

Operational Guidelines to the State Biodiversity Boards for Processing of Applications for Access to Biological Resources received under section 7 of the Biological Diversity Act, 2002

1. Preamble and Scope

a) The objectives of the Biological Diversity Act (BD Act), 2002 are to provide for 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 and associated knowledge. Under Section 7 of the BD Act, the State Biodiversity Board (SBB) is the competent authority for granting approvals to Indian citizens (other than NRIs)/ entities (body corporate, association or organization incorporated or registered in India under any law for the time being in force which has no non-Indian participation in its share capital or management) who give prior intimation to the SBB for obtaining biological resources for commercial utilisation or bio-survey and bio-utilisation for commercial utilisation.

b) The SBBs are also mandated to advise the State Government on matters relating to biological diversity. The operational guidelines in the following sections act as an aiding tool for SBBs in processing of access and benefit sharing (ABS) applications received by them under Section 7 of the BD Act.

c) The operational guidelines aim to ensure that the regulatory activities of SBBs are compliant with the provisions of the BD Act and the Biological Diversity Rules (BD Rules), 2004.

d) These guidelines provide clarity with respect to examination and processing of the applications submitted by the Indian citizens/ entities who fall under section 7 of the BD Act, in the Form prescribed in the relevant State Biodiversity Rules, seeking approval to access biological resources for specific purposes. The set of guidelines shall also provide a framework to ensure uniform procedure to be adopted by the SBBs in processing the applications.

2. Procedure for scrutiny of applications by the officer or person concerned:

2.1 Receipt of application

On receipt of the completed application form,

- a) The officer or person concerned shall allot a reference number to the application.
- b) See whether the requisite application fee has been received and if so arrange for depositing the same in the State Biodiversity Fund.

- c) Generate a receipt for the application fee and forward the same to the applicant.

2.2 Status of the applicant

The officer or person concerned shall *prima facie* satisfy that the applicant is covered under Section 7 of the BD Act. This shall be done by examining the identity proof and address proof of the applicant furnished along with the Form. If the applicant is an entity (company / institution/ organization), the share holding pattern of the entity needs to be examined or a declaration on status of nationality/entity shall be obtained from the applicant. A copy of the format is appended as **Annex-01**.

Provided, if the applicant falls under Section 3(2) of the BD Act, he should apply to NBA in Form-I seeking approval to access the biological resources. Hence, the SBB shall return the application to the applicant with the intimation that the NBA is the competent authority to grant approval under Section 3 of the BD Act.

2.3 Screening of application

- a) On receipt of the application, the officer or person concerned shall ensure that the applicant has filled in the respective columns appropriately and all the requisite documents (Address proof and identity proof of the applicant, authorisation letter for representative/ agents (if any), copies of board resolutions, declaration of nationality, etc.) are duly attached with the application form. If the application is complete in all respects and the requisite application fee has also been paid, then the application can be taken up for further processing.

Provided, if the application lacks vital information such as details of biological resources, geographical locations, purpose, without signature in the application, etc., the same may be returned to the applicant along with the fee.

- b) If the application form is incomplete and needs certain minor details or clarification, the applicant may be addressed to provide the same by giving reasonable time. If there is no response, two reminders ought to be given after a gap of one month between the two reminders. In the event of non-response within the time limit specified or receipt of ambiguous replies, such applications may be treated as closed with the approval of the competent authority and the applicant informed accordingly without returning the application fee.

2.4 Purpose of access

- a) The officer or person concerned shall verify whether the applicant has mentioned the exact purpose of accessing biological resources i.e, for commercial utilisation or for bio-survey and bio-utilisation for commercial utilisation.

b) It should be noted that no application should be entertained by SBBs if the purpose is for

- Research on a biological resource or associated knowledge.
- Obtaining Intellectual Property Rights for inventions based on any research or information on a biological resource obtained from India,
- Transfer of results of research related to biological resources occurring in, or obtained from India, to any non-Indian/ non-Indian entity, as defined u/s 3(2) of the BD Act
- Transfer of biological resource and/ or associated knowledge to any non-Indian/ non-Indian entity.

2.5 Biological resources

- a) The officer or person concerned shall verify whether the biological resources to be accessed are clearly specified in the application along with common and scientific names, their parts and quantity.
- b) The officer or person concerned shall also verify if the biological resource to be accessed is from wild (forest area) or cultivated or sourced from traders or communities or Joint Forest Management Committee. In case of any discrepancy or lack of information, the same shall be got clarified from the applicant.

2.6 Geographical location

- a) The SBB is expected to entertain an application for access to biological resources only if the biological resources specified occur within the territorial jurisdiction of the State concerned. The officer or person concerned needs to verify the exact geographical location like name of the village, panchayat, block, taluk and district is within the State from where the particular biological resource is proposed to be accessed.
- b) If the biological resource is proposed to be bought from a trader or from local market, institution or communities, etc. the officer or person concerned needs to verify that the complete details (Name, complete address, contact details, etc.) of such sources are also provided by the applicant. This is important while sharing benefits to the concerned.
- c) In case a person other than the applicant is authorised for collecting the biological resources, the name and contact details of the person so authorised have to be verified. The authorisation letter in favour of the person so authorised, needs to be obtained. A format of authorization letter is appended as **Annex-02**

2.7 Quantity of biological resources

- a) The officer or person concerned shall verify the exact quantity of biological resources and their parts proposed to be collected from each geographical location. This exercise may also involve a judicious assessment of the availability of some of the biological resources depending on their particular parts to be gathered in the light of sustainable harvesting.
- b) The officer or person concerned shall verify whether the applicant furnished the proposed period / duration for collection of biological resources. If the applicant is proposed to collect the biological resources in different time interval, SBB may call for reasons/ justification for the same from the applicant.
- c) If the applicant is intending to access of biological resources in a large quantity/ number of biological resources, SBB may call for reasons/ justification for the same from the applicant.

2.8 Threatened species

The officer or person concerned shall verify the threat (Rare, endangered and threatened) status of the biological resources sought to be accessed and evaluate whether obtaining the particular biological resources from their natural habitat is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity. The officer or person concerned shall also check the relevant notifications related to the threat status of the species under question before processing the application further.

2.9 Exemptions under the BD Act

While examining the applications received for access to biological resources, the examiner shall note that certain activities, as indicated below are exempted from the purview of the BD Act:

- a) Human genetic material is excluded from the definition of biological resources.
- b) Indian citizens or entities accessing biological resources occurring in or obtained from India, for the purposes of research or bio-survey and bio-utilization for research in India;

[Explanatory note: Indian citizens or entities need to obtain prior approval of NBA when they intend to obtain IPR on the results of research related to accessed biological resources and/ or associated knowledge obtained from India.]

- c) Accessing value added products, which are products containing portions or extracts of plants and animals in unrecognizable and physically inseparable form;
- d) Accessing biological resources, normally traded as commodities as and when notified by the Central Government under section 40 of the BD Act. *(for the specific purposes as indicated in the Notification)*

[Explanatory note: As per MoEFCC notification dated 7th April, 2016 & 07th November, 2017, a list of 421 items of biological resources are exempted from the purview of the BD Act when normally traded as commodities. The products that are derived from these listed items and traded as a matter of common practice are also to be treated as NTACs. However, the provisions of the BD Act shall apply to these items if there is an intention to use them for any other purpose.]

- e) The local peoples and communities of the area including growers and cultivators of biological resource and *vaid*s and *hakim*s who have been practicing indigenous medicines, except for obtaining intellectual property rights.
- f) Accessing biological resources for conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping, in India.

3. Consultation with Biodiversity Management Committees (BMCs)

- a) In the event of accessing biological resources from wild or cultivated or from communities or traders, the SBB may consult the BMC, as outlined in the State-specific Rules. Wherever no BMC is constituted, the SBB may consult the respective local body.

Provided, if the biological resources are proposed to be collected from the ex-situ collection like ZSI, BSI, ICAR, CSIR, NBPGR, IARI institutes, etc., the process of consultation may be dispensed with.

[Explanatory note: The biological resources in the ex-situ collections are having no threat to conservation. Hence, the BMC consultation may be waived off.]

- b) After consulting the BMC or the local body, the SBB may decide the application in consultation with the expert committee, wherever necessary.

4. Consultation with an Expert Committee

The SBB may form a committee having experts drawn from various fields for conclusive examination of the applications, determination of benefit sharing and advising the SBB on the techno-legal issues. The officer or person concerned may prepare an agenda on the application along with remarks of the SBB and place the same before the expert committee for its consideration. Nevertheless, the Board of

the SBB (Governing Body) is the competent authority to decide either to accept or reject the recommendations of the EC.

5. Determination of benefit sharing

- a) With regard to the determination of benefit sharing, the SBB shall follow the broad principles outlined in the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014.
- b) When the biological resources are sourced from the jurisdiction of two or more BMCs, the total amount of the accrued benefits shall be shared among them in proportion as decided by the Governing body of SBB with due diligence.
- c) When a particular biological resource is of high economic value, the benefit sharing may include an upfront payment as decided by the SBB on a case by case basis. The guidelines developed by the NBA for upfront payment (hosted in the NBA's website) may be followed (**Annex-03**). This clause will not be applicable in case of commercial utilization, where ABS under regulation (3) and (4) are applicable.
- d) In the event of IPR holder, who obtained approval from the NBA under Section 6 of the BD Act, applying to SBB for access to biological resources for commercial utilization, the SBB shall not fix benefit sharing as the applicant is already under obligation to NBA for sharing the benefits.

[Explanatory note: The person who falls under Section 3(2) or Section 7 needs to obtain prior approval of NBA before applying for IP rights in or outside India, as required under section 6 of the BD Act. Accordingly, if a person falls under section 7 applied to NBA seeking approval to obtain IP rights, the NBA while granting approval will fix benefit sharing on the commercial sale of the product using biological resources. Here, the approval granted by NBA is only to obtain IP rights from the Patent office. However, the applicant while accessing the biological resources for commercial production on the IP rights, he needs to obtain approval from the SBB. The above clause (d) explains that the SBB need not fix benefit sharing while granting approval to the applicant as the benefit sharing component has already been determined by the NBA.]

6. Grant of approval

- a) The approval for accessing the biological resources shall be in the form of an agreement executed between the applicant and the competent authority of the SBB as per Regulation 2 (2) of the ABS Guidelines of 2014.
- b) Upon approval of the Board, the SBB shall send a draft agreement to the applicant with a request to send two copies of the duly signed agreement (on a

non-judicial stamp paper of the value in vogue in the respective State) with witnesses' signatures to the SBB for execution. Once the Competent Authority of the SBB signed the agreement, one copy of the agreement shall be sent to the applicant which will be construed as the approval of SBB to the intimation of access to the biological resources for the purpose requested.

- c) If a final decision is reached to the effect that no approval can be granted on an application, for any reason, such an application may be rejected, by recording the reasons for non-consideration of the application. However, the applicants shall be given an opportunity to be heard before such rejection.

7. Sharing of benefits and monitoring mechanism

- a) SBBs may retain a share not exceeding 5% of the benefits realized towards administrative charges and the remaining 95% share of the benefits shall be passed on to the BMC concerned or to the benefit claimers, if identified.
- b) Where benefit claimers are not identified, such funds shall be deposited in the State Biodiversity Fund and it may be applied to support conservation and sustainable use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed as per sub-section (2) of section 32 of the BD Act.
- c) SBB may obtain periodical reports from the applicant about the activities carried out on the accessed biological resources. After the Agreement is executed, proper monitoring of the commercialization shall be carried out by obtaining annual reports from the applicant which may contain the quantity of the biological resources accessed and the products developed, gross sales, etc. Annually a certificate of sales attested by a Chartered Accountant shall be obtained from the applicant.
- d) Fees, if levied by the BMC for accessing or collecting any biological resources for commercial purposes from areas falling within its territorial jurisdiction shall be in addition to the benefit sharing payable to the SBB.
- e) The SBB shall maintain a Register (both in hard and soft) of Benefit Sharing, wherein the details of the Application, approval granted, benefit sharing component fixed and received and the ultimate defraying of the amount realized shall be entered.

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DECLARATION

I am aware that the Section 3 (2) of the Biological Diversity Act 2002 states as under: -

Section 3 (2) - The persons who shall be required to take the approval of the National Biodiversity Authority under sub section (1) are the following, namely:

- (a) a person who is not a citizen of India;
- (b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income Tax Act, 1961;
- (c) a body corporate, association or organization-
 - (i) not incorporated or registered in India; or
 - (ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.

In this connection, I am herewith submitting the following declaration: -

I / we hereby declare that I / we ~~“fall”~~ / ~~“do not fall”~~ under the scope of the provisions contained in Section 3(2) of the Biological Diversity Act 2002.

** Strike out which is not applicable*

Signature of the Applicant

Date:

Seal

To

AUTHORISATION LETTER FOR AGENT/REPRESENTATIVE*

I/We/Mr./Ms./M/s.* _____ hereby authorize Mr./Ms./M/s.* _____ as my/our* agent/representative* to submit an application under **Form**... of the (**name of the State specific Rules**) to the (**Name of the State Biodiversity Board**) for the purpose of obtaining the prior approval as required under the (**Name of the State Rules**) , for access to biological resources for commercial utilization or bio-survey and bio utilization for commercial utilization.*

I/We* hereby authorize and declare that all actions committed by the agent / representative* with regard to the above purpose and all communications by the agent/representative* with the (Name of the State) SBB in this regard shall bind me/us* entirely.

Signature of Applicant
(Common seal if applicable)

Signature of Agent
(Common seal if applicable)

Date:

Date:

Station:

Station:

Instructions

** Strike out whichever is not applicable*

- The signature and seal (wherever applicable) in this authorisation letter must be in original.
- The SBB shall construe that the signature and seal (wherever applicable) of the agent/representative as being verified and confirmed by the applicant.

Guidelines for Upfront Payment

Amount of Upfront Payment for Access to Biological Resources for bio-survey and bio-utilization leading to commercial utilization					
Purpose	1. Quantity of biological resource for one species upto 5 Kg of biomass per site; 2. Upto 500 gm or 500 ml for soil, water (microorganisms) respectively per site				Traditional knowledge associated with biological
	From natural habitat	From cultivated source/ institution / market	From Industrial effluent and	Threatened species from natural	
1	2	3	4	5	6
Nutraceutical or Agricultural	Rs.10,000	Rs.3,000	Rs 1,000	Rs.15,000	30% more than the normal rate
Pharmaceutical, Chemical and Diagnostic	Rs.15,000	Rs.5,000	Rs 1,000	Rs.20,000	30% more than the normal rate
Cosmetics and Luxury products	Rs.20,000	Rs.7,000	Rs 1,000	Rs.30,000	30% more than the normal rate
Environmental bio-remediation or waste conversion/	Rs.2,000	Rs.1,000	Rs 1,000	Rs.4,000	---
Other Research	Rs.5,000	Rs.2,000	Rs 1,000	Rs.10,000	30% more than the normal rate

* quantity of biological resources will be decided by the NBA on case by case basis.

Calculation of Payment:

- aggregate of each species multiplied by quantity and multiplied by number of sites;
- wherever the soil/water is being accessed the basis of assessment for this purpose shall be in terms of ml/mg, as the case may be, & multiplied by number of sites.

Note: 1.The accrued amount will be shared as per the provisions given in the ABS Regulations, 2014
2. Above rates may be revised from time to time.