

GUIDELINES ON ACCESS TO BIOLOGICAL RESOURCES AND ASSOCIATED KNOWLEDGE AND BENEFITS SHARING REGULATIONS, 2014

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GUIDELINES ON ACCESS TO BIOLOGICAL RESOURCES AND ASSOCIATED KNOWLEDGE AND BENEFITS SHARING REGULATIONS, 2014¹

In exercise of the powers conferred by section 64 read with sub-section (1) of section 18 and sub-section (4) of section 21 of the Biological Diversity Act, 2002 (18 of 2003), hereinafter referred to as the Act, and in pursuance of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity dated the 29th October, 2010, the National Biodiversity Authority hereby makes the following regulations, namely.—

Short title and commencement.—(1) These regulations may be called Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014.

(2) They shall come into force on the date² of their publication in the Official Gazette.

1. Procedure for access to biological resources and/or associated traditional knowledge for research or bio-survey and bio-utilization for research.—(1) Any person referred to under sub-section (2) of section 3 of the Act, who intends to have access to biological resources and/or associated traditional knowledge for research or bio-survey and bio-utilization for research shall apply to the National Biodiversity Authority (NBA) in Form I of the Biological Diversity Rules, 2004 for obtaining access to such biological resource and/or associated knowledge, occurring in India.

(2) The NBA shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for access to biological resource for research referred to in that sub-regulation:

Provided that in case of biological resources having high economic value, the agreement may contain a clause to the effect that the benefit sharing shall include an upfront payment by applicant, of such amount, as agreed between the NBA and the applicant.

2. Procedure for access to biological resources, for commercial utilization or for bio-survey and bio-utilization for commercial utilization.—(1) Any person who intends to have access to biological resources including access to biological resources harvested by Joint Forest Management Committee (JFMC)/ Forest dweller/Tribal cultivator/Gram Sabha, shall apply to the NBA in Form-I of the Biological Diversity Rules, 2004 or to the State Biodiversity Board (SBB), in such form as may be prescribed by the SBB, as the case may be, along with Form 'A' annexed to these regulations.

1. Vide G.S.R. 827(E), dated 21st November, 2014, published in the Gazette of India, Extra., Pt. II, Sec. 3(i), No. 612, dated 21st November, 2014.

2. Came into force on 21-11-2014.

(2) The NBA or the SBB, as the case may be, shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for access to biological resources, for commercial utilization or for bio-survey and bio-utilization for commercial utilization referred to in that sub-regulation.

3. Mode of benefit sharing for access to biological resources, for commercial utilization or for bio-survey and bio-utilization for commercial utilization.—(1) Where the applicant/trader/manufacturer has not entered into any prior benefit sharing negotiation with persons such as the Joint Forest Management Committee (JFMC)/Forest dweller/Tribal cultivator/Gram Sabha, and purchases any biological resources directly from these persons, the benefit sharing obligations on the trader shall be in the range of 1.0 to 3.0% of the purchase price of the biological resources and the benefit sharing obligations on the manufacturer shall be in the range of 3.0 to 5.0% of the purchase price of the biological resources:

Provided that where the trader sells the biological resource purchased by him to another trader or manufacturer, the benefit sharing obligation on the buyer, if he is a trader, shall range between 1.0 to 3.0% of the purchase price and between 3.0 to 5.0%, if he is a manufacturer:

Provided further that where a buyer submits proof of benefit sharing by the immediate seller in the supply chain, the benefit sharing obligation on the buyer shall be applicable only on that portion of the purchase price for which the benefit has not been shared in the supply chain.

(2) Where the applicant/trader/manufacturer has entered into any prior benefit sharing negotiation with persons such as the Joint Forest Management Committee (JFMC)/Forest dweller/Tribal cultivator/Gram Sabha, and purchases any biological resources directly from these persons, the benefit sharing obligations on the applicant shall be not less than 3.0% of the purchase price of the biological resources in case the buyer is a trader and not less than 5.0% in case the buyer is a manufacturer.

(3) In cases of biological resources having high economic value such as sandalwood, red sanders, etc. and their derivatives, the benefit sharing may include an upfront payment of not less than 5.0%, on the proceeds of the auction or sale amount, as decided by the NBA or SBB, as the case may be, and the successful bidder or the purchaser shall pay the amount to the designated fund, before accessing the biological resource.

4. Option of benefit sharing on sale price of the biological resources accessed for commercial utilization under regulation 2.—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% 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:—

Annual Gross ex-factory sale of product	Benefit sharing component
Up to Rupees 1,00,00,000	0.1%
Rupees 1,00,00,001 up to 3,00,00,000	0.2%
Above Rupees 3,00,00,000	0.5%

5. Collection of fees.—Collection of fees, if levied by Biodiversity Management Committee (BMC) for accessing or collecting any biological resource for commercial purposes from areas falling within its territorial jurisdiction under sub-section (3) of section 41 of the Act, shall be in addition to the benefit sharing payable to the NBA/SBB under these regulations.

6. Procedure for transfer of results of research relating to biological resources.—(1) Any person who intends to transfer results of research relating to biological resources occurring in or obtained from India, to persons referred to under sub-section (2) of section 3 of the Act for monetary consideration or otherwise, shall—

- (a) apply to the NBA in Form II of the Biological Diversity Rules, 2004 for transfer of the results of research relating to biological resources occurring in or obtained from India for any purpose;
- (b) provide evidence of approval of NBA for access to the biological resource and/or associated knowledge involved in the research:
Provided that the requirement of evidence under this clause shall not apply to an applicant who is a citizen of India or a body corporate, association or organization which is registered in India and not having any non-Indian participation in its share capital or management;
- (c) provide complete information on potential commercial value within the knowledge of the applicant, of the results of research.

(2) The NBA shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for transfer of the results of research referred to in that sub-regulation.

7. Mode of benefit sharing for transfer of results of research.—Applicant shall, in case of transfer of results of research under regulation 6, pay to the NBA such monetary and/or non-monetary benefit, as agreed between the applicant and the NBA:

Provided that in case of monetary benefit received by him, if any, on such transfer, the applicant shall pay to the NBA 3.0 to 5.0% of the monetary consideration.

8. Procedure for obtaining Intellectual Property Rights (IPR).—(1) Any person who intends to obtain any intellectual property right by whatever name called, in or outside India, for any invention based on any research or information on any biological resources obtained from India, shall make an application to the NBA in Form III of the Biological Diversity Rules, 2004:

Provided that if the applicant is a person referred to under sub-section (2) of section 3 of the Act, he shall provide evidence of approval of NBA for access

to the biological resources and/or associated knowledge used in the research leading to the invention:

Provided further that any person applying for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (53 of 2001) shall be exempted from this sub-regulation.

(2) The NBA shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for obtaining IPR.

9. Mode of benefit sharing in IPR.—(1) 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.

(2) Where the applicant himself commercialises the process/product/innovation, the monetary sharing shall be in the range of 0.2 to 1.0% based on sectoral approach, which shall be worked out on the annual gross ex-factory sale minus government taxes.

(3) Where the applicant assigns/licenses the process/product/innovation to a third party for commercialisation, the applicant shall pay to NBA 3.0 to 5.0% of the fee received (in any form including the license/assignee fee) and 2.0 to 5.0% of the royalty amount received annually from the assignee/licensee, based on sectoral approach.

10. Obligations of applicant in the event of commercialisation of IPR.—

(1) An applicant, granted IPR, who is a citizen of India or a body corporate, association or organisation which is registered in India and not having any non-Indian participation in its share capital or management, shall give prior intimation to the concerned SBB for access to biological resources, in the form prescribed by the SBB, and shall comply with such terms and conditions, if any, imposed by the SBB in the interest of promoting conservation and sustainable use.

(2) An applicant, granted IPR, who is a person or a body corporate or an association or an organization referred to under sub-section (2) of section 3 of the Act shall apply in Form I of the Biological Diversity Rules, 2004 to the NBA for access to biological resources.

11. Procedure for transfer of accessed biological resource and/ or associated knowledge to third party for research/commercial utilization.—(1) Any person who intends to transfer the biological resources and/or associated knowledge which has been granted access under regulation 1 to a third party for research or for commercial utilization, shall apply to NBA in Form IV of the Biological Diversity Rules, 2004 for transfer to such third party.

(2) The NBA shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant, which shall be deemed as grant of approval for transfer of accessed biological resource and/or associated knowledge referred to in that sub-regulation.

12. Mode of benefit sharing for transfer of accessed biological resource and/ or associated knowledge to third party for research/commercial utilization.—(1) The applicant shall pay to the NBA such monetary and/or non-monetary benefit, as agreed between the applicant and the NBA.

(2) Applicant (transferor) shall pay to the NBA 2.0% to 5.0 % (following a sectoral approach) of any amount and/or royalty received from the transferee, as benefit sharing, throughout the term of the agreement.

(3) In case the biological resource has high economic value, the applicant shall also pay to the NBA an upfront payment, as mutually agreed between the applicant and the NBA.

13. Conducting of non-commercial research or research for emergency purposes outside India by Indian researchers/Government institutions.—

(1) Any Indian researcher/Government institution who intends to carry/send the biological resources outside India to undertake basic research other than collaborative research referred to in section 5 of the Act shall apply to the NBA in Form 'B' annexed to these regulations.

(2) Any Government Institution which intend to send biological resources to carry out certain urgent studies to avert emergencies like epidemics, etc., shall apply in Form 'B' annexed to these regulations.

(3) The NBA shall, on being satisfied with the application under sub-regulation (1) or sub-regulation (2), accord its approval within a period of 45 days from the date of receipt of the application.

(4) On receipt of approval of the NBA under sub-regulation (3), the applicant shall deposit voucher specimens in the designated national repositories before carrying/sending the biological resources outside India and a copy of proof of such deposits shall be endorsed to NBA.

14. Determination of benefit sharing.—(1) Benefit sharing may be done in monetary and/or non-monetary modes, as agreed upon by the applicant and the NBA/SBB concerned in consultation with the BMC/Benefit claimer, etc. Options for such benefit sharing are provided in Annexure-1.

(2) Determination of benefit sharing shall be based on considerations such as commercial utilization of the biological resource, stages of research and development, potential market for the outcome of research, amount of investment already made for research and development, nature of technology applied, time-lines and milestones from initiation of research to development of the product and risks involved in commercialization of the product:

Provided that special consideration may be given to cases where technologies/products are developed for controlling epidemics/diseases and for mitigating environmental pollution affecting human/animal/plant health.

(3) The amount of benefit sharing shall remain the same whether the end product contains one or more biological resources.

(4) Where the biological resources of a product are sourced from the jurisdiction of two or more SBBs, the total amount of the accrued benefits shall be shared among them in proportion as decided by the NBA/SBBs concerned, as the case may be.

15. Sharing of benefits.—(1) Where approval has been granted by the NBA for research or for commercial utilization or for transfer of results of research or for Intellectual Property Rights or for third party transfer, the mode of benefit sharing shall be as under:—

- (a) 5.0% of the accrued benefits shall go to the NBA, out of which half of the amount shall be retained by the NBA and the other half may be passed on to the concerned SBB for administrative charges.
- (b) 95% of the accrued benefits shall go to concerned BMC(s) and/ or benefit claimers:

Provided that where the biological resource or knowledge is sourced from an individual or group of individuals or organizations, the amount received under this clause shall directly go to such individual or group of individuals or organizations, in accordance with the terms of any agreement and in such manner as may be deemed fit:

Provided further that where benefit claimers are not identified, such funds shall be used to support conservation and sustainable use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed.

(2) Where approval has been granted by State Biodiversity Board under these regulations.—

The sharing of accrued benefits shall be as under—the SBB may retain a share, not exceeding 5% of the benefits accrued towards their administrative charges and the remaining share shall be passed on to the BMC concerned or to benefit claimers, where identified:

Provided that where any individual or group of individuals or organizations cannot be identified, such funds shall be used to support conservation and sustainable use of biological resources and to promote livelihoods of the local people from where the biological resources are accessed.

16. Processing of applications received by NBA.—(1) Every application shall be complete in all respects, including all the enclosures referred thereto.

(2) Incomplete applications devoid of any relevant information specifically sought, including ambiguous replies, incomplete disclosure, absence of proof, etc., shall be returned to the applicants.

(3) The time limit specified for processing the applications shall commence only when the application complete in all respects including fee prescribed is received.

(4) Any information specified in the application as confidential shall not be disclosed, either intentionally or unintentionally, to any person not concerned thereto.

(5) While processing the application for access to any biological resource (including plants and/or animals and/or their parts or genetic material or derivatives), the NBA may consider the following factors, namely:—

Whether the biological resource is –

- (i) cultivated or domesticated or wild;
- (ii) rare or endemic or endangered or threatened species;
- (iii) accessed directly through the primary collectors living in natural habitat or obtained through intermediaries like traders;

- (iv) developed or maintained under *ex-situ* conditions;
- (v) of high value/importance to livelihoods of local communities;
- (vi) restricted under the Act or any other law for time being in force;
- (vii) exempted under section 40 of the Act;
- (viii) included in crops listed under Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), to which India is a contracting party;
- (ix) included in the Appendices of the Convention on International Trade on Endangered Species (CITES).

(6) The NBA while taking any decision on the application relating to the use of biological resources and/or knowledge associated thereto may consult through the SBBs, the BMCs within whose jurisdiction the biological resources and/or the knowledge occur.

(7) The NBA shall reject the application requesting access to biological resources for the reasons specified under rule 16 of the Biological Diversity Rules, 2004.

(8) On receipt of application, the NBA may make enquiries, as it may deem fit, and if necessary, may consult an expert committee constituted for this purpose.

(9) The NBA may upon such enquiry and/or consultation referred to in sub-regulation (8), by order, grant approval or reject the application:

Provided that where the NBA has rejected such application, the reasons for such rejection shall be recorded in writing after giving an opportunity of being heard to the applicant.

(10) Approval granted by the NBA shall be in the form of written agreement duly signed by an authorised officer of the NBA, the applicant and others as applicable:

Provided that the NBA may grant approval without a written agreement for the purposes of conducting of non-commercial research or research for emergency purposes outside India by Indian researchers/Government institutions under regulation 13.

(11) Based on any complaint or *suo moto*, the NBA may withdraw the approval granted for access and revoke the written agreement on the grounds specified under rule 15 of the Biological Diversity Rules, 2004:

Provided that a copy of the order of such revocation shall be issued to the concerned State Biodiversity Board and the Biodiversity Management Committees for the purposes of prohibition of access.

(12) Where a request has been made by the applicant for withdrawal of his application or the applicant fails to respond to queries of the NBA within the stipulated time, the NBA shall close the applications or initiate action under these regulations as it deems appropriate:

Provided that if the applicant wishes to revive the application, he shall make a fresh application with the requisite fee.

Note.—Application forms for access to biological resources and/or associated knowledge, guidelines for filling them and form of agreements, are available in the NBA website: www.nbaindia.org.

17. Certain activities or persons exempted from approval of NBA or SBB.—The following activities or persons shall not require approval of the NBA or SBB, namely:—

- (a) Indian citizens or entities accessing biological resources and/or associated knowledge, occurring in or obtained from India, for the purposes of research or bio-survey and bio-utilization for research in India;
- (b) collaborative research projects, involving the transfer or exchange of biological resources or related information, if such collaborative research projects have been approved by the concerned Ministry or Department of the State or Central Government and conform to the policy guidelines issued by the Central Government for such collaborative research projects;
- (c) local people and communities of the area, including growers and cultivators of biological resources, and *vaid*s and *hakim*s, practising indigenous medicine, except for obtaining intellectual property rights;
- (d) 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;
- (e) publication of research papers or dissemination of knowledge, in any seminar or workshop, if such publication is in conformity with the guidelines issued by the Central Government from time to time;
- (f) accessing value added products, which are products containing portions or extracts of plants and animals in unrecognizable and physically inseparable form; and
- (g) biological resources, normally traded as commodities notified by the Central Government under section 40 of the Act.

FORM A

(See regulation 2)

INFORMATION TO BE FURNISHED FOR USE OF BIOLOGICAL RESOURCES BY THE APPLICANT SELF-DISCLOSURE

Common Name of the biological resource proposed to be used:.....

Scientific Name:.....

Plants or animals or parts thereof traded:.....

Specific purpose of access:.....

Locations/source from where procured*	Quantity in Kgs	Rate per unit	State Biodiversity Board	Prospective Buyers/ Users (if known)

*List of local body/BMCs, if already identified shall be attached.

Undertaking

1. I have read and understood the terms and conditions of ABS guidelines and I undertake to abide by relevant legal provisions applicable to biological resource.
2. I undertake to obtain the approval of the NBA/SBB before making any change in the stated purpose.
3. I undertake to furnish/share the relevant records with the NBA/SBB, as and when required.
4. I further declare that the Information provided in the form is true and correct and I shall be liable for any incorrect/wrong information and wilful suppression of the facts.

.....
Signature

.....
Name of the trader/company/manufacture/ Authorized Representative
Complete Address of the trader/company/manufacture
along with phone number and e-mail address

Place.....

Date.....

FORM B

(See regulation 13)

CONDUCTING OF NON-COMMERCIAL RESEARCH OR RESEARCH FOR EMERGENCY PURPOSES OUTSIDE INDIA BY INDIAN RESEARCHERS/ GOVERNMENT INSTITUTIONS USING THE BIOLOGICAL RESOURCES

1.	Name of the Applicant (Indian Researcher/Government Institution)	
2.	Complete Address*	
	a. Permanent	
	b. Present	
3.	Name and address of Institution in India	
4.	Name of the Supervisor or Head of Institution at the place of work in India	
5.	Name and contact details of the Institution or Organization who shall guide the proposed research/receiving the biological resources.	
6.	Details of the Supervisor or Head of Institution or Organization who guides the proposed research or recipient of the biological resources	
7.	Name of the funding agency supporting the proposed research	
8.	Brief description of the research	

9.	Details of biological resources proposed to be carried along or sent for the research	
	i. Name of the biological resource (scientific/common name)	
	ii. Location of collection (Village/Taluk/Dist./State)	
	iii. Quantity required	
	iv. Duration of the research	
10.	If it is for emergency purpose, specify details	

* Attach self-attested address/ID proof such as Aadhaar card/PAN card (I) Passport, etc.

Undertaking

I,Son/Daughter/Wife/Husband of.....aged..... residing at.....in.....holding a permanent I.D. No.....(PAN Card/ Aadhaar Card/Passport, etc.) hereby declare that all the information provided above is correct and true. I hereby affirm that the biological resources shall be used only for the purposes as stated in the application. I shall not share/provide/part/leave behind any biological resource at my collaborator's facility/laboratory without approval of the NBA. I, along with my supervisor and collaborator, individually and severally declare that we shall not put to commercial utilization, nor shall seek any IPR claim on the biological resources and associated traditional knowledge used in this research/collaboration. In case such a situation arises we shall apply to National Biodiversity Authority to seek prior approval. Results, process(es), products or other outcomes arising out of this activity shall be shared with the NBA during and/or upon completion of research intended along with the copy of relevant documents and publications.

Signature:

Date:

Place:

Declaration by the Supervisor/Head of Institution

I,working as.....in.....(Name of institution) confirm that the details provided by Mr./Dr./Mrs./Ms.are true and correct

Date:

Place:

Signature:

Designation:

Official Seal:

Declaration by the Recipient/Collaborator

I,working as.....in..... (Name of Institution/Organization) hereby affirm that I or my institution/organization shall use the biological resources for the purposes as stated in the application and which, were sent by.....(Name of the institution) or being brought by Mr./Dr./Mrs./Ms.....The said biological resources shall be destroyed in full after the completion of the studies/partnership or upon completion of the studies the biological resources shall be sent back to the institution from where the biological resources were received as the case may be. I or the institution I am associated with shall not claim any ownership under instant application nor shall claim any IP Rights over the biological resources, derivatives or other such components without prior approval of the applicant, institution affiliated and the National Biodiversity Authority.

Signature:.....

Designation:

Official Seal:

ANNEXURE 1

FAIR AND EQUITABLE BENEFIT SHARING OPTIONS

The following options, either one or more, may be applied in accordance with mutually agreed terms between the applicant and the NBA, on a case by case basis, in accordance with the provisions of sub-rule (3) of rule 20 of the Biological Diversity Rules, 2004. These options are indicative in nature and other options, as approved by the NBA in consultation with the Central Government, may also be adopted:

(a) Monetary benefits options:

- (i) Up-front payment;
- (ii) One-time payment;
- (iii) Milestone payments;
- (iv) Share of the royalties and benefits accrued;
- (v) Share of the license fees;
- (vi) Contribution to National, State or Local Biodiversity Funds;
- (vii) Funding for research and development in India;
- (viii) Joint ventures with Indian institutions and companies;
- (ix) Joint ownership of relevant intellectual property rights.

(b) Non-monetary benefits options:

- (i) Providing institutional capacity building, including training on sustainable use practices, creating infrastructure and undertaking development of work related to conservation and sustainable use of biological resources;
 - (ii) Transfer of technology or sharing of research and development results with Indian institutions/individuals/entities;
 - (iii) Strengthening of capacities for developing technologies and transfer of technology to India and/or collaborative research and development programmes with Indian institutions/individuals/entities;
 - (iv) Contribution/collaboration related to education and training in India on conservation and sustainable use of biological resources;
 - (v) Location of production, research, and development units and measures for conservation and protection of species in the area from where biological resource has been accessed, contributions to the local economy and income generation for the local communities;
 - (vi) Sharing of scientific information relevant to conservation and sustainable use of biological diversity including biological inventories and taxonomic studies;
 - (vii) Conducting research directed towards priority needs in India including food, health and livelihood security focusing on biological resources;
 - (viii) Providing scholarships, bursaries and financial aid to Indian institutions/individuals preferably to regions, tribes/sects contributing to the delivery of biological resources and subsequent profitability if any;
 - (ix) Setting up of venture capital fund for aiding the cause of benefit claimers;
 - (x) Payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.
-