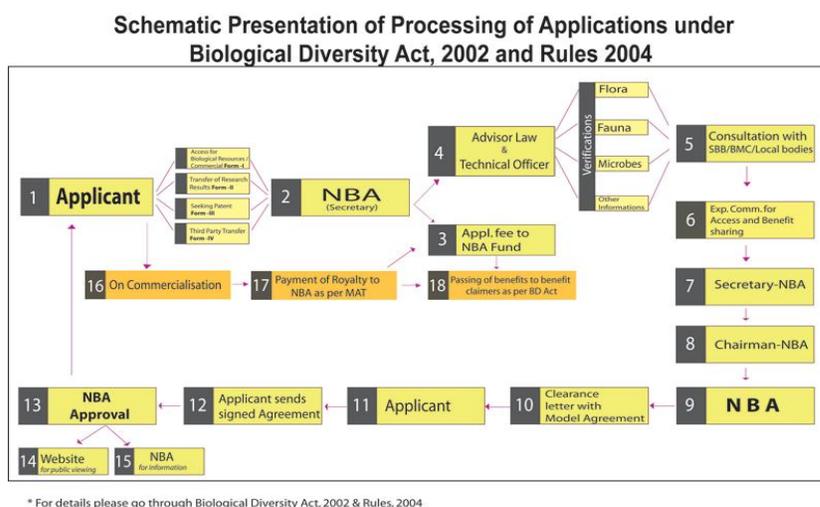
<sup>22</sup> <http://nbaindia.org/content/18/21/notifications.html>

<sup>23</sup> Section 3 of the BDA

<sup>24</sup> Section 7 of the BDA

<sup>25</sup> Section 6 of the BDA

mechanisms,<sup>26</sup> notification of species, which are on the verge of extinction,<sup>27</sup> declaration of biodiversity heritage sites (BHS),<sup>28</sup> and opposing grant of IPR outside India on the BR obtained illegally. Imposition of penalty on the violators of the provisions of the Act is also envisaged in the Act.<sup>29</sup> The Act extends to the whole of India.<sup>30</sup> Foreigners, NRIs, commercial firms, associations or organizations not incorporated in India or incorporated in India with non-Indian participation in its share capital or management require prior approval of the NBA when they use BR occurring in India for commercial or research purposes or for the purposes of bio-survey or bio-utilisation. Indians and Indian institutions do not require the approval of the NBA when they engage in these activities. However, they would need to inform the SBBs prior to undertaking such activities. However, any I application relating to commercial utilization of BR should be approved by the NBA. The scheme of the processing of applications under the BDA and BDR is presented below<sup>31</sup>:



### Who owns GR in your country? Who owns BR?

BDA vests sovereign rights over its BR on the State. The NBA, the SBBs and BMCs provide the institutional structure to regulate the exploitation of the BR occurring in India<sup>32</sup>, including the activities of those that apply for access to BR for research, commercial utilization<sup>33</sup> or transfer of result of research relating to any BR<sup>34</sup> or any IPRs for an invention based on any research or information on BR<sup>35</sup>. NBA also ensures fair and equitable sharing of benefits arising out of the use of accessed BR in accordance with Mutually Agreed Terms (MATs) and conditions between the person applying for such approval, local bodies concerned and the benefit claimers<sup>36</sup>. According to the Act, where payment of any amount of money is ordered by way of BS, the NBA may direct the amount to be deposited in the

<sup>26</sup> Section 21 of the BDA

<sup>27</sup> Section 38 of the BDA

<sup>28</sup> Section 37 of the BDA

<sup>29</sup> Sections 55, 56 and 57 of the BDA

<sup>30</sup> Section 1 (2) of the BDA

<sup>31</sup> Source: <http://nbaindia.org/uploaded/images/application-process-with-benefit-sharing-component-14-07-11.jpg>

<sup>32</sup> Section 18 of the BDA

<sup>33</sup> Section 3 of the BDA

<sup>34</sup> Section 4 of the BDA

<sup>35</sup> Section 6 of the BDA

<sup>36</sup> Section 21 (1) of the BDA

National Biodiversity Fund (NBF). However, where BR were acquired from specific individual or group of individuals or organizations, the NBA may direct that the amount be paid directly to such individual or group or organization in accordance with the terms of any agreement<sup>37</sup>. The obvious inference is that the government recognises the role of local communities, individuals and groups of individuals or organizations as conservers of BR and therefore sharing of benefits arising from the use of the resources is allowed with these “benefit claimers”<sup>38</sup>. This implies that while the rights over the BR in the country are vested with the State, , the benefits resulting from their utilisation are to be extended to the conservers, and which in many cases are the local communities. However, where such benefit claimers cannot be identified, the amount of BS is to be deposited in the NBF for the benefit and development of the area and people from where the BR is accessed and utilized.

As per the definition accorded to the term “BR”<sup>39</sup> under the BDA, “GR” are included within the meaning of the term BR, and so the provisions, which apply to the BR, also apply to the GR and both are similarly placed as per the provisions of the Act.

### **How is indigenous and local communities and TK defined?**

The terms ‘indigenous and local communities’ and ‘TK’ are not defined in the BDA or BDR. However, the NBA defines the term ‘TK’ as “the knowledge, innovations and practices of local and indigenous communities relevant to conservation and sustainable use of BD”.<sup>40</sup> AK is TK, but only that relating to BR and that includes most of the TK.

### **Who owns TK?**

The BDA does not refer to TK *per se*; the provisions refer to this body of knowledge as one “associated with ... biological resource which is derived from India”<sup>41</sup>. The provisions, which are applicable to ownership of the BR, are also applicable to the TK/AK which means that TK/AK is owned by the “benefit claimers” as in the case of GR and BR.<sup>42</sup>

### **What types of measures were adopted and implemented: Policy, legislation, regulations?**

The CG enacted and adopted the BDA and BDR to provide instruments for the conservation and sustainable use of the BR. A decentralized three-tiered structure established under the Act implements the Act and the Rules at the national, state and local levels respectively, as mentioned above. These bodies are required to coordinate and cooperate in decision-making processes on conservation and sustainable use of the BR and on issues of ABS.

Besides the BDA and the BDR, a number of policies and programmes are in place to protect, conserve and sustainably use the country’s BR. These include National Biodiversity Action Plan, National Forest Policy, National Wildlife Action Plan, National Forestry Action Programme, National Environment Policy and National Action Plan on Climate Change. There are several other legislations addressing the issue of BD as listed in Box 1.

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<sup>37</sup> Section 21 (3) of the BDA

<sup>38</sup> The term “benefit claimers” is defined in Section 2 (a) of the BDA

<sup>39</sup> The term “BR” is defined in Section 2(c) of the BDA

<sup>40</sup> As defined in ABS terminology. Available at: [www.nbaindia.org](http://www.nbaindia.org), visited on 11. 09. 2013.

<sup>41</sup> Section 18(4).

<sup>42</sup> Section 3, 6 and 7 of the BDA

### **Box 1: Legislations that address the issue of Biodiversity**

1. The Fisheries Act 1897
2. The Destructive Insects and Pests Act, 1914
3. The Indian Forest Act, 1927
4. The Agriculture Produce (Grading and Marketing) Act, 1937
5. The Indian Coffee Act, 1942
6. The Import and Export (Control) Act 1947
7. The Rubber (Production and Marketing) Act, 1947
8. The Tea Act, 1953
9. The Mining and Mineral Development (Regulation) Act 1957
10. The Prevention of Cruelty to Animal Act, 1960
11. The Customs Act, 1962
12. The Spices Board Act, 1986
13. The Seeds Act, 1966
14. The Patents Act, 1970
15. The Wildlife (Protection) Act, 1972
16. The Marine Products Export Development Authority Act, 1972
17. The Water (Prevention and Control of Pollution) Act, 1974
18. The Tobacco Board Act, 1975
19. The Territorial Water, Continental Shelf, Exclusive Economic Zone and other Maritime Zones Act, 1976
20. The Water (Prevention and Control of Pollution) Cess Act, 1977
21. The Maritime Zones of India (Regulation and Fishing by Foreign Vessels) Act 1980
22. The Forest (Conservation) Act, 1980
23. The Air (Prevention and Control of Pollution) Act 1981
24. The Agricultural and Processed Food Products Export Development Authority Act 1985
25. The Environment (Protection) Act, 1986
26. The National Dairy Development Board Act, 1987
27. Rules for the manufacture, use/import/export and storage of hazardous microorganism/genetically engineered organisms or cells, 1989
28. The Foreign Trade (Development and Regulation) Act, 1992
29. The Protection of Plant Varieties and Farmer's Rights Act, 2001
30. The Plant Quarantine (Regulation of Import into India) order 2003
31. The Food Safety and Standards Act, 2006
32. The Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006
33. The National Green Tribunal Act 2010

### **How were national users of GR considered (e.g. research institutes, universities)? Were they covered by the national measures? How?**

The national users of GR are better placed in terms of procedural regulations required under the BDA and under the BDR in comparison to non-Indian entities. All individuals, other than resident Indians, must take the prior approval of the NBA for obtaining BR occurring in India for commercial or research purposes or for the purposes of bio-survey or bio-utilization.<sup>43</sup> Prior approval of NBA is also required where results of any research relating to any BR occurring in or obtained from India are to be transferred for monetary consideration or otherwise to any person other than Indian citizens, or to NRIs

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<sup>43</sup>Supra note 15

or any foreign company.<sup>44</sup> However, Indian citizens, commercial firms and other entities registered in India that obtain BR for commercial utilization, or bio-survey and bio-utilization for commercial utilization, must do so after giving prior intimation to the SBBs. A resident Indian researcher does not require prior approval nor does she need to give prior intimation to SBBs for obtaining BR for conducting research in India, as long as she does not use her research results for commercial purposes. In case of collaborative research projects involving transfer or exchange of BR or information between institutions, including government sponsored institutions of India, and such institutions in other countries, prior approval from NBA is not required if such research is approved and in conformity with the policy guideline issued by the CG in this respect.<sup>45</sup> Also exempt from the regulatory requirements are local people and communities of the area, including growers and cultivators of BD, and *vaids* and hakims (traditional healers), who have been practising indigenous medicine.<sup>46</sup>

### **What is the procedure for Prior Informed Consent (PIC)?**

The procedure for obtaining PIC, which is primarily concerned with the access to BR occurring in India, is laid down in sections 19 and 20 of the BDA and Rules 14 – 19 of the BDR.

#### *PIC in case where non – Indian citizen or NRI citizen is involved*

PIC is required where any person other than a resident Indian citizen intends to obtain any BR occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization. Such person is to make application in the prescribed form and also pay the prescribed fees to the NBA in case he intends to obtain any BR or knowledge associated thereto.<sup>47</sup>

#### *PIC in case where any person (Indian or Non – Indian) is involved*

PIC is required where any person intends to transfer the result of any research relating to BR occurring in, or obtained from India for monetary consideration or otherwise to foreign nationals, companies or NRIs. Such person shall make application in such form and pay such fees as prescribed by the NBA.<sup>48</sup> Also, where any person intends to apply for a patent or any other form of IP protection whether in India or outside India by whatever name called, for any invention based on any research on BR or AK obtained from India is to make an application in the form and in the manner as prescribed by the NBA.<sup>49</sup> Where any person who has been granted approval for access to BR and associated knowledge, intends to transfer the accessed BR or knowledge subject matter of that approval to any other person or organization is not do so except with the permission of the NBA.<sup>50</sup>

#### *PIC in case where Indian Citizens are involved*

Indian researchers, both citizens and institutions based in India, neither require prior approval nor need to give prior intimation to SBBs for obtaining BR for conducting research in India. Prior intimation of SBB is required when an Indian citizen or body corporate, association or organization obtains BR for commercial utilization or bio-survey or bio-utilization for commercial utilization or in case research results are used for commercial purposes.<sup>51</sup>

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<sup>44</sup> Section 4 of the BDA

<sup>45</sup> Section 5 of the BDA

<sup>46</sup> Section 7 of the BDA

<sup>47</sup> Section 3 and 19(1) of the BDA

<sup>48</sup> Section 4 of the BDA

<sup>49</sup> Section 6 and 19(2) of the BDA

<sup>50</sup> Section 20 (1) of the BDA

<sup>51</sup> Section 7 of the BDA

### PIC in case of Collaborative Projects

In case of collaborative research projects involving transfer or exchange of BR or information between institutions, including government sponsored institutions of India, and such institutions in other countries, prior approval from NBA is not required if such research is approved or in conformity with the policy guidelines issued by the CG in this respect.<sup>52</sup> The CG has also notified ‘the *Guidelines for International Collaboration Research Projects Involving Transfer or Exchange of BR or Information relating thereto between institutions including government sponsored institutions and such institutions in other countries*’. They specifically provide that in case the results from the research from the project subsequently prove likely to lead to any IPRs, the collaborating partners have to enter into a fresh agreement with the NBA to ensure sharing of benefit, prior to filing of application for IPR<sup>53</sup>.

### Exemption from PIC or Prior Intimation

Local people and communities, including growers and cultivators of BD, and *Vaid*s and *Hakim*s, practising indigenous medicines do not have to comply with the requirement of PIC and prior intimation.<sup>54</sup> This exemption is also applicable in case a person makes an application for any right under any law relating to protection of plant varieties enacted by Parliament.<sup>55</sup>

### Revocation of access or approval

Revocation of access or approval granted to an applicant is to be done only on the basis of any complaint or *suo motu* under the following conditions<sup>56</sup>:

- (i) Violation of the provisions of the Act or conditions on which the approval was granted.
- (ii) Non – compliance of the terms of the agreement.
- (iii) Failure to comply with any of the conditions of access granted.
- (iv) Overriding public interest or for protection of environment and conservation of BD.

After having withdrawn the access permit, the NBA is required to send an order of revocation to the relevant BMC and the SBB for prohibiting the access and to assess the damage, if any, caused and steps to recover the damages.<sup>57</sup>

### Restriction for access to BR

The Act imposes certain restrictions on request related to access to BR and TK if the request is<sup>58</sup>:

- (i) On endangered taxa
- (ii) On endemic and rare taxa
- (iii) Likely to have adverse effects on the livelihood of the local people
- (iv) Likely to have adverse and irrecoverable environment impact

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<sup>52</sup> Section 5 of the BDA

<sup>53</sup> Ministry of Environment and Forests Notification SO 1911 dated 8 November, 2006 available at <http://nbaindia.org/uploaded/pdf/notification/7%20%20collaborative%20guidelines.pdf>

<sup>54</sup> Section 7 of the BDA

<sup>55</sup> Section 6 (3) of the BDA. India has a Protection of Plant Varieties and Farmers’ Rights Act, which was enacted 2001.

<sup>56</sup> Rule 15 (1) of the BDR

<sup>57</sup> Rule 15 (2) of the BDR

<sup>58</sup> Rule 16 of the BDR

- (v) Likely to cause genetic erosion or affect ecosystem function, or
- (vi) For a purpose contrary to national interest and other related international agreements to which India is party.

### **What are the key conditions for obtaining PIC?**

The key conditions for obtaining PIC are:

- Person applying for access to BR for research or for commercial utilization is to make an application in Form I<sup>59</sup> together with a fee of Rs. 10,000.<sup>60</sup>
- Person applying for approval for transferring results of research relating to BR obtained from India for monetary consideration to foreign nationals, companies and NRIs, is to make an application in Form II<sup>61</sup> together with a fee of Rs. 5,000.<sup>62</sup>
- Person applying for any IPR based on research on biological material and knowledge obtained from India is to make an application in Form III<sup>63</sup> together with a fee of Rs. 500.<sup>64</sup>
- Person, who has been granted approval for access to BR and AK, intends to transfer the accessed BR or AK to any other person or organization is to make an application to the NBA in Form IV<sup>65</sup> together with a fee of Rs. 10,000.<sup>66</sup>

While granting approval to any person for access or for transfer of results of research or for applying for IPR or for third party transfer of the accessed BR and AK, the NBA may impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and AK.<sup>67</sup> Apart from this, the NBA may put forth such other terms and conditions as it may deem fit, including the imposition of charges by way of royalty.<sup>68</sup>

### **Who may grant PIC for use of GR and TK?**

In case of foreign nationals and companies and NRIs approval is granted by the NBA,<sup>69</sup> whereas in case of Indian nationals and companies the competent authorities to grant approval for use of GR and TK are the SBBs.<sup>70</sup> In case of foreign nationals, PIC is required for research and commercial utilization of the BR and AK<sup>71</sup>. In case of Indian nationals, prior approval of NBA is required to transfer the results of any research relating to any BR occurring in India to a foreign person or firm or institution<sup>72</sup>

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<sup>59</sup> Rule 14 (1) of the BDR

<sup>60</sup> Rule 14 (2) of the BDR

<sup>61</sup> Rule 17 (1) of the BDR

<sup>62</sup> Rule 17(2) of the BDR

<sup>63</sup> Rule 18 (1) of the BDR

<sup>64</sup> Rule 18 (2) of the BDR

<sup>65</sup> Rule 19 (1) of the BDR

<sup>66</sup> Rule 19 (2) of the BDR

<sup>67</sup> Rule 20 (4) of the BDR

<sup>68</sup> Section 19 (3) of the BDA

<sup>69</sup> Section 3 of the BDA

<sup>70</sup> Section 7 of the BDA

<sup>71</sup> Section 3 of the BDA

<sup>72</sup> Section 4 of the BDA.

### **Is the procedure different when GR are accessed for basic research purposes or for commercialization purposes?**

The BDA prescribes different procedures for application for foreign natural or legal person, NRI,<sup>73</sup> resident Indian<sup>74</sup> and collaborative research project.<sup>75</sup> Under the Act, the following are required to obtain prior approval from the NBA to access to BR for research or for commercial utilization: (a) person who is not a citizen of India; (b) legal person not incorporated or registered in India or having any non-Indian participation in its share capital or management; (c) NRI<sup>76</sup>. Any person seeking approval of the NBA is to make an application in form I<sup>77</sup> along with a fee of Rs. 10,000.<sup>78</sup> However in case of any natural or legal person who is citizen of India or registered in India no intimation or prior approval is required for research but where BR is obtained by such person for commercial utilization it can be done only after giving prior intimation to the SBB concerned. However, these regulations restricting the access are not applicable for local people, and communities including growers and cultivators of BD and *vaid*s and *hakims* practising indigenous medicine.<sup>79</sup>

### **If a two-phase approach is in place, providing PIC for research and requiring a new PIC for commercialisation, what is the trigger for the second phase? For example clinical trials, patenting?**

If an applicant obtains a PIC for utilization of BR for basic research, and which the at a later stage she decides to use for commercial considerations, a fresh PIC should be entered into between the NBA and the applicant so as to decide the equitable sharing of benefits, monetary or otherwise.<sup>80</sup> In such cases, the trigger point is the commercial utilization<sup>81</sup> of the BR. Apart from this, the application for the IPR in or outside India for any invention based on any research or information on a BR can also be a trigger point for a second phase.<sup>82</sup>

### **Are there different PIC requirements for different types of GR (e.g. marine, forest)?**

There is no explicit provision in the BDA, which mentions different PIC requirements for different types of GR. The Act endows the NBA with power to set different terms and conditions for different cases.<sup>83</sup>

### **What is the average delay in obtaining PIC from the time access is officially requested?**

Different time-periods have been prescribed for disposal of different kinds of applications:

- Application for access to BR for research or for commercial utilization is to be disposed of within 6 months from the date of its receipt.<sup>84</sup>
- Application for approval for transferring results of research relating to BR for monetary consideration to foreign nationals, companies and NRIs is to be disposed of within 3 months.<sup>85</sup>

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<sup>73</sup> Section 3 of the BDA

<sup>74</sup> Section 7 of the BDA

<sup>75</sup> Section 5 of the BDA

<sup>76</sup> Section 3 and 19 (1) of the BDA

<sup>77</sup> Rule 14 (1) of the BDR

<sup>78</sup> Rule 14 (2) of the BDR

<sup>79</sup> Section 7 of the BDA

<sup>80</sup> Section 17 (1) and 19 (1) of the BDA

<sup>81</sup> The term “Commercial Utilization” is defined in Section 2 (f) of the BDA

<sup>82</sup> Section 6 and 19 (2) of the BDA, 2002 and Rule 18 of the BDR

<sup>83</sup> Section 19 (3) and 20 (3) of the BDA

<sup>84</sup> Rule 14 (3) of the BDR

- Application for approval for applying for IPR, by whatever name called, in or outside India for any invention based on any research or knowledge on biological material obtained from is to be disposed of within 3 months.<sup>86</sup>
- Where any person, who has been granted approval for access to BR and AK, intends to transfer the accessed BR or AK to any other person or organization makes an application before the NBA, then such application is to be disposed of within a period of six months from the date of its receipt.<sup>87</sup>

There are, however, instances when the authorities have exceeded the above-mentioned time-limits for granting approvals.

#### **Is PIC awarded for a particular period of time?**

Though there is no specific provision in the BDA which provides the terms of the tenure for which the PIC is awarded the NBA has power to specify the tenure while entering into the agreement for access.<sup>88</sup> However, in most of the cases access has been granted for specified periods of one or two years.

#### **Is a permit issued when PIC is granted?**

As per the requirement of the BDA the approval for access, i.e., PIC, is to be in the form of a written agreement signed by an authorized officer of NBA and the applicant.<sup>89</sup> The agreement should contain the terms and conditions for the access.<sup>90</sup>

#### **What is the procedure in place for the negotiation of MAT?**

MAT is an agreement reached between the provider of GR and a user with respect to the conditions of access to GR and the benefits to be shared between both parties, which may arise from the commercial or other uses of these resources. The BDA and the BDR provide for the inclusion of appropriate BS provisions in the access agreements and MATs related to access and transfer of BR for commercial utilization, bio-survey, bio-utilization or any other monetary purposes. The agreements are mostly negotiated and signed between those accessing the GR and the NBA, but the latter consults the SBBs who are also to consult the BMCs concerned. The NBA may also make such enquiries as it may deem fit and, if necessary, consult an Expert Committee constituted for this purpose. BS is determined on a case by case basis.<sup>91</sup> The NBA, while granting approval to any person for access to or for transfer of results of research or for applying for IPR or for third party transfer of the accessed BR, may impose terms and conditions for ensuring equitable BS arising out of the use of accessed BR<sup>92</sup>. NBA is also expected to ensure that these terms and conditions are in accordance with MATs and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.<sup>93</sup>

The quantum of benefits should be mutually agreed upon between the persons applying for such approval and the NBA, in consultation with local bodies and benefits claimers, and may be decided with

<sup>85</sup> Rule 17 (3) of the BDR

<sup>86</sup> Rule 18 (3) of the BDR

<sup>87</sup> Rule 19 (3) of the BDR, 2004

<sup>88</sup> Rule 14 (6) (XII) of the BDR

<sup>89</sup> Rule 14 (5) of the BDR

<sup>90</sup> Rule 14 (6) of the BDR

<sup>91</sup> Section 19 (3) and 20 (3) of the BDA and Rule 20 (3) of the BDR

<sup>92</sup> Rule 20 (4) of the BDR

<sup>93</sup> Section 21 (1) of the BDA

due regard to the defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels, including measures ensuring conservation and sustainable use of BD<sup>94</sup>. Also depending upon each case, the NBA is to stipulate the period for assessing BS on short, medium and long-term benefits.<sup>95</sup> Where BR or knowledge is accessed from a specific individual or a group of individuals or organizations, the NBA may take steps to ensure that the agreed amount is paid directly to them through the district administration. Where such individuals or group of individuals or organizations cannot be identified, the monetary benefits are to be deposited in the NBF.<sup>96</sup> The NBA is required to monitor the flow of benefits as and in the manner determined by it.<sup>97</sup>

Also, as a matter of natural justice, rejection of an application can be made only after giving an opportunity of being heard to the applicant<sup>98</sup>.

### **Are MATs a condition for obtaining PIC?**

One of the primary objectives behind the enactment of the BDA is to ensure BS arising from the use of BR and for this very purpose the Act envisaged the establishment of a decentralized structure of institutions for implementing the provisions of the Act. Thus the NBA while granting approvals for access, is to ensure equitable sharing of benefits arising out of the use of accessed BR, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto are in accordance with MATs and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.<sup>99</sup> The MATs thus form a part of PIC.

### **Are key elements of MAT set out (content requirements)? Is a template for MAT available?**

No specific template has been devised for MATs. A case-by-case approach has been adopted in this as well as in BS. However, the *Draft Guidelines on ABS*<sup>100</sup> developed by the NBA gives some indications regarding user obligations.

The *Draft Guidelines* also include the non-monetary benefits identified in the *Bonn Guidelines*.

The NBA has also devised the following ready-to-apply monetary BS formula<sup>101</sup>, which could be incorporated in the MATs. The royalty payments in such cases are to be made to NBA, to be ploughed back to the benefit claimers/conservers/growers of BR.

1. Applicant must pay to the NBA during the term of the agreement annual royalty @ 2 to 5 per cent of the gross ex-factory sale of the product derived from the use of the BR and/or AK accessed.
2. Applicant must pay during the term of the agreement annual royalty @ 5% of the total ex-factory sales of the product derived from the use of the BR and AK accessed as ascertained from the annual progress reports of the user duly certified by chartered accountants.
3. Researcher must pay during the term of the agreement annual royalty @ 5% of the upfront payment if the patent is licensed/transferred to others and also 5% of the ex-factory sales in the

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<sup>94</sup> Rule 20 (5) of the BDR

<sup>95</sup> Rule 20 (6) of the BDR

<sup>96</sup> Rule 20 (8) of the BDR

<sup>97</sup> Rule 20 (10) of the BDR

<sup>98</sup> Section 19(3) proviso of the BDA.

<sup>99</sup> Section 21 (1) of the BDA

<sup>100</sup> [http://nbaindia.org/uploaded/docs/Access\\_Guidelines.doc](http://nbaindia.org/uploaded/docs/Access_Guidelines.doc).

<sup>101</sup> [http://nbaindia.org/uploaded/pdf/ABS\\_Factsheets\\_1.pdf](http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf)

event of commercial production by the company from the use of BR and AK accessed as ascertained from the annual progress reports of the user, duly certified by chartered accountants.

4. Exporter must pay 5% of Free on Board (FOB) value of the export consignments as evidenced by a copy of the shipping bill and chartered accountant certificate, subject to licensing by Director General of Foreign Trade (DGFT).

Further, the NBA has developed separate formats for the following agreements: (i) access to BR for research/bio-survey and bio-utilization, (ii) access to BR for commercial uses, (iii) transfer of research results, (iv) seeking IPRs and (v) third party transfers. These include conditions for access to BR and/or AK, liabilities and indemnification and terms and termination. An Expert Committee had suggested amendments to the agreement formats in 2011 in the light of experiences gained in implementation of the BDA, with a view to making them simpler and easier for stakeholders. However, the changes have not yet been carried out.

#### **Are specific requirements in place for the sharing of monetary and non-monetary benefits?**

While granting approvals for access, NBA is to determine and impose the terms and conditions so as to secure equitable sharing of benefits, subject to any regulations made by the CG in respect of BS. These terms and conditions are to be implemented in any of the following manner:<sup>102</sup>

- (a) Grant of joint ownership of IPRs to the NBA, or where benefit claimers are identified, to such benefit claimers;
- (b) Transfer of technology;
- (c) Location of production, research and development units in such areas, which will facilitate better living standards to the benefit claimers;
- (d) Association of Indian scientists, benefit claimers and the local people with research and development in BR and bio-survey and bio-utilization;
- (e) Setting up of venture capital fund for assisting the benefit claimers;
- (f) Payment of appropriate monetary compensation and non-monetary benefits to the benefit claimers.

Where any amount of money is ordered by way of BS, the NBA can direct the amount to be deposited in the NBF. However, where the BR were obtained from specific individual or group of individuals or organization, the NBA may direct that the amount be paid directly to them in accordance with the terms of any agreement and in such manners as it deems fit.<sup>103</sup> The BDA provides for the constitution of funds, namely, the NBF,<sup>104</sup> the State Biodiversity Fund (SBF)<sup>105</sup> and the Local Biodiversity Fund (LBF)<sup>106</sup> at the national, state and local level respectively. Each of the institutions formed by the BDA, namely, the NBA, the SBBs and the BMCs, have the powers to charge the users for the utilisation of the BR. The Act also

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<sup>102</sup> Section 21 (2) of the BDA

<sup>103</sup> *ibid*

<sup>104</sup> Section 27 (1) of the BDA

<sup>105</sup> Section 32 (1) of the BDA

<sup>106</sup> Section 43 (1) of the BDA

provides that BMCs may levy charges by way of collection fees from any person for accessing or collecting any BR for commercial utilization from areas falling within their jurisdictions.<sup>107</sup>

The money received by these funds from grants, loans, charges and royalties are used for channelling benefits to the benefit claimers, conservation and promotion of BR and development of areas from where such BR or AK has been accessed, and socio-economic development of such areas in consultation with the local bodies concerned<sup>108</sup>.

**What types of compliance measures are in place in order to ensure that users respect ABS requirements in your country?**

There is a three-tiered organisational structure,<sup>109</sup> namely, NBA, SBB and BMC, for the purpose of supervising the measures provided in the BDA and for the monitoring of the compliance by the users of the ABS agreement as entered into between the NBA and the applicant. In case of non compliance, the NBA can revoke the approval granted to the applicant and cancel the agreement entered into between the NBA and the applicant. Revocation of access or approval granted to an application will be done only on the basis of any complaint or *suo motu* under the conditions mentioned above on page 9:<sup>110</sup>

**Who are relevant stakeholders at the national level (e.g. research community, universities, *ex situ* collections, indigenous and local communities, and private landowners)?**

Research community and universities are the main stakeholders at the national level. Most of the BR accessed are for the purpose of research and the commercial production or use of the end products has not started till date in most of the cases as is evident from the ABS agreements between the NBA and the users. Perhaps this is the reason that only in very few cases benefit has been shared with the NBA. The benefit claimers are conservers of BR, and holders of knowledge and information relating to the uses of BR. The benefit claimers are identified through the Peoples' Biodiversity Registers (PBRs). As per the BDR, the main function of the BMC is to prepare the PBRs. These registers are used, where available, to identify the BMCs wherefrom the BR are accessed and for payment of benefits to the LBF concerned. In cases where specific individuals or group of individuals are identified, the monetary benefits are to be paid directly to the LBF to be used by the BMC concerned.

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<sup>107</sup> Section 41(3) of BDA.

<sup>108</sup> Section 27 (2) and Section 32 (2) of the BDA

<sup>109</sup> Sections 8) 22 and 41 of the BDA

<sup>110</sup> Rule 15 of the BDR

## Providers of genetic resources

**Where are GR mostly being accessed in your country (where is the greatest demand for access to GR)? In forest areas, marine areas, other?**

The greatest demand for access to GR is in the agriculture sector followed by forest areas.

**Do foreigners carry out bio-prospection in your country or do they access GR from intermediaries (e.g. *ex situ* collections, universities or national research institutes)? In other words are GR accessed *in situ* or *ex situ* by foreigners?**

As per the NBA, there is no evidence of direct bio-prospecting by foreigners in India. In most cases, GR are accessed from intermediaries, with agricultural universities playing an active role in this respect. GR are accessed *ex situ* by foreigners in most of the cases.

**Do intermediaries play an important role for ABS in your country (e.g. universities, research institutes, *ex situ* collections)?**

Intermediaries, in particular, agricultural universities, which are assisting foreigners in accessing the BR, are playing an important role in ABS. Most of these universities are working in collaborative research projects involving the use of BR accessed from India with foreign legal and/or natural persons. Commonly traded commodities<sup>111</sup> are available with the traders. It is not clear from the available information whether traders are also supplying biological material that is not included in the notified list of commonly traded commodities.

**Who are the main providers of GR accessed *in situ* in your country: the State? Private landowners? Indigenous and local communities?**

The State exercises sovereign rights over GR in the country. However, the mechanism and procedures established under the BDA are to ensure that local communities have their say over the use of GR existing in their area. That is the rationale for the establishment of BMCs.<sup>112</sup> Thus, the NBA and the SBBs are required to consult the BMCs while taking any decision relating to the use of BR and associated knowledge occurring within the territorial jurisdiction of the BMCs.<sup>113</sup>

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<sup>111</sup> The Government of India, in consultation with the NBA, notified on 26 October, 2009 a list of 190 BR as commonly traded commodities to which the BDA will not be applied. These include 35 medicinal plants, 28 spices, and 127 horticultural crops. See SO 2726 dated 26 October, 2009.

<sup>112</sup> Section 41 of the BDA.

<sup>113</sup> Section 41(2) of BDA.

## Users of genetic resources

**Who are the main users of GR in your country? The research community, the private sector? For what purpose do they access GR, (e.g. basic research, commercialization)? Are they mostly foreigners or nationals?**

The main users of the GR are the research community and in most cases GR are used for basic research. Further, most researchers are resident Indians. In few cases GR were accessed for commercial utilization.

**If GR are accessed for commercial purposes, what types of sectors are interested in these GR (e.g. pharma, cosmetics, agriculture, industrial biotech)?**

In cases where GR are accessed for commercial purposes, they are accessed by agricultural sector (seed industry), the pharmaceuticals and cosmetics sectors, followed by other sectors. There have also been cases of access for export only.

**Does the national ABS system in place also address the obligation of your country as user of GR accessed in foreign countries? In other words, are obligations imposed on users in your jurisdiction who have accessed GR in foreign countries to respect ABS requirements of foreign countries?**

Patents Act, 1970 provides that a patent applicant should disclose the source and geographical origin of the biological material in the patent specification, when used in an invention.<sup>114</sup>

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<sup>114</sup> Section 10, sub-section (4), proviso (ii) D of the Patents Act, 1970.

## ABS agreements

**How many ABS agreements have been concluded? Is this information recorded? If not, please provide an indication.**

According to the NBA, 117 ABS agreements have been concluded till date, out of a total of 844 applications<sup>115</sup>.

The year-wise figures of applications received, and their status at various stages of processing are given in the following tables.<sup>116</sup>

**Table I**

**Total Applications Received**

Year	Form I Access of BR for Research/Commercial Purpose	Form II Transfer of Research Results	Form III Applying for IPRs	Form IV Third Party Transfer	Not applied in prescribed Form and Fee	Total
2003-2004	1	0	0	0	4	5
2004-2005	3	1	1	3	4	12
2005-2006	7	3	0	3	3	16
2006-2007	14	1	94	3	2	114
2007-2008	22	1	174	10	0	207
2008-2009	15	7	58	2	0	82
2009-2010	22	11	97	11	0	141
2010-2011	12	9	15	12	0	48
2011-2012	10	0	35	15	0	60
2012-2013	25	0	63	11	0	99
2013-2014	13	3	38	6	0	60
Total	144	36	575	76	13	844

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<sup>115</sup>Status as on 31 August, 2013 available at <http://nbaindia.org/text/24/TOTALAPPLICATIONRECEIVED.html>.

<sup>116</sup><http://nbaindia.org/text/21>

**Table II**

**Total Applications Cleared**

Year	Form I	Form II	Form III	Form IV	Total
2006-2007	5	4	0	3	12
2007-2008	5	0	223	6	234
2008-2009	10	5	41	6	62
2009-2010	4	2	16	3	25
2010-2011	3	3	9	2	15
2011-2012	6	0	40	13	59
2012-2013	4	1	55	5	65
2013-2014	0	0	4	1	5
Total	37	15	387	38	477

**Table III**

**Agreement Signed by the Applicant with NBA (MATs)**

Year	Form I	Form II	Form III	Form IV	Total
2006-2007	4	1	0	2	7
2007-2008	3	3	11	6	23
2008-2009	4	4	21	6	35
2009-2010	2	1	9	1	13
2010-2011	3	1	4	1	9
2011-2012	1	2	6	0	9
2012-2013	1	0	8	7	16
2013-2014	1	0	4	0	5
Total	19	12	63	23	117

**Table IV**

**Applications under Processing**

Status of	Form I	Form II	Form III	Form IV	Total
Applications	74	11	169	28	282

**Table V**

**Closed Applications**

Status of Applications	Form I	Form II	Form III	Form IV	Not applied in prescribed form and fee	Total
Closed Applications	37	12	26	11	13	99

All the applications for permission to apply for IPRs are from Indians, with a large share from the Council of Scientific and Industrial Research (CSIR), a government body. Many of the Indian R&D institutions have tie-ups with foreign institutions. For instance, Gujarat Agricultural University had a tie-up with BP International of London. Indian R&D and other institutions send the GR outside mainly because of lack of infrastructure facilities in the country for the particular investigation/study.

**Were these ABS agreements for non-commercial or commercial utilization of GR?**

In most cases, ABS Agreements are for non-commercial utilization of GR such as research except for few cases where these agreements are for commercial utilization of GR. In cases of commercial utilization benefits have been shared with the NBA by those accessing the GR.

**Were any benefits derived from these agreements?**

ABS agreements have yielded some benefits, although the number of such cases is very few. NBA has entered into 117 ABS agreements out of 844 applications received until August, 2013. The general practice is for the NBA to collect annually two to five per cent of gross ex-factory sales revenue of the products derived from BR obtained from India, during the period of the agreement. In case of exports, the amount collected is equivalent to five per cent of free on board (FoB) value of export consignments. An inventor who has obtained a patent based on the research has to pay five per cent of the upfront payment if the patent is licensed to others. The NBA has received more than Rs. 4.3 million as royalty from seven agreements of which Rs. 20,000 has been sent to a BMC and the rest remains with the NBA<sup>117</sup>. In two cases in the state of Madhya Pradesh, monetary benefits have been transferred directly either to the SBB or the BMC concerned. The following table presents the monetary accruals from the BS cases:

**Table VI**

**Category wise Details of Actual BS with the NBA**

Category	Amount in Rupees
Access and transfer of BR and associated TK(Forms I and IV)	39,09,765
Access of BR and associated TK (Form I)	4,25,993
IPRs (Form III)	3,940
Total	43,39,698

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<sup>117</sup> Data source NBA.

Almost 90% of the monetary benefits have come from a single case and source, namely, from PepsiCo India Holdings Pvt. Ltd (henceforth PepsiCo) for seaweed export. There are cases in which although the NBA had directed payment of monetary benefits, actual payments have not been made. For example, in the case of a patent for a process for preparation of a herbal formulation of *Tejan*, *Bhootkeshi* and *Nilnirgundi* as a Bronchodilator, (patent No. 212041 dated 11 November 2007), the patentee was directed by NBA to pay 5% of the net sales to NBA, but actual payments have not materialised.

**What are the types of benefits generated from these ABS agreements? Monetary, non-monetary? How are they shared? What type of support, if any, is provided to beneficiaries receiving benefits arising from MAT and ABS agreements?**

Accrued benefits have been largely monetary in nature, but, as stated above, the number of such cases is very few. The benefits received by the NBA are to be shared with the BMCs for the protection and conservation of the BR and TK. This dimension has remained unaddressed. In a solitary case, one involving PepsiCo, training was given to women self help groups. Apart from this, the locals get employment opportunities, where the resources are collected. Access to BR linked with conservation could also be a means for women's empowerment as has happened in the case of Gram Mooligali Company, which is a community managed enterprise of collectors and cultivators of medicinal plants that cover tribal dominated districts in Tamil Nadu, Karnataka, Kerala and Maharashtra<sup>118</sup>. There are also cases where, while there may not be any individual ABS agreement, there can be BS. For example, active participation in the in eco-tourism, which provides for sustainable access to BR and conservation, can be a source of income for local people. Eco-tourism in Periyar Tiger Reserve in Kerala is a case in point. In this case, tribal and local people are trained to work as guides for trekking, jungle walk, nature walk, bamboo rafting, tiger trailing and bullock cart riding. They also get orders for local special food preparation for camps as well as cultural shows from tourists, which also add to their income<sup>119</sup>. These may not be flowing out of the BDA directly, but could be considered a welcome step towards BD protection.

### **Examples of implemented ABS agreements**

Most of the cases relate specifically to the utilization of GR and one case to IPRs, as explained below:

- PepsiCo exported 2000 MT seaweed (*kappaphycus alvarezii/Euchemia cottonii*) to Malaysia, Philippines and Indonesia. The seaweed was grown by fishermen community from districts of Ramanathapuram, Tuticorin, Pudukottai and Tanjore. It was collected, cleaned, baled and exported. The collection, cleaning and baling was done by women self help groups. They were given training by the company. The NBA was paid royalty @ 5% of FoB amounting to Rs. 3.9 million by the exporter. Efforts are being made by the SBB to form BMCs of the 754 benefit claimers spread across four districts. Due to claims that this seaweed is becoming an invasive species, NBA has now stopped providing access permits.
- Bio India Biologicals Company exported 2000 kilograms of *Neem* Leaves (*Azadirachta indica*) to Japan. They were collected from Amarchinta village BMC of Mahboobnagar district, Andhra Pradesh. The NBA was paid a royalty @5% of FOB amounting to Rs. 55,035 by the exporter which transferred Rs. 20,000 to the BMC for planting *Neem* saplings and creation of awareness about BD conservation.

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<sup>118</sup> <http://www.financialexpress.com/story-print/104258> dated 12 April, 2004. Also see <http://www.keralabiodiversity.org/images/pub/jan2013.pdf>.

<sup>119</sup> [http://www.periyartigerreserve.org/ecotourism\\_activities.php](http://www.periyartigerreserve.org/ecotourism_activities.php)

- Natural Remedies Pvt. Ltd, Bengaluru, purchased *kalmegh (Andrographis paniculata)*, a medicinal herb, from BMC of Malajkhand in the Balaghat district of MP. They paid Rs. 21,000 directly to the BMC.
- Dr. Geeta Pandurang Pawar, an Ayurvedic doctor from Pune, had applied for No objection Certificate for obtaining a patent for an Ayurvedic anti snake venom comprising four medicinal plants. This tablet 'Pinak' acts as a temporary relief instantly before victim is taken to the hospital. In this case NBA had fixed the BS as 2% of the gross sales or gross revenue of the product." On commercialization of the patented product, the applicant paid Rs. 3,940 as BS to the NBA.

Of the above-mentioned examples of the actual BS it is only in one case that BS has been shared by the NBA with the BMC. There is, however, a case of an agreement between the Madhya Pradesh SBB and the Gram Moolige Company Ltd. from Jabalpur, MP for the collection of *Satavar (Asparagus racemosus)*, *Arni*, *Nagarmoth*, *Agnimanth*, *Arjuna*, *Kutaj*, *Giloy*, *Amla*, *Beheda*, *Guggul* and *Shankhpushpi* from Vijapur and Bichia. The company paid Rs. 22,265 to the SBB in April 2013.

#### **Have these ABS agreements contributed to conservation and sustainable use of BD in your country?**

As stated above, tangible benefits from the implementation of BDA have come in the form of financial payments accruing from the ABS agreements. The accrued amounts have been small and have therefore made no significant contribution towards conservation and sustainable use of BD in the country. At the same time, some of the institutions under the BDA have made progress in conservation efforts. The most notable of these is Kerala SBB's project on 'Conservation of tuber crop diversity in Wayanad and its popularization among the villagers of the district' at Edavaka *Gramapanchayat* through BMCs. Under this project, a community germplasm centre has been established to conserve neglected and underutilized root and tuber crops and also to serve as a source of seed material. Fifty-two varieties of roots and tubers have been collected and raised, of which seven are wild-types, procured from forest with the help of tribal communities. In order to create awareness about the nutritional value and production potential of tuber crops among children, two schools at Edavaka Gramapanchayat, and one each at Mananthavady and Vellamunda Gramapanchayats, have also established germplasm centres. Seed material is distributed to farmers depending on their varietal needs<sup>120</sup>.

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<sup>120</sup> [http://www.keralabiodiversity.org/index.php?option=com\\_content&view=article&id=150&Itemid=162](http://www.keralabiodiversity.org/index.php?option=com_content&view=article&id=150&Itemid=162)

## Key lessons learnt

### What will you do differently in future?

**Based on your experience, what are key elements for a functional ABS system? in relation to procedures for PIC, negotiation of MAT, sharing and distribution of benefits, compliance, and other? (e.g. scope? ownership of GR?)**

At present, the BMCs, which should play the pivotal role in the ABS system, appears as the weak link. Local communities are not very enthusiastic about this institution, which possibly explains why sizeable number of BMCs has not been established in most states. As of October 2013, only 32,221 BMCs have been established in a country that has about 638,000 villages. Further, in the institutional framework, the BMCs do not seem to be playing a significant role. They are often not consulted before the SBBs convey their opinions to the NBA.

Our view is that in the absence of adequate awareness among the local communities, the system of PIC and ABS has not brought the desired benefits to the local people. What is, therefore, needed is an effective awareness generation programme. Such a programme should cover local communities, general public, SG and CG employees serving in relevant departments, civil society organisations, industry and academic institutions. This should be done in a time-bound and focussed manner and cover the entire country. The NBA has already developed a training module on the BDA, which could be used as training material for the awareness generation programmes.

The NBA has not issued any guideline(s) for the SBBs regarding the quantum of benefits to be shared, the regulatory powers of SBB, and the powers of SBB to issue orders prohibiting or restricting activities that are inimical to BD protection. NBA should come out with proper guidelines on ABS, which will help and equip different SBBs to deal with various requests in a systematic manner.

The possibilities of delegating more powers and authority to SBBs in dealing with ABS matters are also worth consideration. Decisions need to flow from local to national level instead of being *vice versa*, as of now. This should make the SBBs more responsible and answerable for the access cases in their respective states. Further, SBBs may be given more autonomy by the SGs while acting as per the provisions of the BDA.

There are various departments of a SG concerned with BR and AK. All of them need to be involved in the ABS mechanism, at least in the state and local level bodies such as BMCs. This should be done to ensure that the conflict between the *gram sabhas* (village councils) and the BMCs are minimized and both work in the interest of the local people.

PBRs form the basic database for ABS system. However, they have not been prepared in most states. There is an urgent need to get them all completed. This should be done at the village/ *Panchayat* level. The SBBs, as in the case of Kerala, should take major initiative in this regard.

The SBBs may consider appointment of Master Trainers to train the local people and the BMCs for preparation of PBRs, opening of bank accounts and collection of the BR in a manner that does not disturb the BD. They may also create Technical Support Groups for assisting the BMCs.

NBA may also issue specific guidelines relating to determination of the amount in case of BS. This should bring in clarity in the matter of ABS to both those accessing the GR and the benefit claimers and will help in sustainable economic development and conservation.

It may be worth consideration to have a prior intimation to NBA/SBB/BMC for access by Indians too. This will facilitate monitoring.

**Based on your experience, what were key challenges faced with implementation? In terms of process (e.g. to gather support for the system at the national level, by various stakeholders, i.e. what were key messages conveyed by stakeholders regarding the implementation of the system)? In terms of procedures established. In terms of content.**

Collection of the benefits from the commercial entities accessing the GR is one of the most daunting problems. For example, the Madhya Pradesh SBB has received 25 applications under BDA, of which in only two cases, actual benefits have accrued through ABS agreements, as stated above. Apart from these two cases, the SBB has issued orders to six companies for the compliance of the BS provisions. Of the six companies, three have challenged the SBB order before the National Green Tribunal (NGT) through an appeal and remaining three have still not complied with the order.

Applicants who seek to use BR and AK are required to provide the NBA with information on the quantities, timing and exact geographic location from where they would access such BR and knowledge. However many of the applicants appear to have accessed the resources or knowledge not directly from *in-situ* sites but through various intermediaries including local markets. Given the wide spread availability of GR, it is a significant challenge for the NBA to identify the potential beneficiaries thereby causing undue delays in the processing ABS applications.<sup>121</sup>.

Almost all the applications received by NBA so far deal with plant material and a few microbial organisms. Given the richness of animal and fish diversity existing in India there is a concern that these resources are being accessed without the prior approval of the NBA<sup>122</sup>. There has, however, been a couple of cases of transfer of animal DNA samples<sup>123</sup>. In one case, the National Dairy Development Board sent DNA samples of buffalos and cattle to the University of Missouri, USA to be used for DNA marker assisted selection of cattle and buffalos. In another case, the National Chemical Laboratory sent the DNA of two Indian sheep breeds to Commonwealth Scientific and Industrial Research Organisation (CSIRO), Canberra, Australia. There is no evidence of BS in either of these cases.

Section 40 of the BDA exempts normally traded commodities from the purview of the Act. While a list of 190 such commodities has been notified thus far, there is no consensus yet on an agreed definition of what constitutes a 'commodity' for the purposes of the Act, and, therefore, stakeholder groups have varied interpretations of this term<sup>124</sup>.

Section 5 of the Act exempts collaborative research from the purview of the BDA. The exemption covers collaborative research between Indian and foreign institutions and aims to facilitate research and remove any encumbrances to the same. For research to qualify as "collaborative", it would have to conform to the CG guidelines for collaborative research and should be approved by the CG. However, clear guidelines for identifying collaborative research projects are lacking. There is a need clarify as to what constitutes collaborative research and how it can be distinguished from exchange of specimens between institutions<sup>125</sup>.

Lack of clarity is also there in regard to certain expressions in the BDA. For example, section 21(1) provides that BS is to be there in regard to 'by products' of accessed BR, but this term has not been defined either in BDA or BDRs. This leads to confusion as to what is a by product and what is a derivative. Such confusion needs to be removed through issue of proper clarifications.

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<sup>121</sup> [http://nbaindia.org/uploaded/pdf/ABS\\_Factsheets\\_1.pdf](http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf)

<sup>122</sup> Ibid.

<sup>123</sup> Ibid

<sup>124</sup> Ibid.

<sup>125</sup> Ibid.

BR accessed under an ABS agreement may involve transfer of resources to third parties that are part of a value chain. In addition, transfers to third parties and countries by Indian institutions or governments also take place in emergencies or based on bilateral trade/ research/ technology transfer agreements including diplomatic channels. Tracking and monitoring such transfers have been posing a major challenge to the NBA.<sup>126</sup>

Issues of uncertainty as to the need for seeking approval have occurred where non-Indian entities obtain BR through Indian companies/ exporters.<sup>127</sup>

A major problem as observed above is that even the paltry monetary benefits accruing from commercial use of BR have not reached the local communities who are the preservers and conservers of BR and AK.

The SBBs are also facing a number of major challenges in their performance. There are disputes over the issue whether SBBs have the power to issue notices to the persons using BR for commercial utilization and also for granting of approvals for commercial utilization or bio-survey and bio-utilization of any BR by Indians. This issue was even agitated before the NGT by the Madhya Pradesh SBB. The dispute occurred when the SBB issued notice against 260 industries that were accessing the BR directing them to share the benefits arising from the commercial utilization of the BR. It is interesting to note that when the affected industries approached the SG, the department concerned took a view that BS was in the nature of a tax and the government only could tax. The government was informed that the amount of benefit to be shared by the industry was not a tax but as per the BDA it was the amount to be deposited with the NBF for the benefit of the people of the locality from where the industries were accessing the BR for commercial utilization. It was further conveyed to them that the NBA was vested with the powers of determining the percentage of BS, and that the SG can only make a request to NBA for reducing the percentage of BS.

Another problem faced by SBBs is the insufficiency of funds at their disposal due to which SBBs are unable to organize awareness raising and training programme to the extent required for the effective implementation of the BDA.

There are differences between the NBA and some SBBs whom the study team members consulted, regarding the definition of several terms appearing in the BDA. In fact, there are differences of opinion on the definition of BR and commercial utilization. There is a mistaken understanding about the BDA that it is applicable only to forest species and medicinal plants. One such difference in opinion arose on whether coal was a BR or whether extraction of coal was commercial utilization as defined by the BDA. This case arose when the Madhya Pradesh SSB opined that coal was a BR. Accordingly, on 11 January 2013, it served notices to the three subsidiaries of Coal India Limited, namely, South Eastern Coalfields, Western Coalfields and Northern Coalfields, stating that the extraction of coal for commercial purpose without informing the SBB was a punishable offence and that under the BDA. The SBB has also stated that the coal mining companies should share profits with stakeholders or BMCs. Since then, the NGT has also issued notices to the parties asking why there has been no sharing of royalties. Such problems could be sorted out through issuance of proper guidelines by the NBA after due consultation.

There are no clear guidelines for the SBBs from the NBA regarding the determination of the amount of BS, because of which they are handicapped in respect of the percentage of BS when industries access BR. At present, the SBBs are following a general rule, based on which they have fixed the benefit to be shared between 2–5 percent of the gross ex–factory sale of the product derived from the use of the BR

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<sup>126</sup> Ibid.

<sup>127</sup> Ibid.

accessed. Despite this, specific guidelines for monetary BS are required as the scope for manoeuvring still exists

A major challenge is regarding enforcement. Inadequate monitoring is a serious problem that one could find in the large number of ABS agreements signed by the NBA. It may be necessary to strengthen the institutional and human resource capacities at national, state and local levels to address this problem. Perhaps check points could be identified and developed. Further, it may also be necessary to conduct awareness programmes among the stakeholders considering the low financial and educational levels of local communities in most states.

Documentation has also been a critical challenge, though it has been envisaged as the main activity of BMCs.<sup>128</sup> The PBRs are to be developed in consultation with the local people and the registers are need to contain comprehensive information on availability and knowledge of local BR, their medicinal or any other use or any AK. The registers are expected to provide information on the economic benefits of the resources to the local communities and will help in equitable sharing of benefits arising out of commercial utilization of them. They could also contain rules of access to such BR and AK. In the absence of PBR it has been difficult to trace BR accessed or used by outsiders. Preparation of the PBRs has been given special attention by some of the SBBs like Madhya Pradesh and Kerala<sup>129</sup>, which have the largest number of PBRs (741 and 670 respectively)<sup>130</sup>. Of course, at national level there is a database of TK, namely, Traditional Knowledge Digital Library (TKDL), but this, as of now, limited to TK in various ancient texts and has been prepared with a view to preventing grant of patents on such TK and may not be much use in deciding BS at local levels. Emergent and concerted action will have to be taken in this regard, including technical training of the local communities for the preparation of the PBRs. The NBA has issued *Revised Guidelines for preparation of PBRs*. They contain details of the methodology and process to be adopted, general details, list of traditional practitioners of the knowledge systems such as *vaids*, details of access to BR and AK already granted, collection fee imposed and the benefits derived and the mode of their sharing. They also provide different formats for obtaining information on various kinds of resources such as agro-biodiversity, domesticated biodiversity, wild biodiversity, urban biodiversity. Within each category, different formats have been prescribed, for example, for crop plants, fruit plants, fodder crops, weeds, pests of crops, markets for domesticated animals, peoplescape about community and its practices, landscape, waterscape, soil type, medicinal plants, ornamental plants, domesticated animals, fisheries, aquatic biodiversity, and others.

Another issue that affects BS and access approval is that of coordination between NBA and SBBs and BMCs. The Study Team felt that consultation between the three agencies is generally inadequate, which has hampered the implementation of the BDA. In most states, the number of BMCs remains vastly inadequate, because of which this important agency is not effectively involved while the Act is being implemented. Two issues must be mentioned in this context. First, efforts must be made to establish the BMCs, all over the country, particularly in the states that do not have adequate number of them. Secondly, there is a need to create a formal consultative mechanism among the three agencies that would help in overcoming the deficiencies in the implementation of the BDA.

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<sup>128</sup> Rule 22(6) of the BD Rules, 2004.

<sup>129</sup> [http://www.keralabiodiversity.org/index.php?option=com\\_content&view=article&id=87&Itemid=91](http://www.keralabiodiversity.org/index.php?option=com_content&view=article&id=87&Itemid=91)

<sup>130</sup> Karnataka and Uttarakhand are the two other states that show some progress in the development of PBRs (267 and 139 respectively). For details see, <http://nbaindia.org/content/105/30/1/pBRs.html>.

## Concluding Remarks

The BDA is a well-crafted legislation that takes into consideration the imperatives of implementing a complex law given the realities facing a large country with a huge variety of BR. The three-tiered organisational structure adopted in the legislation sits well with the overall decentralised governance system existing in India. In keeping with the spirit of this governance system, the BDA brings the BMCs, comprising of local communities, within the decision-making ambit, concerning the use of BR and AK occurring within the territorial jurisdiction of each of the Committees.

The Study Team felt that despite its well-crafted nature, the implementation of the BDA has some weaknesses. The ABS provisions have not been implemented effectively, which, as this Study Team found, was mainly due to inadequate awareness about the law among various stakeholders and the weakness of institutional mechanisms. Moreover, well-articulated guidelines, without which no legislation can be effectively implemented, are not yet in place. Considering the importance of promoting conservation and sustainable use of BR, there is an urgent need to remove the shortcomings being faced for proper implementation of the Act so that benefits can accrue to the communities who protect and nurture BR and AK. Strengthening of institutional and human resources will have to be carried out to ensure any meaningful BS from access to BR and AK in India.