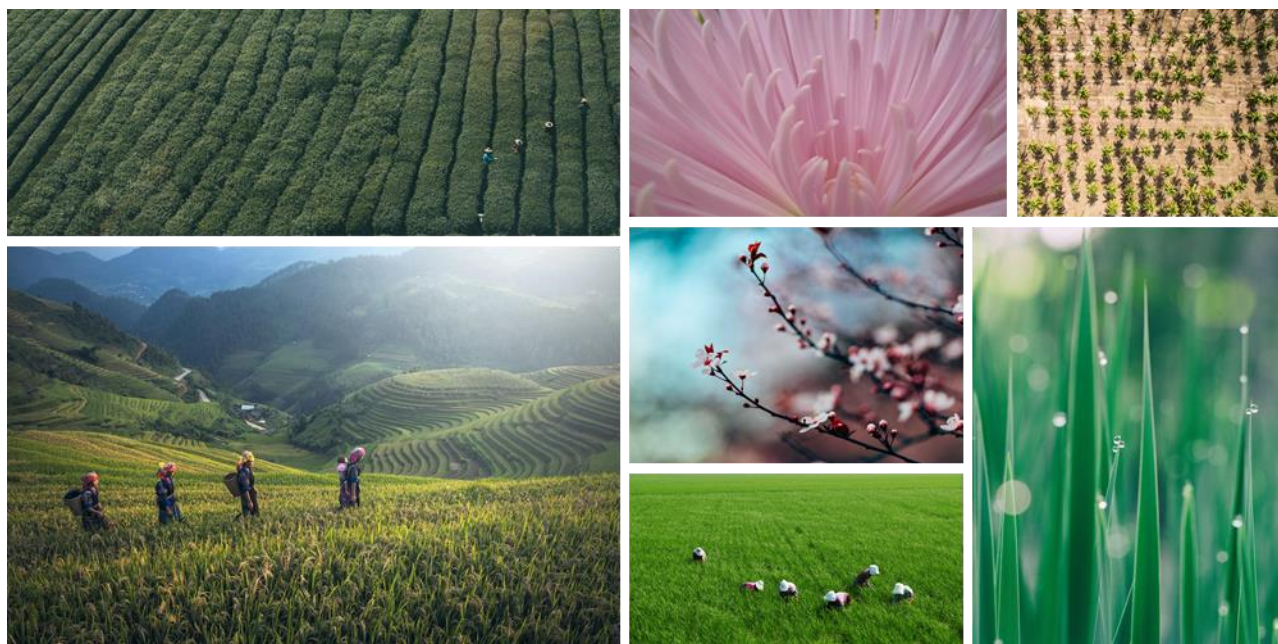




IFRA-IOFI Guidance Document  
for the Flavor and Fragrance Industry  
for dealing with the Nagoya Protocol  
and Access and Benefit Sharing (ABS) Regulations

Annex – India



IFRA-IOFI Nagoya Protocol TF  
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## 1 Party Status

India is a Party of the Convention of Biological Diversity (CBD), the Nagoya Protocol (NP) and the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA). Table 1 provides the dates of signature, ratification and entry into force of each of these international treaties by India.

**Table 1: Signature and Ratification of international treaties by India**

Convention/Treaty/Protocol	Signed	Ratified	Entered into force
Convention on Biological Diversity, 1992	5 June 1992	18 February 1994	19 May 1994
Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, 2010	11 May 2011	9 October 2012	12 October 2014
International Treaty for Plant Genetic Resources for Food and Agriculture, 2001	10 June 2002	10 June 2002	29 June 2004

## 2 National Authorities and Relevant institutions

The Biological Diversity Act, 2002 (BDA) provides for the establishment of three types of bodies, namely:

- A National Biodiversity Authority (NBA)<sup>1</sup>
- State Biodiversity Boards (SBBs)<sup>2</sup>
- Biodiversity Management Committees (BMCs)<sup>3</sup>

The **NBA**, headquartered in Chennai, is entrusted with the following functions<sup>4</sup> –

- Regulates and grants approval for activities involving the utilization of biological resources by non-Indians, including intellectual property rights;
- Advises the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources;
- Advises the State Governments in the selection of areas of biodiversity importance as heritage sites and measures for the management of such areas;
- Takes any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource from India.

The **State Biodiversity Boards** are required to carry out the following duties:<sup>5</sup>

<sup>1</sup> § 8, Biological Diversity Act, 2002

<sup>2</sup> § 22, Biological Diversity Act, 2002

<sup>3</sup> § 41, Biological Diversity Act, 2002

<sup>4</sup> § 18, Biological Diversity Act, 2002

<sup>5</sup> § 23, Biological Diversity Act, 2002

- Advise the State Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources;
- Regulate by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilization of any biological resource by Indians;

The **Biodiversity Management Committees** are local bodies formed for the purposes of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge relating to biodiversity.<sup>6</sup>

Finally, the statute provides an opportunity for appeal from any order passed by the NBA or SBB which will be heard by the National Green Tribunal,<sup>7</sup> established by the National Green Tribunal Act, 2010. This is the specialized body to handle environmental disputes in India.

### **3 Access to genetic/biological resources and TK**

#### **3.1 Applicable Legislation**

The applicable legislation is the Biological Diversity Act, 2002 (BDA). The BDA is in force since July 2004. This Act is aimed at conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for incidental matters.<sup>8</sup>

The BDA defines “biological resources” as plants, animals and micro-organisms or parts thereof, their genetic material and by-products with actual or potential use or value but does not include human genetic material.<sup>9</sup>

Further, “commercial utilization” is defined as the end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavors, fragrance, cosmetics, emulsifiers, oleoresins, colors, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee-keeping.<sup>10</sup>

#### **3.2 Main Legislative Principles**

The BDA provides for the regulation of Access to Biological resources. The relevant provisions under this Chapter are Sections 3, 4, 6 and 7 of the BDA.

Prior approvals from the NBA are required **before obtaining** any biological resource occurring in India or associated knowledge for research or for commercial utilization or bio-survey/bio-utilization. These approvals are required specifically by the following persons:

- Non-Indian citizens;
- Citizens who fall within the definition of non-resident under the Income Tax Act; and

<sup>6</sup> § 41, Biological Diversity Act, 2002

<sup>7</sup> § 52A, Biological Diversity Act, 2002

<sup>8</sup> Preamble, Biological Diversity Act, 2002

<sup>9</sup> § 2(c), Biological Diversity Act, 2002

<sup>10</sup> § 2(f), Biological Diversity Act, 2002



- A body corporate, association or organization not registered in India or registered in India under any law for the time being in force but has non-Indian participation in its share capital or management.<sup>11</sup>

The BDA provides that prior approval of the National Biodiversity Authority (NBA) is required **before transferring the results of research** on any biological resource occurring in or obtained from India for monetary consideration to any of the persons specified in the preceding paragraph.<sup>12</sup>

Prior approval of the NBA is also required **before applying for any intellectual property rights** in or outside India for any invention based on any research/information on a biological resource obtained from India.<sup>13</sup>

The NBA imposes a benefit sharing fee or royalty or both or imposes conditions including the sharing of financial benefits arising out of the commercial utilization of such rights while granting approval.<sup>14</sup>

Additionally, citizens of India, or companies registered in India, are required to obtain prior approval from the State Biodiversity Boards before obtaining any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization.<sup>15</sup>

## 4 Benefit-Sharing

### 4.1 Principles and Requirements

India having ratified the Nagoya Protocol, it has committed to set up a legislative framework requires India to complying with Article 6(3) of the Protocol, which establishes that Parties requiring prior informed consent shall take the necessary legislative, administrative or policy measures. The Ministry of Environment, Forests and Climate Change (MoEFCC) has been designated as the National Focal Point, the NBA as the Competent National Authority, the MoEFCC as the National Publishing Authority and the NBA as the National Authorised User, for the ABS Clearing House.<sup>16</sup>

The approval of the NBA/SBB is a pre-requisite for obtaining biological resources for research purposes, commercial utilization, bio-survey and bio-utilization among others. Further, the Traditional Knowledge Digital Library has been established by Ministry of AYUSH in collaboration with National Council for Scientific & Industrial Research to transcribe coded traditional knowledge for wider use and protection.<sup>17</sup>

The National Biodiversity Authority, when granting approvals for the aforementioned activities, is entitled to make enquiries and consult an expert committee before granting approval. During this process, it may also impose conditions relating to the payment of charges by way of royalty.<sup>18</sup>

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<sup>11</sup> § 3, Biological Diversity Act, 2002

<sup>12</sup> § 4, Biological Diversity Act, 2002

<sup>13</sup> § 6(1), Biological Diversity Act, 2002

<sup>14</sup> § 6(2), Biological Diversity Act, 2002

<sup>15</sup> § 7, Biological Diversity Act, 2002

<sup>16</sup> 6<sup>th</sup> National Report for the Convention on Biological Diversity, India, 2018, p. 151, Available at <https://chm.cbd.int/database/record?documentID=241351>

<sup>17</sup> *Id.* at p. 159

<sup>18</sup> §§ 19(3), 20(3), Biological Diversity Act, 2002

## 4.2 Options for Benefit-Sharing

Benefit sharing can be carried out in any of the following ways, as determined by the National Biodiversity Authority-

- Grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
- Transfer of technology;
- Location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
- Association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;
- Setting up of venture capital fund for aiding the cause of benefit claimers;
- Payment of monetary compensation and non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.<sup>19</sup>

A summary of the benefit sharing modes specified in the “Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014” is attached as Annexure A. These Guidelines adopted by the National Biodiversity Authority have the status of regulations in Indian Law and are published in the Official Journal. Thus, for all practical purposes, the Guidance documents are followed. However, in case of any dispute or contradiction between any Guidelines with the Act itself, the Act would prevail.

*NB: It may be noted that the NBA has initiated a revision process of these guidelines. A new version is expected to be published soon.*

## 5 Known Grey Zones

### 5.1 Bio-resources and Intellectual property rights (IPR)

The approval of the NBA/SBB is a pre-requisite for obtaining biological resources for research purposes, commercial utilization, bio-survey and bio-utilization among others. Furthermore, when granting approval for applications for intellectual property rights (IPR), a time limit of 90 days is set for processing such applications so that inventors are not put to great hardships.<sup>20</sup> Though the Patents Act, 1970, does not statutorily require permission from the NBA for use of biological resources in the disclosed invention, the patent office practice necessitates NBA permissions before a patent is granted.

The issue lies in the fact that there are a number of instances where biological resources may have been utilized in the disclosed invention which may not require any approval of the NBA or be outside the purview of the BDA, however, the patent office insists for the same as there is no guideline for the applicant to follow in such situations.

Further, there have been instances where the Indian Patents Office has refused the grant of a patent on the ground that importing of biological material that was otherwise available in India commercially, would make the patented product costly for the Indian public, and hence could not effectively be worked.

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<sup>19</sup> § 21(2), Biological Diversity Act, 2002

<sup>20</sup> Implementation of Nagoya Protocol on Access and Benefit Sharing: India's Experience, 2018, p. 6

## 5.2 Clarity on Value Added Product

The exclusion of Value Added product (VAP) from the definition of biological resources in the BDA is not clarified and hence the interpretations as to what would require or not require permission if the product in question appears to be a VAP are as per the discretion of the NBA with no say for the applicant.

## 5.3 Multiple Approvals

Foreign entities looking to participate in the utilization of biological resources obtained from India and wanting to apply for IPR are forced to undergo a number of approvals and benefit sharing agreements under Section 3 and 6 of the Act.

Similarly, Indian entities wishing to commercially utilize biological resources, or transfer it to non-citizens or apply for IPR would have to obtain the necessary approvals under Sections 7, 4 and 6 respectively.

## 6 Exclusions

### 6.1 Explicit exclusions from the scope of the Biological Diversity Act and allied Rules and Guidelines

The BDA provides for two exclusions from the definition of biological resources in Section 2(c). The first exclusion is that of **value-added products**, which is defined as products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.<sup>21</sup> The second exclusion is that of **human genetic material**.<sup>22</sup>

The definition of commercial utilization also contains certain exclusions namely **conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or beekeeping**.<sup>23</sup>

The BDA provides for the Central Government to exclude, by way of notification, certain items, including **biological resources normally traded as commodities**.<sup>24</sup>

The Government of India, through Notification dated 17 December 2014, has exempted crops listed in Annex – 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) from the purview of the Biological Diversity Act, 2002 in order to enable them to be utilized for conservation, breeding, research and training for food and agriculture.<sup>25</sup>

### 6.2 Exemptions from the Benefit-Sharing obligation

The Act exempts the following from ABS obligations:

- Local people and communities of the area who may freely use the biological resources in India.<sup>26</sup>

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<sup>21</sup> § 2(p), Biological Diversity Act, 2002

<sup>22</sup> § 2(c), Biological Diversity Act, 2002

<sup>23</sup> § 2(f), Biological Diversity Act, 2002

<sup>24</sup> § 40, Biological Diversity Act, 2002

<sup>25</sup> Implementation of Nagoya Protocol on Access and Benefit Sharing: India's Experience, 2018, p. 8

<sup>26</sup> Proviso to § 7, Biological Diversity Act, 2002

- Growers and cultivators of biodiversity, along with Vaidas (practitioners of Ayurvedic medicine) and Hakims (physicians using traditional medicine).<sup>27</sup>
- Collaborative research projects through Government sponsored or Government approved institutions subject to overall policy guidelines and approval of the Central Government.<sup>28</sup>

Further, Indian researchers and government institutions may access genetic resources to carry or send biological resources outside India for basic non-commercial research or for emergency purposes.<sup>29</sup> A declaration between the user and the recipient is required to be submitted to the NBA. Such applications are dealt with on an expeditious timeline, and no fee is charged for such applications.<sup>30</sup>

## 7 Adequacy and Regularization

In addition to the Biological Diversity Act, 2002, India has also passed the **Biological Diversity Rules, 2004**, which primarily provide for procedures to be followed when applying for approvals for initiating research on biological resources, transferring the results of such research outside India and for applying for IPR that involves the use of biological resources.<sup>31</sup> The Rules also provide for the criteria for equitable benefit sharing,<sup>32</sup> application of the National Biodiversity Fund,<sup>33</sup> and the constitution of Biodiversity Management Committees.<sup>34</sup>

Following this, the National Biodiversity Authority formulated the **Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014**. These guidelines further add to the procedural requirements in obtaining approval from the requisite Authority. They also provide the mode of benefit sharing and the considerations to be taken when determining the amount of benefit sharing.

Section 21 read with Rule 14(6) lay down the minimum conditions that must be imbibed in the grant of access to genetic resources, their by-products, and traditional knowledge.

India has shared implemented provisions for the Internationally Recognized Certificate of Compliance (IRCC) to be issued through ABS Clearing House system. The NBA has set up an inter-ministerial, inter-disciplinary expert group for formulating a policy for the designation of checkpoints and procedures for their effective functioning.<sup>35</sup>

### 7.1 Sanctions

The BDA provides specific sanctions in case of breach of its provisions.

In case of Sections 3, 4 and 6, a violation or abetment of such violation is punishable with imprisonment for a term up to 5 years, or with fine up to Rs. 1,000,000 (about USD 14350) and

<sup>27</sup> *Id.*

<sup>28</sup> § 5, Biological Diversity Act, 2002

<sup>29</sup> Regulation 13, Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014

<sup>30</sup> Implementation of Nagoya Protocol on Access and Benefit Sharing: India's Experience, 2018, p. 8

<sup>31</sup> Rules 14, 17 and 18, Biological Diversity Rules, 2004

<sup>32</sup> Rule 20, Biological Diversity Rules, 2004

<sup>33</sup> Rule 21, Biological Diversity Rules, 2004

<sup>34</sup> Rule 22, Biological Diversity Rules, 2004

<sup>35</sup> Implementation of Nagoya Protocol on Access and Benefit Sharing: India's Experience, 2018, p. 9

where the damage caused exceeds Rs. 1,000,000 (USD 14350), the fine would be commensurate with the damage, or may be more.<sup>36</sup>

In case of Section 7 and 24(2), a violation or abetment of such violation shall be punishable with imprisonment up to 3 years, or with fine up to Rs. 500,000 (USD 7175), or both.<sup>37</sup>

Further, if any person contravenes any direction or order given or made by the Central Government, State Government, NBA or SBB for which there is no separate punishment under the Act, he shall be punished with fine up to Rs. 100,000 (USD 1435) and for a subsequent offence, with fine up to Rs. 200,000 (USD 2870). If a continuous contravention occurs, an additional fine up to Rs. 200,000 (USD 2870) per day shall be levied.<sup>38</sup>

For any offence committed by a company, every person who was in charge of and responsible to the company for the conduct of its business at the time the contravention was committed shall be deemed to be guilty of the offence along with the company, and shall be proceeded and punished accordingly, unless he may prove that the contravention was without his knowledge or he had exercised all due diligence to prevent the contravention.<sup>39</sup>

There are several cases which were centered around the scope of the regulation, such as the case of Divya Pharmacy vs. Union of India and Ors.<sup>4041</sup> or the case of BioDiversity Management Committee, Chhindwara, Madhya Pradesh vs. Union of India and Ors.<sup>4243</sup>

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<sup>36</sup> § 55(1), Biological Diversity Act, 2002

<sup>37</sup> § 55(2), Biological Diversity Act, 2002

<sup>38</sup> § 56, Biological Diversity Act, 2002

<sup>39</sup> § 57, Biological Diversity Act, 2002

<sup>40</sup> W. P. (M/S) No. 3437 of 2016

<sup>41</sup> In the case of Divya Pharmacy v. Union of India and Ors., before the High Court of Uttarakhand at Nainital, the Petitioner was aggrieved by the order of the Uttarakhand Biodiversity Board under the head of "Fair and Equitable Benefit Sharing" and the 2014 Regulations framed therein. While the Petitioner admitted that biological resources constituted a main component in the manufacture of Ayurvedic and Nutraceutical products, it contended that the Board has neither the powers nor the jurisdiction to raise a demand under the aforementioned head, and that the petitioner was not liable to pay any amount or make any kind of contribution under the particular head. The Court thus held that the SBB has the power to demand a fee from the Petitioner in the form of Fair and Equitable Benefit Sharing. It also held that the NBA had the powers to frame regulations in order to give payment of monetary compensation and other non-monetary benefits to the benefit claimers, and that the SBB has the power and duty to collect FEBS under the regulatory power it has under Section 7 read with Section 23 (b) of the Act.

<sup>42</sup> O. A. No. 17/2014

<sup>43</sup> In the case of Bio Diversity Management Committee, Chhindwara, Madhya Pradesh v. Union of India and Ors., before the National Green Tribunal, the issue before the Tribunal was whether coal would be considered as a biological resource, and subsequently whether benefit sharing could be enacted between the Applicant and the Respondents. The Tribunal held that though coal was of plant origin, but does not retain, in fossilized form, any genetic characteristics which can be linked to the plants or vegetation from which it was originally formed, and accordingly it was not a biological resource. Subsequently, it was held that since coal was not a biological resource, there could be no benefit sharing relationship established under the Biological Diversity Act, 2002.

## 8 Annex: benefit sharing provisions as per the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014

### 8.1 Mode of Benefit Sharing for Access to Biological Resource

**Table 2: Mode of benefit sharing for access to biological resources in India**

For Direct Purchases of Biological Resources	Trader	Manufacturer
When not entered into prior benefit sharing negotiation with Joint Forest Management Committee / Forest Dweller / Tribal Cultivator / Gram Sabha*	1.0 – 3.0% of the purchase price	3.0 – 5.0% of the purchase price
When entered into prior benefit sharing negotiation with Joint Forest Management Committee / Forest Dweller / Tribal Cultivator / Gram Sabha	Not less than 3.0% of the purchase price	Not less than 5.0% of the purchase price

\* Provided that if trader further sells to another trader or manufacturer, the buyer, if a trader, shall have an obligation between 1.0 – 3.0%, and if a manufacturer, shall have an obligation between 3.0 – 5.0%.

If the buyer submits proof of benefit sharing by the immediate seller, then his benefit sharing obligations shall extend only to that portion of the purchase price which had no benefit sharing obligation imposed.

a) In case of high economic value bio-resources such as sandalwood, red sanders, etc. and their derivatives, benefit sharing may include an upfront payment of not less than 5.0% on the proceeds of the auction or the sale amount as decided by the NBA or SBB.

b) When the biological resources are accessed for commercial utilization or the bio-survey and bio-utilization leads to commercial utilization, the applicant shall have the option to pay the benefit sharing ranging from 0.1 to 0.5% (Table 3:) at the following graded percentages of the annual gross ex-factory sale of the product which shall be worked out based on the annual gross ex-factory sale minus government taxes as given below:-

**Table 3: Range of benefit sharing to be addressed by applicants depending on the percentages of the annual gross ex-factory sale of the product which shall be worked out.**

Annual Gross ex-factory sale of product	Benefit sharing component
Up to Rupees 10,000,000 (USD 143500)	0.1 %
Rupees 10,000,001 (USD 143500) up to 30,000,000 (USD 430000)	0.2 %
Above Rupees 30,000,000 (USD 430000)	0.5 %

### **8.2 Mode of Benefit Sharing for Transfer of Results of Research**

- a) Applicant shall pay to the NBA such monetary and/or non-monetary benefit, as agreed between the applicant and the NBA.
- b) In case of monetary benefit received by him on such transfer, the applicant shall pay to the NBA 3.0 – 5.0% of the monetary consideration.

### **8.3 Mode of Benefit Sharing in IPR**

The Applicant shall, in case of commercializing the IPR obtained, pay to the NBA such monetary and/or non-monetary benefit as agreed between the Applicant and the NBA (Table 4).

**Table 4: Percentages to be payed to NBA in case of Mode of Benefit Sharing in IPR.**

When Applicant himself commercializes the IPR	When Applicant assigns/licenses the IPR to a third party for commercialization
0.2 – 1.0% based on sectoral approach, which shall be worked out on annual gross ex-factory sale minus government taxes.	Applicant to pay to NBA 3.0 – 5.0% of the fee received (licensing/assignment fee) and 2.0 – 5.0% of the royalty amount received annually, based on sectoral approach.

### **8.4 Mode of benefit sharing for transfer of accessed bio-resource and/or associated knowledge to third party for research/commercial utilization**

- Applicant shall pay to NBA such monetary and/or non-monetary benefit, as agreed between the Applicant and the NBA.
- Applicant shall pay to NBA 2.0 – 5.0% on sectoral approach of any amount and/or royalty received from the transferee as benefit sharing.
- If the bio-resource has high economic value, the Applicant shall also pay a mutually determined amount upfront to the NBA.

## **9 Abbreviations**

BDA	Biological Diversity Act, 2002
BMC	Biodiversity Management Committees
CDB	Convention of Biological Diversity
IPR	Intellectual Property Rights
IRCC	Internationally Recognized Certificate of Compliance
ITPGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
MoEFCC	Ministry of Environment, Forests and Climate Change
NBA	National Biodiversity Authority
SBB	State Biodiversity Boards
VAP	Value Added Product
USD	USA dollars





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