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PROCEEDINGS
71st AUTHORITY MEETING
(Emergency Meeting)

26.12.2024

(Online Mode)

NATIONAL BIODIVERSITY AUTHORITY
Chennai

DRAFT PROCEEDINGS OF THE 71st AUTHORITY MEETING (EMERGENCY MEETING) OF THE NATIONAL BIODIVERSITY AUTHORITY, HELD ON 26TH DECEMBER 2024

The 71st Authority meeting of the National Biodiversity Authority (NBA) was held on 26th December, 2024 in online mode at NBA, Chennai under the Chairmanship of Shri. C. Achalender Reddy, IFS (Retd.) Chairman, National Biodiversity Authority. The list of participants is given in the Annexure-I.

At the outset, Dr. B. Balaji, Secretary NBA welcomed the Chairman, and Members of NBA present virtually for the meeting. He informed the esteemed members that Shri. Vinod Kumar Yadav, IFS, (Retd.), Non-Official member of the Authority had demised in the month of July, 2024. In this regard, a two- minute silence was observed in the memory and honour of (Late) Shri. Vinod Kumar Yadav. A condolence resolution has been passed in the meeting and Secretary to the Authority has been requested to pass it on to the bereaved family members on behalf of the Authority.

Thereafter, Secretary, NBA informed that the meeting was called for in emergency as per Rule 10 (3) of the Biological Diversity Rules 2024. This meeting was mainly to deliberate and consider the Draft ABS Regulations 2025 along with two other Agenda items which are as follows:

71.01: To consider the draft ABS Regulations along with the observations of NBA Secretariat
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The Secretary, NBA informed the members that the Biological Diversity (Amendment), Act 2023 came into force on 1st April 2024 and the Biological Diversity Rules 2024 was notified by the Ministry of Environment, Forest and Climate Change on 22nd October 2024 which came into force on 21st December 2024. In the meantime, NBA with the help of the expert committee has started revising the Access and Benefit Sharing Regulations, 2014 as per the amended BD Act and BD Rules.

2. He further informed the members that during the revision of the ABS Regulations, NBA received a representation from the Indian Vaccine Manufacturer Association addressed to Principal Scientific Advisor, Government of India, seeking to hear their views



before framing the regulations. As per the discussion held with MoEFCC, NBA initiated the process of hearing the views of the various Sectors on which the regulations will be having the impact. Accordingly, NBA gave a notification in the website and newspaper on 12th December 2024 inviting public comments on or before 17th December 2024 on the existing ABS Regulations 2014. A total of 49 comments were received from the public. Subsequently, NBA convened a virtual consultation with different sectors *i.e. Ayush / Vaccine and biotechnology/ nutraceuticals/ Pharmaceuticals / Agriculture etc.*, from 19th to 20th December 2024 and ascertained their comments / suggestions to revise the ABS Regulations 2014 in the light of the amendments to the BD Act and BD Rules. The virtual consultation was conducted by the Expert Committee on ABS Regulations where NBA secretariat has participated and MoEFCC officials have also participated as observers. NBA received six (6) written submissions by the Sectors after consultations held virtually. All those representations were compiled and submitted to EC for examination and further revision of the ABS Regulations. A representation received from the Ministry of Ayush for reduction of ABS was also examined by the EC. During the online consultation, some of the associations sought more time to provide comments.

3. The Secretary, NBA made a detailed presentation stating that the Expert Committee had 11 sittings to revise the ABS Regulations since October 2023. He also highlighted the provisions of the ABS Regulations 2014 and proposed draft ABS Regulations 2025. It was informed that the proposed draft regulations having many provisions would provide conducive environment for the companies to invest in research and manufacturing sectors in India. Further, to boost the growth of Indian Ayush and other sectors, companies having less than Rs.5.00 crore turnover are exempted from the ABS obligations. Further, the ABS slab rates are also reduced substantially upto Rs. 50 crores and 30% reduction is also given if the applicant submits proof of payment of collection fee to the Biodiversity Management Committee for the access of biological resources. On analysis of the existing data provided by the Ministry of Ayush, about 75% of the companies are exempted from paying ABS.



4. The Secretary, NBA informed the members that the NBA Secretariat made certain suggestions/ modifications in the draft ABS Regulations submitted by the EC and requested that the same may be considered by the Authority.

5. After the presentation, the running text was displayed before the members for discussion on clause by clause. While considering the text, members were informed about the dissent note from Dr.Kousthuba Upadhyaya, Advisor, Ministry of Ayush. Chairperson, NBA asked Dr.Kousthuba to brief the members about the issues. The deliberation on the issues are as follows:-

(a) *Ayush medicine that are dispensed by the registered Ayush practitioners are usually labeled / using logos by the practitioners themselves. Hence, he suggested to remove phrase "labelling / logo" in the explanation clause of profession for sustenance and livelihood.*

The same was agreed to by the Members.

(b) *Under Regulation 4(3), Note 1, it is stated that any entity with annual turnover up to Rs 5.00 crore is exempted from the ABS obligation. However, prior approval is required before accessing the biological resources. Ministry of Ayush suggested to remove approval process.*

Members expressed that measures towards ensuring the sustainable use of wild biological resources needs to be in place otherwise it may pose threat to the biodiversity. Chairperson expressed that the complete exemption may not be possible as per the Act. However, procedure may be simplified by obtaining an affidavit from the applicant stating that the biological resources are accessed from different sources. Member of Ayush suggested that instead of affidavit, schedule TA prescribed under Drugs and Cosmetics Act may be submitted to Authority or SBB as the case may be by the manufacturer at the end of every year. After discussion, members decided that the applicant (manufacturer) has to submit the affidavit about the details of biological resources used by them on half yearly basis to the NBA or SBB as the case may be. Accordingly, following texts have been added as a second sentence under the Note-1



“However, such entity shall submit the consumption data of raw material (biological resources) to the Authority / State Biodiversity Boards /Union territory Biodiversity Councils in the form of an affidavit at the end of the year subject to submission of details of the biological resources used by them on half yearly basis.”

(c) Under Regulation 4(3), explanation provided for “end user” has been included in the context of Rule 19(5) and the onus of proof of source of origin of medicinal plants lies on the end users. The representative of Ayush said that this provision will adversely affect the Ayush sector at the ground level. The Ministry of Ayush suggested that the onus of proof should lie on the applicant. The reference to end users in the BD Rules, 2024 is not required. (expressed by Ministry of Ayush representative)

Members observed that the ABS Regulations ~~doesn't govern this issue and the same~~ may be dealt in the sector specific guidelines. Hence, members decided to delete the explanation clause “end user” from this Regulation.

(d) The Certificate of Origin of cultivated medicinal plants should be issued within 7 days of application otherwise it is deemed to have been issued so that the farmer can start planting of medicinal plants.

It was informed that as per the amended Act the certificate of origin can only be issued by BMCs. However, to facilitate the issuance of certificate of origin within the stipulated time period by the BMCs, provision will be incorporated in the proposed ABS portal.

6. Dr.D.K. Yadava, ADG(Seeds), ICAR made following suggestions that breeders of national agriculture system to be exempted under the conventional breeding, bureaus of ICAR to be exempted for accessing biological resources for undertaking research; reciprocal exchange of biological resources between foreign and Indian institutions and clarification on publication of research papers. Chairperson, NBA informed that the above comments will be examined in the sector specific guidelines and he was requested to submit a detailed note on the above points.

7. After having detailed deliberation, members unanimously agreed to the draft ABS Regulations 2025 with minor modifications which is appended as Annex.



8. Keeping in view of the exigency, the Authority directed the secretariat to forward the revised draft ABS Regulations 2025 to the Ministry directly for approval.

Decisions:

- a) The Authority considered the draft ABS Regulations 2025 after thorough deliberation and approved the same with certain minor modifications, as appended in the Annexure-II.
- b) Keeping in view of the urgency on this matter, the Authority directed the secretariat to forward the revised draft ABS Regulations 2025 to the Ministry directly for approval. In other words, this Agenda item need not be circulated to members for final approval as done usually.
- c) Authority also placed on record its appreciation to the Chair, Co-chair and Members of the Expert Committee for bringing out the draft ABS Regulations 2025.

Action: Secretary, NBA.

71.02: To consider the draft proposal of CEBPOL Project submitted by the NALSAR

Secretary, NBA explained about the Centre for Biodiversity Policy and Law (CEBPOL) Project that was implemented and concluded by NBA earlier with the support of the Norwegian government. He further mentioned that this project was very successful and many knowledge products were developed under this project. In this regard, he mentioned that there is a proposal for setting up the CEBPOL project as a collaborative project with National Academy of Legal Studies and Research (NALSAR) University of Law, Hyderabad (Knowledge Partner) as a joint initiative with the NBA. Members were further informed that there is a need for engaging techno-legal experts to develop different knowledge products on biodiversity. In this regard, it was proposed that similar to the earlier project, the Norwegian government agencies may also be involved in reviewing of this project. Meantime, to move forward, an MoU may be signed by NBA with the NALSAR University. Chairman, NBA explained that this collaboration with an eminent university like NALSAR is required as NBA/ MoEFCC needs an anchor institution to support in shaping responses to international developments in the field of biodiversity.



2. The members of the Authority agreed and appreciated the efforts taken by NBA in this regard and approved the MoU for revival and establishing CEBPOL in collaboration with NALSAR University

Decision: The Authority members appreciated the efforts taken by NBA and approved the MoU between NBA and NALSAR University for establishing CEBPOL.

Action: Secretary, NBA

71.03: To consider for using old application Forms and Fee

Secretary, NBA informed that the Biological Diversity Rules 2024 was notified in the Gazette on 22nd October 2024 and has come in to force on 21st December 2024. The said Rules has been appended with new Forms and Fee. He further explained that the NBA Secretariat is working with NIC Delhi on updating the Forms and Fee as per the BD Rules 2024 in the existing portal (absefiling.nic.in). Secretary, NBA mentioned that the software requires security auditing after updation and before it is made available to the public. He also informed that the Security Audit is in process and will be completed at the earliest.

2. In this regard, he mentioned that during the interim period of the updation, the NBA Secretariat has notified in its website that the old application forms and fee as per BD Rules 2004 may be used till January 2025. This is a stop gap arrangement till the revised software is put in operation for the benefit of the applicants. In this regard, Dr. Joykumar Laishram mentioned that the NBA may expedite the process with the NIC to update the Forms and Fee as per the BD Rules 2024 so that the new forms and fee is operational in January 2025.

Decision: a) The Authority ratified the action of NBA Secretariat for using the old forms and fee till the new software is in place.

b) Members also decided that the NBA Secretariat may expedite the process with the NIC to update the Forms and Fee as per the BD Rules 2024.

Action: Secretary, NBA

The meeting ended with a vote of thanks from and to the chair



Annexure I

List of members –Participated

Sl No	Chairman of the Authority
1	Shri C. Achalender Reddy, IFS (Retd.), Chairperson, NBA
	Ex officio members
2	Dr. Achuta Nand Shukla, Additional Director/Scientist – E,CS-III (Biodiversity Division) , MoEFCC, New Delhi
3	Dr. D.K. Yadav, Assistant Director General Seed, ICAR, New Delhi
4	Dr. Kousthubha Upadhyaya, Adviser (Ay.), Ministry of Ayush
5	Shri. M. Gunasekaran, Deputy Commissioner (Seeds), Dept. of Agriculture and Family Welfare, New Delhi
6	Dr. Sudesh Yadav, Director, IIHBT, Palampur
	Non official Members
7	Dr. Joykumar Meitei Laishram, Retired Dean, College of Agriculture, Central Agriculture University Imphal, Manipur
8	Dr. Gouri Joshi, 401, Balwant ashram, Behind Nirmitti Elite, Law College Road, Erandwane, Pune, Maharashtra - 411004.
9	Shri Hanchinal R. Ramappa, 1, Haudin Road, Ulsoor, Bengaluru - 560001
	Secretary, NBA
10	Dr. B. Balaji, IFS, Secretary, NBA



Annexure II

Draft

**Access to Biological Resources and Knowledge Associated thereto and
Fair and Equitable Sharing of Benefits Regulations, 2025**

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

(National Biodiversity Authority)

NOTIFICATION

New Delhi,, 2025

G.S.R.....: In exercise of the powers conferred by section 64 of the Biological Diversity Act, 2002 (No.18 of 2003) read with sub-section (1) of section 18 and sub-section (4) of section 21 of the Biological Diversity (Amendment) Act, 2023 (No. 10 of 2023), hereinafter referred to as 'Act', the Biological Diversity Rules, 2024, hereinafter referred to as 'Rules', 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 adopted on the 29th October, 2010, to which India is a Party, and in supersession of the "Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014", published vide notification number G.S.R. 827 (E), dated the 21st November, 2014, the National Biodiversity Authority, hereinafter referred to as 'Authority', with the approval of the Central Government, hereby makes the following regulations, namely:—

1. Short title and commencement. -

- (1) These regulations may be called "Access to Biological Resources and Knowledge Associated thereto and Fair and Equitable Sharing of Benefits Regulations, 2025".
- (2) These regulations shall come into force from the date of their publication in the Official Gazette.

2. Scope. -

- (1) The Authority may grant approvals, relating to biological resources including digital sequence information and/or knowledge associated thereto, under these regulations in exercise of the powers conferred under sections 3, 4, 6, 7, 19, 20, 21 and 36A of the Act.
- (2) The State Biodiversity Boards and Union territory Biodiversity Councils shall follow these regulations while granting approvals to persons regulated under section 7 read with sections 23 and 24 of the Act.

3. Procedure for obtaining prior approval for access to biological resources and/or knowledge associated thereto for research or for bio-survey and bio-utilisation, in respect of persons covered under sub-section (2) of section 3 of the Act and mode of benefit sharing thereof. -

- (1) Such person who intends to access any biological resource including digital sequence information occurring in India, and/or knowledge associated thereto, for research or for

bio-survey and bio-utilisation shall apply on the web portal of the Authority in Form 1 of the Rules:

Provided that any person, referred to in sub-section (2) of section 3 of the Act, having possession of a biological resource prior to coming into force of the Biological Diversity (Amendment) Act, 2023, intends to use the same for research or bio-survey and bio-utilization shall also seek approval under this regulation.

(2) The Authority shall, on being satisfied with the application under sub-regulation (1), take a decision on the application within a period of ninety days for access to biological resource including digital sequence information and/or knowledge associated thereto, for research or for bio-survey and bio-utilisation.

Provided that if the requisite information sought by the Authority has not been made available by the applicant within a period of thirty days from the date of seeking information, the application shall be closed and the applicant shall be informed about the closure.

(3) The approval to access shall be in the form of an agreement on mutually agreed terms duly signed by an authorised officer of the Authority and the applicant:

Provided that the application is deemed to be closed, if the applicant does not sign the agreement within a period of sixty days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of half of the fee prescribed under sub-rule (3) of rule 13 of the Rules within a period of ninety days.

(4) Mode of benefit sharing.- In case a biological resource including digital sequence information and/or knowledge associated thereto, having conservation value and or high economic value such as red sanders, sandalwood, agarwood etc., and including those notified under section 38 of the Act, is accessed for research or for bio-survey and bio-utilisation, the benefit sharing including the upfront payment may be determined, as prescribed by the Authority:

Provided that the Authority may also impose upfront payment on certain biological resources including digital sequence information and/or knowledge associated thereto, when accessed for research or for bio survey and bio-utilization, on case-by-case basis.

Provided further, that in case a biological resource including digital sequence information and/ or knowledge associated thereto, is accessed for conducting academic research, the Authority may waive the benefit sharing including upfront payment, as it deems fit, on case-by-case basis.

4. Procedure for obtaining prior approval for access to biological resources and/or knowledge associated thereto for commercial utilisation, and mode of benefit sharing thereof. —

(1) Procedure for obtaining prior approval by persons referred to in sub-section (2) of section 3 of the Act shall be as follows:

(a) such person who intends to access to biological resources including digital sequence information and/or knowledge associated thereto, for commercial utilisation shall apply on the web portal of the Authority in Form 2 of the Rules:

Provided that any such person who was in possession of a biological resource before the coming into force of the Biological Diversity (Amendment) Act, 2023, and intends to use the same for commercial utilisation, shall also seek approval under this regulation.

(b) the Authority shall, on being satisfied with the application under clause (a), take a decision on the application within a period of ninety days for access to biological resource including digital sequence information or knowledge associated thereto for commercial utilisation.

Provided that if the requisite information sought by the Authority has not been made available by the applicant within a period of thirty days from the date of seeking information, the application shall be closed and the applicant shall be informed about the closure.

(c) The approval to access shall be in the form of an agreement on mutually agreed terms duly signed by an authorised officer of the Authority and the applicant:

Provided that the application is deemed to be closed, if the applicant does not sign the agreement within a period of sixty days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of half of the fee specified under sub-rule (3) of the rule 13 of the Rules within a period of ninety days.

(2) Procedure for obtaining prior approval by persons covered under section 7 of the Act shall be as follows:

(a) such person who intends to access biological resources including digital sequence information and/or knowledge associated thereto, for commercial utilisation shall apply to the State Biodiversity Board or Union territory Biodiversity Council concerned in such form as may be prescribed under the respective State Biological Diversity Rules:

Note: In the case of Union territory Biodiversity Councils, the Biological Diversity Rules, 2024 will be applicable.

Provided further that in case the biological resources including digital sequence information and/or knowledge associated thereto, is accessed by such persons for commercial utilisation of a patent as per the provisions of

sub-regulation (4) of the regulation 7, the benefit sharing shall be applicable as determined by the Authority and no further benefit sharing amount can be fixed by the State Biodiversity Board or Union territory Biodiversity Council concerned:

Provided also that the following shall be exempted from the provisions of section 7 of the Act:

- (i) access to codified traditional knowledge;
- (ii) access to cultivated medicinal plants subject to obtaining a certificate of origin from the Biodiversity Management Committee concerned by applying in Form 11 of the Rules:

Provided that this exemption will not be applicable for the non-cultivated medicinal plants, which are growing naturally;

- (iii) access to products of cultivated medicinal plants;
- (iv) local people and communities of the area, including growers and cultivators of the biological resources, *vaid*s, *hakim*s and registered Ayush practitioners only who have been practising indigenous medicines, including Indian systems of medicine as profession for their sustenance and livelihood.

Explanation: For the purpose of this regulation, “profession for sustenance and livelihood” means where a vaid/hakim/registered Ayush practitioner is dispensing the products prepared using biological resource but not commercializing the same with brand name/trademark.

(b) The State Biodiversity Board or Union territory Biodiversity Council, on being satisfied with the application under clause (a), after processing the application as per the provisions of regulation 12, shall take a decision on the application within a period of ninety days.

Provided that if the requisite information sought by the State Biodiversity Board or the Union territory Biodiversity Council has not been made available by the applicant within a period of thirty days from the date of seeking information, the application shall be closed and the applicant shall be informed about the closure.

(c) The approval to access shall be in the form of an agreement on mutually agreed terms duly signed by the authorised officer of the State Biodiversity Board or Union territory Biodiversity Council and the applicant:

Provided that the application is deemed to be closed, if the applicant does not sign the agreement within a period of sixty days from the date of communication of the draft agreement by the State Biodiversity Board or Union territory Biodiversity Council, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of the fee specified under the State Biological Diversity Rules or under sub-rule (3) of the rule 13 of the Biological Diversity Rules, 2024 in the case of Union territories, within a period of ninety days.

(3) Mode of benefit sharing. — The benefit sharing, through monetary and or non-monetary mode, shall be determined on mutually agreed terms between the Authority or State Biodiversity Board or Union territory Biodiversity Council, as the case may be, and the applicant, as given below:

When the biological resource including digital sequence information and/or knowledge associated thereto, is accessed for commercial utilisation, the applicant shall have to pay the benefit sharing, upto point six percent (0.6%) of the annual gross ex-factory sale price of the product excluding Government taxes, on mutually agreed terms, with the Authority or State Biodiversity Board or Union territory Biodiversity Council, on case- by-case basis, as given below: —

S. No	Annual turnover of the entity (in rupees)	Benefit sharing component [Percentage of annual gross ex-factory sale price of product excluding Government taxes]
1	Up to 5,00,00,000	Nil
2	5,00,00,001 up to 25,00,00,000	0.2%
3	25,00,00,001 up to 50,00,00,000	0.4%
4	Above 50,00,00,000	0.6%

*Note: (1) If an entity has an annual turnover of up to rupees five crore, it will be exempted from payment of benefit sharing amount. This exemption is applicable to both section 3(2) and section 7 entities. **However, such entity shall submit the consumption data of raw material (biological resources) to the Authority / State Biodiversity Boards/Union territory Biodiversity Councils in the form of an affidavit at the end of the year subject to submission of details of the biological resources used by them on half yearly basis.***

(2) If an entity covered under section 7 of the Act, having an annual turnover of more than rupees five crore, has procured biological resources (medicinal plants) from different sources and produces certificates of origin for cultivated medicinal plants, the benefit sharing obligations shall be reduced in proportion to the value of the cultivated medicinal plants on pro rata basis.

(3) The above turnover criteria will not be applicable in case the applicant obtained any intellectual property rights and commercialized the same.

Provided that in the event of the applicant submitting a proof of payment of collection fee to the Biodiversity Management Committee under sub-section (3) of section 41, the benefit sharing component payable to the Authority or State Biodiversity Board or Union territory Biodiversity Council shall be reduced up to thirty percent of the benefit sharing amount due, as decided by the Authority or State Biodiversity Board or Union territory Biodiversity Council, as the case may be:

Provided also that, in case an applicant accesses biological resources and submits evidence of payment of collection charges to the Biodiversity Management Committee for some of them only, the rebate shall be calculated on *pro rata* basis:

Provided further that where an applicant submits a proof of sharing of benefits by the intermediary, the access and benefit sharing obligation shall be reduced on the already paid amount on *pro rata* basis:

Provided also that there shall be no benefit sharing obligation on an applicant under this regulation if the applicant furnishes a copy of the approval granted by the Authority under sub-regulation (1) of regulation 7:

Provided also that in case of biological resource including digital sequence information having conservation value including those notified under section 38 of the Act, and/or knowledge associated thereto, and or high economic value such as red sanders, sandalwood and agarwood etc., the benefit sharing component shall be twenty percent more than the benefit sharing amount due.

Provided also that in case of biological resource having conservation value and or high economic value such as red sanders, sandalwood and agarwood etc., and including those notified under section 38 of the Act, the benefit sharing shall not be less than five percent (5.0%) of the proceeds of the auction or sale amount or the purchase price, as the case may be, as determined by the Authority or State Biodiversity Board or Union territory Biodiversity Council, on case-by-case basis, as upfront payment.

Illustrations

(I) Illustration 1: A company is engaged in the business of manufacturing cosmetics products using biological resources.

Annual turnover: Rs. 4.90 crore

Annual gross ex-factory sale price of products derived from the biological resources: Rs.5 lakh

ABS obligations: Nil, but such an entity has to follow the application process prescribed in the regulation.

(II) Illustration 2: A company is engaged in the business of manufacturing cosmetics products using biological resources.

Annual turnover: Rs. 23.5 crore

Annual gross ex-factory sale price of products derived from the biological resources: Rs.5 crore

ABS obligations: 0.2% of Rs.5 crore =Rs. 1,00,000/-

(III) Illustration 3: A company is engaged in the business of producing seeds using biological resources.

Annual turnover: Rs. 48 crore

Annual gross ex-factory sale price of products derived from biological resources: Rs. 24 crore

ABS obligations: 0.4% of Rs. 24 crore: Rs. 9,60,000/-.

*(IV) **Illustration 4:** A company is engaged in the business of producing seeds using biological resources.*

Annual turnover: Rs. 90 crore

Annual gross ex-factory sale price of products derived from the biological resources: Rs. 60 crore

ABS obligations: 0.6% of Rs. 60 crore: Rs. 36,00,000/-.

*(V) **Illustration 5:** A company is engaged in the business of producing nutraceutical products using biological resources, having conservation value.*

Annual turnover: Rs. 7.5 crore

Annual gross ex-factory sale price of products derived from the biological resources: Rs. 1.5 crore

ABS obligations: 0.2% of Rs. 1.5 crore and 25% of ABS obligations for using bioresources having conservation value.

ABS payable: Rs 37,500 [30,000 (0.2% of Rs. 1.5 crore) + Rs 7500 (25% of ABS obligations)]

*(VI) **Illustration 6:** A company is engaged in the business of producing nutraceutical products using biological resources and paid Rs 2,00,000/- to BMC as levy fee.*

Annual turnover: Rs. 40 crore

Annual gross ex-factory sale price of products derived from the biological resources: Rs. 30 crore

ABS obligations: 0.4% of Rs. 30 crore: Rs 12,00,000/-

Rebate in the ABS on account of proof of payment of collection fee to BMC, 30% on the ABS due = 3,60,000/-

ABS payable: (12,00,000 – 3,60,000) = Rs 8,40,000/-

*(VII) **Illustration 7:** An entity covered under section 7 of the Act has accessed rupees ten crore worth of cultivated medicinal plants, and rupees twenty crore worth of other biological resources for manufacture of various products for commercial utilization. The annual turnover of the entity is rupees fifty five crore and the ex-factory sale price of all those products is rupees forty crore. The ABS obligation of the entity is as below:-*

Annual turnover: Rs.55 crore

Annual ex-factory sale price of all products using biological resources: Rs.40 crore

Total input cost of biological resources: Rs.30 crore

Proportion of cultivated medicinal plants used Rs.10 crore: $(10/30) \times 100 = 33.33\%$

ABS obligation on Rs. 40 crore @ 0.6% = Rs. 24 lakh

Rebate of 33.33% on account of cultivated medicinal plants used = Rs. 8 lakh

Total ABS obligations = Rs.16 lakh

5. Collection of fees. — Biodiversity Management Committee may levy charges by way of collection fees from any person or entity irrespective of the annual turnover 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. A collection fee, if levied by the Biodiversity Management Committee, shall be in addition to the benefit

sharing payable to the Authority or State Biodiversity Board or Union territory Biodiversity Council, as the case may be, under these Regulations.

6. Procedure for seeking prior approval for sharing or transferring results of research relating to biological resource or traditional knowledge associated thereto and mode of benefit sharing thereof. —

(1) Procedure for seeking prior approval for sharing or transferring results of research

(a) Any person who intends to share or transfer results of research relating to biological resource including digital sequence information and/or traditional knowledge associated thereto, occurring in or obtained from India to persons referred in sub-section (2) of section 3 of the Act for monetary consideration or otherwise, shall apply on the web portal of the Authority in Form 3 of the Rules and provide evidence of approval of the Authority for access to the biological resource and traditional knowledge associated thereto involved in the research:

Provided that the requirement of evidence under this clause shall not apply to persons covered under section 7 of the Act:

Provided further that in case the transfer of results of research involves accessing associated biological resource including digital sequence information also for undertaking commercial utilization, the transferee shall have to follow the procedure mentioned under regulation 4.

(b) The Authority shall, on being satisfied with the application under clause (a), take a decision on the application within a period of ninety days for transferring results of research.

Provided that if the requisite information sought by the Authority has not been made available by the applicant within a period of thirty days from the date of seeking information, the application shall be closed and the applicant shall be informed about the closure.

(c) The approval to access shall be in the form of an agreement duly signed by the authorised officer of the Authority and the applicant on mutually agreed terms:

Provided that the application is deemed to be closed, if the applicant under Form 3 does not sign the agreement within a period of sixty days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of half of the fee prescribed under sub-rule (2) of rule 15 of the Rules within a period of ninety days.

(d) In case, the biological resources are required to be transferred along with results of research, a special procedure will be evolved in the sector specific approach to further simplify the existing procedure.

(2) Mode of benefit sharing.- The applicant under Form 3 shall, in case of sharing or transfer of results of research under sub-regulation (1), pay to the Authority such monetary and/or share non-monetary benefit, as agreed between the applicant and the Authority:

Provided that in case the monetary benefits have been received by the applicant, on such transfer, the applicant shall pay to the Authority up to five percent (5.0%) of the monetary consideration:

Provided further that before coming into force of these Regulations, in cases of sponsored projects where no budget had been earmarked for payment of benefit sharing, the sponsoring organization shall give an undertaking that in case the results of research are used for commercialization, the benefits shall be shared with the Authority. The Indian entities availing sponsorship of such projects shall keep the sponsorer informed of this requirement.

(3) Procedure for using the results of research obtained under sub-regulation (1) for further research by the transferee {persons covered under sub-section (2) of section 3 of the Act} shall be as follows:

(a) such person, who intends to use the results of research relating to biological resource including digital sequence information and/or traditional knowledge associated thereto, for conducting further research shall do prior registration on the web portal of the Authority in Form 4 of the Rules;

(b) the person so registered under Form 4 shall submit a status report to the Authority in a manner as specified by the Authority;

(c) if the Authority is of the opinion that such an activity is detrimental or contrary to the objectives of the Act, may by order, prohibit or restrict any such activity.

(4). Procedure for seeking prior approval to use the results of research for commercial utilisation by the transferee {persons covered under sub-section (2) of section 3 of the Act} shall be as follows:

(a) such person, who intends to use the results of research relating to biological resource or traditional knowledge associated thereto, for commercial utilization, shall apply on the web portal of the Authority in Form 5 of the Rules and provide evidence of approval of the Authority for accessing the results of research involved in the commercial utilization:

Provided that in case the transfer of results of research involves accessing associated biological resource including digital sequence information also, the transferee shall have to follow the procedure mentioned under regulation 4.

(b) the Authority shall, on being satisfied with the application under clause (a), take a decision on the application within a period of ninety days for using the results of research for commercial utilization:

Provided that if the requisite information sought by the Authority has not been made available by the applicant within a period of thirty days from the date of seeking information, the application shall be closed and the applicant shall be informed about the closure:

Provided further that the application shall not be rejected unless the applicant has been given a reasonable opportunity of being heard.

(c) the approval to access shall be in the form of an agreement on mutually agreed terms duly signed by the applicant under Form 5 and an authorised officer of the Authority:

Provided that the application is deemed to be closed, if the applicant does not sign the agreement within a period of sixty days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of half of the fee prescribed under sub-rule (2) of rule 15 of the Rules within a period of ninety days.

(5). Mode of benefit sharing.- When the results of research are used for commercial utilisation, the applicant under Form 5, shall have to pay the benefit sharing, as per sub-regulation (3) of regulation 4.

(6). Procedure for seeking prior approval to use the results of research for obtaining intellectual property rights by the transferee {persons covered under sub-section (2) of section 3 of the Act} shall be as follows:

(a) such person, who intends to use the results of research relating to biological resource including digital sequence information and/or traditional knowledge associated thereto, for obtaining intellectual property rights, shall apply on the web portal of the Authority in Form 6 of the Rules and provide evidence of approval of the Authority obtained by the transferor for transfer of the results of research which are being used for obtaining intellectual property rights:

(b) the Authority shall, on being satisfied with the application under clause (a), take a decision on the application within a period of ninety days for using the results of research for obtaining intellectual property rights:

Provided that if the requisite information sought by the Authority has not been made available by the applicant within a period of thirty days from the date of seeking information, the application shall be closed and the applicant shall be informed about the closure:

Provided further that the application shall not be rejected unless the applicant has been given a reasonable opportunity of being heard.

(c) the approval to access shall be in the form of an agreement duly signed by authorised officer of the Authority and the applicant on mutually agreed terms:

Provided that the application is deemed to be closed, if the applicant does not sign the agreement within a period of sixty days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of half of the fee prescribed under sub-rule (2) of rule 15 of the Rules within a period of ninety days.

(7) Mode of benefit sharing: (i) When the applicant under Form 6, himself uses the intellectual property rights for commercialisation, the monetary benefit sharing shall be in the range of up to one percent (1.0%) based on sectoral approach, which shall be worked out on the annual gross ex-factory sale price of product excluding Government taxes, on case-by-case basis.

(ii) When the applicant under Form 6, assigns/licenses the intellectual property rights to a third party for commercialisation, the applicant shall pay to the Authority up to five percent (5.0%) of the fee received (in any form including the license or assignee fee) and up to five percent (5.0%) of the royalty amount received annually from the assignee or licensee, based on sectoral approach, on case-by-case basis.

7. Procedure for obtaining intellectual property rights and mode of benefit sharing thereof. —

(1) Procedure for obtaining prior approval by persons covered under sub-section (2) of section 3 of the Act shall be as follows:

(a) such person who intends to obtain any intellectual property rights, by whatever name called, in or outside India, for any invention based on research or information on any biological resource including digital sequence information which is accessed from India, including those deposited in repositories outside India, or traditional knowledge associated thereto, shall apply on the web portal of the Authority in Form 7 of the Rules. The applicant shall provide evidence of approval of the Authority for access to biological resource including digital sequence information and/or knowledge associated thereto, used in the research leading to the invention:

Provided that any person making an application for any right under any law relating to protection of plant varieties within India shall be exempted from the provisions of this sub-regulation.

(b) the Authority shall, on being satisfied with the application under clause (a), take a decision on the application within a period of one hundred and eighty days:

Provided that the application shall be closed if the requisite information sought by the Authority has not been made available by the applicant within a period of ninety days from the date of seeking information and the applicant shall be informed about such closure.

(c) the approval to access shall be in the form of an agreement duly signed by the authorised officer of the Authority and the applicant on mutually agreed terms:

Provided that the application is deemed to be closed, if the applicant does not sign the agreement within a period of ninety days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of half of the application fee prescribed under sub-rule (1) of rule 16 of the Rules within a period of ninety days.

(d) the applicant shall intimate the Authority about grant of the intellectual property rights within forty-five days from the date of the grant, failing which action as deemed fit will be taken by the competent authority;

(e) the Authority, for the reasons to be recorded in writing, may reject an application if it considers that the request cannot be acceded to:

Provided that the application shall not be rejected unless the applicant has been given a reasonable opportunity of being heard.

(2) Mode of benefit sharing. — (a) The applicant shall, in case of commercialisation of the intellectual property rights so obtained, pay to the Authority such monetary benefit and or share non-monetary benefit, as agreed between the applicant and the Authority as given below:

(i) when the applicant himself uses the intellectual property rights for commercialisation, the monetary benefit sharing shall be in the range of up to one percent (1%) based on sectoral approach, which shall be worked out on the annual gross ex-factory sale price of the product excluding Government taxes, on case-by-case basis:

Provided that in case the traditional knowledge is involved in the invention, the benefit sharing obligation shall be twenty-five percent higher than the benefit sharing due:

Provided that any person, if upon cease or revocation of the intellectual property rights, intends to access the biological resource including digital sequence information and/or traditional knowledge associated thereto, to be used in the product or process for which intellectual property rights were obtained, for commercial utilisation, shall seek approval under sub-regulation (1) of regulation 4 and share the benefits as referred to under sub-regulation (3) of regulation 4.

Explanation. —In the event of the applicant accessing biological resource for commercial utilization during the existence of intellectual property rights, the applicant shall share the benefits only under this regulation.

(ii) when the applicant assign/license the intellectual property rights to a third party for commercialisation, the applicant shall pay to the Authority up to five percent (5.0%) of the fee received (in any form including the license or assignee fee) and up to five percent (5.0%) of the royalty amount received annually from the assignee or licensee, based on sectoral approach, on case-by-case basis.

Illustration 1

A company obtained intellectual property rights for a product based on the biological resource and traditional knowledge associated thereto, and also accessed biological resource and knowledge associated thereto for commercial utilization of the patented product during the term of the intellectual property rights, the Authority determines the benefit sharing as 0.2% to that company. The benefit sharing amount will be as given below:

Annual gross ex-factory sale price of the patented product: Rs.20 lakh.

ABS obligation is: 0.2% of Rs.20.00 lakh =Rs. 4,000/-.

Illustration 2

A company obtained intellectual property rights for the process based on the biological resource and traditional knowledge associated thereto, and assigns the intellectual property rights to a third party during the term of the intellectual property rights, the benefit sharing will be as given below: —

(a) If the company assigns the intellectual property rights to a third party for Rs. 50 lakh, the benefit sharing component will be: 3% If the benefit sharing is fixed by the Authority as 3% of Rs. 50 lakh = Rs.1,50,000/- .

(b) If the company also receives royalty from the third party on an annual basis of Rs. 10 lakh, then the benefit sharing component will be: 2% If the benefit sharing is fixed by the Authority as 2% of Rs.10 lakh =Rs. 20,000/- annually plus Rs. 1,50,000/- as mentioned under (a) above. The total amount payable to Authority is Rs.1,70,000/-

Illustration 3

A company obtained intellectual property rights for the product based on the biological resources and traditional knowledge associated thereto and is also accessing biological resources for commercial utilization of the patented product after the cessation or expiry of the term of intellectual property rights. The benefit sharing obligation will be calculated as per the formula given in sub-regulation (3) of regulation 4.

Annual turnover of the company is: Above Rs.1.0 crore

Annual gross ex-factory sale price of products derived from the biological resources: Rs.10 lakh.

Benefit sharing obligation will be: Nil

(b) such person who intends to access the biological resource including digital sequence information, for commercialisation of the intellectual property rights, shall apply to the Authority or State Biodiversity Board or Union territory Biodiversity Council, as the case may be, under regulation 4.

(3) Procedure for persons covered under section 7 of the Act shall be as below:

(a) such person who intends to obtain any intellectual property rights, by whatever name called, in or outside India, for any invention based on research or information on any biological resource including digital sequence information which is accessed from India, including those deposited in repositories outside India, and/or traditional knowledge associated thereto, shall make an application by registering on the web portal of the Authority in Form 8 of the Rules:

Provided that any person making an application for any right under any law relating to protection of plant varieties within India shall be exempted from the provisions of this sub-regulation.

(b) if the Authority is of the opinion that such an invention is the result of access to the knowledge held by a community or an individual or a group of individuals, in an illegal manner, the Authority may in a complaint to the adjudicating officer recommend imposing higher penalty with regard to damage and also value assessed or realised, as the case may be.

(c) the person so registered under this regulation shall submit a status report in a manner as prescribed by the Authority.

(4) Procedure for commercialization of the patent by persons covered under section 7 of the Act shall be as follows:

(a) such person who intends to commercialise the intellectual property rights, shall obtain prior approval of the Authority by applying on the web portal of the Authority in Form 9 of the Rules:

(b) the Authority shall, on being satisfied with the application under clause (a), take a decision on the application within a period of one hundred and eighty days.

(c) the approval shall be in the form of an agreement on mutually agreed terms duly signed by the authorised officer of the Authority and the applicant:

Provided that the application is deemed to be closed if the applicant does not sign the agreement within a period of ninety days from the date of communication of the draft agreement by the Authority, upon intimation to the applicant:

Provided further that such closed application may be revived on receipt of payment of the half of the fee specified for fresh application under clause (b) of sub-rule (3) of rule 16 of the Rules within a period of ninety days.

(5) Mode of benefit sharing: The applicant shall pay to the Authority such monetary benefit and or share non-monetary benefit, as agreed between the applicant and the Authority.

(i) When the applicant himself uses the intellectual property rights for commercialisation, the monetary benefit sharing shall be in the range of up to one percent (1%) based on sectoral approach, which shall be worked out on the annual gross ex-factory sale price of the product excluding Government taxes, on case-by-case basis:

Provided that in case the traditional knowledge is involved in the invention, the benefit sharing obligation shall be twenty-five percent higher than the benefit sharing due:

Provided that any person, if upon cease or revocation of the intellectual property rights, intends to access the biological resource including digital sequence information or traditional knowledge associated thereto, to be used in the product or process for which intellectual property rights were obtained, for commercial utilisation, shall seek approval under sub-regulation (2) of regulation 4 and share the benefits as referred to under sub-regulation (3) of regulation 4.

Explanation. —In the event of the applicant accessing biological resource for commercial utilization during the existence of intellectual property rights, the applicant shall share the benefits only under this regulation.

(ii) When the applicant assigns/licenses the intellectual property rights to a third party for commercialisation, the applicant shall pay to the Authority up to five percent (5.0%) of the fee received (in any form including the license or assignee fee) and up to five percent (5.0%) of the royalty amount received annually from the assignee or licensee, based on sectoral approach, on case-by-case basis.

8. Conducting non-commercial research or research for emergency purposes outside India by Indian researchers or institutions. —

(1) Any Indian researcher or institution who intends to carry or send the biological resource including digital sequence information, outside India to undertake non-commercial research including to carry out certain urgent studies to avert emergencies like epidemics, etc., shall apply on the web portal of the Authority in Form 13 of the Rules:

Provided that in case the traditional knowledge associated thereto is also to be transferred or carried along with the biological resource, the approval of the Authority shall be taken by the concerned foreign individual or institution under rule 13 of the Rules.

(2) The Authority shall, on being satisfied with the application under sub-regulation (1), accord its approval in the form of a letter within a period of forty-five days from the date of receipt of the application.

(3) On receipt of approval of the Authority under sub-regulation (2), the applicant shall deposit voucher specimen of the biological resources in the designated national repositories before carrying or sending it outside India and a copy of proof of such deposit shall be endorsed to the Authority.

9. Deposition of novel microbial strain in the repositories outside India for publication.

(1) Any Indian researcher or scientist who has discovered a novel microbial strain from India and intends to deposit the same in the repositories outside India for publication in the journals for claiming novelty as per the agreed international requirements, shall apply on the web portal of the Authority in Form 'A' as appended to these Regulations.

(2) The applicant shall deposit one voucher specimen in the designated repository as required under sub-section (3) of section 39 of the Act.

(3) The designated repositories in and outside India shall inform any user about the Indian legal requirements for obtaining prior approval of the Authority for undertaking any research or bio-survey and bio-utilisation or commercial utilisation as per section 3 of the Act:

Provided that if any researcher desires to refer to the voucher specimen for taxonomical identification purposes, such approval is not required.

(4) The applicant shall submit a copy of the acknowledgement of the receipt of voucher specimen issued by the designated repository concerned in India to the Authority.

10. Criteria for determination of benefit sharing. –

(1) Benefit sharing by the applicant may be in monetary and or non-monetary modes, as mutually agreed with the Authority or State Biodiversity Board or Union territory Biodiversity Council in consultation with the Biodiversity Management Committee or the benefit claimer, on case-by-case basis as provided at Annexe to these Regulations.

(2) Determination of benefit sharing under regulations 3, 4, 6 and 7 shall be sector specific and based on considerations such as nature and quantity of biological resource used and its sustainability, ecological impact, nature of technology applied, potential commercial use of the proposed activity, etc. The Authority shall specify the formula for determining the percentage of benefit sharing component including upfront payment to be fixed. The same shall be followed by the State Biodiversity Board or Union territory Biodiversity Council, from amongst the range specified in the respective regulation, on case-by-case basis, for undertaking different activities:

Provided that special consideration may be given to cases where access to biological resources including digital sequence information or knowledge associated thereto is for technologies or innovations or products that are developed leading to intellectual property rights for controlling epidemics, mitigating environmental pollution affecting human, animal or plant health, or for food security or conservation of biodiversity, and in such cases, the benefit sharing may be at a lower percentage in the range, as decided by the Authority or State Biodiversity Board or Union territory Biodiversity Council, on case-by-case basis:

Provided further that in the event of contribution to non-monetary benefit as mutually agreed, the monetary benefit sharing obligation, if any, may be reduced,

as determined by the Authority or State Biodiversity Board or Union territory Biodiversity Council.

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

(4) Where the biological resource is sourced from the jurisdiction of two or more State Biodiversity Boards or Union territory Biodiversity Councils, the total amount of the accrued benefits shall be shared with the State Biodiversity Boards or Union territory Biodiversity Councils concerned, proportionately, on a case-by-case basis, after setting aside ten percent of the accrued benefits for the State where the manufacturing unit is located using the biological resources.

11. Sharing of benefits among the Authority, State Biodiversity Board or Union territory Biodiversity Council and benefit claimer. —

(1) Where approval has been granted by the Authority for research or for commercial utilisation or for sharing or transferring results of research or for intellectual property rights, the mode of benefit sharing shall be as under: —

(a) a minimum of ten percent to maximum of fifteen percent of the accrued benefits shall go to the Authority, out of which half of the amount may be retained by the Authority, as the case may be, and the other half may be shared with the State Biodiversity Board or Union territory Biodiversity Council concerned.

(b) the remaining amount of benefit sharing shall be distributed among the benefit claimers including Biodiversity Management Committee. In case where the biological resource including digital sequence information is accessed from an unknown source, the Authority may retain the full amount of the accrued benefit which may be utilized in a manner as decided by the Authority for meeting the objectives of the Act through the State Biodiversity Board, Union territory Biodiversity Council and Biodiversity Management Committee.

(c) where the biological resource including digital sequence information and or knowledge associated thereto is sourced from an individual or a group of individuals or organisations, the amount received under clause (b) shall be directly transferred to such individual or a group of individuals or organisations, in accordance with the terms and conditions of the agreement entered into, if any, and in such manner as deemed fit.

(2) Where approval has been granted by the State Biodiversity Board or Union territory Biodiversity Council under these Regulations, the sharing of accrued benefits shall be as under:

(a) a minimum of ten percent to maximum of fifteen percent of the accrued benefits shall be retained by the State Biodiversity Board/Union territory Biodiversity Council.

(b) the remaining amount of benefit sharing shall be distributed among the benefit claimers including Biodiversity Management Committee. In case where the biological

resource including digital sequence information is accessed from an unknown source, the State Biodiversity Board/Union territory Biodiversity Council may retain the full amount of the accrued benefit, which may be utilized in a manner as decided by the State Biodiversity Board or Union territory Biodiversity Council for meeting the objectives of the Act through Biodiversity Management Committees.

(c) where the biological resource including digital sequence information and/or knowledge associated thereto is sourced from an individual or a group of individuals or organisations, the amount received under clause (b) shall be directly transferred to such individual or a group of individuals or organisations, in accordance with the terms and conditions of the agreement entered into, if any, and in such manner as deemed fit.

(3) The interest earned on the benefit sharing amount deposited in the National Biodiversity Fund or the State Biodiversity Fund or Union territory Biodiversity Fund shall be utilised in a manner as decided by the Authority or State Biodiversity Board or Union territory Biodiversity Council.

(4) All penalties together with interest earned thereof accrued in the National Biodiversity Fund or the State Biodiversity Fund or the Union territory Biodiversity Fund concerned, shall be used to support conservation and sustainable use of the biological resources, promote livelihoods of the local people of the area where such biological resources occur and to undertake various activities to meet the objectives of the Act.

12. Processing and disposal of applications received by the Authority or State Biodiversity Board or Union territory Biodiversity Council. —

(i) Every application shall be submitted online to the Authority or State Biodiversity Board or Union territory Biodiversity Council including scanned copies of documents, duly authenticated, as prescribed.

(ii) The application shall be closed if the requisite information sought by the Authority or State Biodiversity Board or Union territory Biodiversity Council has not been made available by the applicant within the time limit specified under the respective regulations. The applicant shall be informed about the closure.

(iii) Any approval granted under these Regulations for access to biological resource including digital sequence information and/or knowledge associated thereto, is non-transferable.

(iv) The time limit specified for disposal of an application shall commence only from the date of receipt of application complete in all aspects including the application fee.

(v) Any information specified in the application as 'confidential' shall not be disclosed to any person not concerned thereto.

(vi) While processing the application for access to any biological resource and/or knowledge associated thereto, the Authority or State Biodiversity Board or Union territory Biodiversity Council may consider whether these relate to biological resource.

- (a) cultivated or domesticated or wild;
- (b) endemic or threatened species;
- (c) accessed directly through the providers or obtained through traders;
- (d) developed or maintained under *ex situ* conditions;
- (e) of conservation and or economic value such as red sanders, sandal wood, agar wood, etc., including those notified under section 38 of the Act/ having importance to the livelihoods of local communities;
- (f) prohibited or restricted under the Act or any other law for the time being in force;
- (g) crops listed under *Annexe* to the International Treaty on Plant Genetic Resources for Food and Agriculture;
- (h) newly discovered taxa.

(vii) The Authority or State Biodiversity Board or Union territory Biodiversity Council, as the case may be, while taking any decision on the application relating to the use of biological resource including digital sequence information and/or knowledge associated thereto shall consult the Biodiversity Management Committee within whose jurisdiction the biological resource or knowledge associated thereto occur:

Provided that the Biodiversity Management Committee before conveying its views may consult, wherever required, the community, individual or entity concerned to whom the biological resource belongs to, as the case may be, to ensure their prior informed consent:

Provided further that in case, the biological resource is to be accessed from an institution or repository for undertaking the activities envisaged under section 3 of the Act, the Authority may waive the process of referring the request to the Biodiversity Management Committee:

Provided also that the Authority may waive the process of referring the request to the Biodiversity Management Committee while considering the request for transfer of results of research under section 4 and for obtaining intellectual property rights under section 6 of the Act:

Provided also that if no response is received from the State Biodiversity Board or Union territory Biodiversity Council within a period of fifteen days from the date of making a reference, the Authority may assume that State Biodiversity Board or Union territory Biodiversity Council concerned has no comments to offer and shall proceed further, as deemed fit.

(viii) On receipt of the application, the Authority or State Biodiversity Board or Union territory Biodiversity Council may make such enquiries, as deemed fit, and if necessary, may consult experts or expert committee constituted for this purpose.

(ix) The Authority or State Biodiversity Board or Union territory Biodiversity Council may reject, restrict or prohibit the request for access to biological resource including digital sequence information and / or knowledge associated thereto, for the reasons specified under these Regulations:

Provided that the Authority or State Biodiversity Board or Union territory Biodiversity Council may permit access to cultivated species referred to in sub-rule (1) of rule 14 of the Rules depending on the merits of each case for a specific period:

Provided further that where the Authority or State Biodiversity Board or Union territory Biodiversity Council has rejected, restricted or prohibited the request for access to biological resource including digital sequence information and / or knowledge associated thereto, the reasons for such rejection, restriction or prohibition shall be recorded in writing after giving a reasonable opportunity of being heard to the applicant.

(x) Approval granted by the Authority or State Biodiversity Board or Union territory Biodiversity Council shall be in the form of an agreement on mutually agreed terms duly signed by an authorised officer of the Authority or State Biodiversity Board or Union territory Biodiversity Council, as the case may be, and the applicant:

Provided that if the applicant does not sign the agreement within the time limit specified under the respective regulations, the Authority or State Biodiversity Board or Union Territory Biodiversity Council shall close the application under intimation to the applicant:

Provided also that the Authority or State Biodiversity Board or Union territory Biodiversity Council may revive the closed application on receipt of payment of half of the fee prescribed under the respective Rules, as applicable, within a further period of ninety days:

Provided also that the Authority may communicate approval in the form of a letter without entering into a written agreement for the purpose of conducting non-commercial research referred to in regulation 8.

(xi) The format of the agreement for approvals under sections 3, 4, 6 and 7 of the Act shall include the following, but not limited to, namely: -

- (a) general objectives and purpose;
- (b) details of the biological resource including digital sequence information and / or knowledge associated thereto including accompanying information;
- (c) intended uses of the biological resource including digital sequence information or knowledge associated thereto
- (d) terms and conditions for the applicant while obtaining intellectual property rights;
- (e) nature and quantum of monetary and or non-monetary benefits;
- (f) restrictions on sharing or transferring the results of research to any third party without prior approval of the Authority;

(g) declaration by the applicant that whenever there is change in the status with regard to sub-section (2) of section 3 of the Act, intimation shall be given to the Authority or State Biodiversity Board or Union territory Biodiversity Council within a period of sixty days.

(h) undertaking by the applicant to deposit a reference sample of the biological resource to be accessed, wherever required by the Authority or State Biodiversity Board or Union territory Biodiversity Council, with the repositories so designated under section 39;

(i) submission of periodic status reports by the applicant about research and other developments, as may be prescribed by the Authority or State Biodiversity Board or Union territory Biodiversity Council;

(j) obligation to abide by the provisions of the Act, Rules and Regulations, and other related legislations in force in the country;

(k) affirmation to facilitate measures for conservation and sustainable use of biological resource to be accessed;

(l) assertion to minimize environmental impacts while collecting the biological resource;

(m) legal provisions such as duration of the agreement, notice period to terminate the agreement, independent enforceability of clauses, provision regarding the extent to which the obligations relating to benefit sharing clauses survive the termination of the agreement, events limiting liability (natural calamities, etc.), arbitration, confidentiality clause, if any, etc.

(n) any other condition which the Authority or State Biodiversity Board or Union territory Biodiversity Council may consider necessary for meeting the objectives of the Act.

(xii) the Authority or State Biodiversity Board or Union territory Biodiversity Council, based on any complaint or *suo moto*, may withdraw the approval granted under these regulations and revoke the agreement after giving an opportunity of being heard to the applicant. The copies of the order so issued shall be communicated to the applicant, and to the State Biodiversity Board or Union territory Biodiversity Council, as the case may be, and to the Biodiversity Management Committee concerned for the purpose of effecting necessary prohibitions.

(xiii) to assess the damages caused, if any, and take steps for compensating the same.

(xiv) where the applicant has made a request for withdrawal of the application, the Authority or State Biodiversity Board or Union territory Biodiversity Council shall close the application. If any violation is noticed during the period of withdrawal and closure of the application by the Authority. the Authority or State Biodiversity Board or Union territory Biodiversity Council, as applicable, may consider initiating action as per the provisions of the Act, Rules, these Regulations and other related laws, as may be applicable.

(xv) The Authority or State Biodiversity Board or Union territory Biodiversity council shall publicise all the approvals granted or rejected on its website and shall ensure that such information is shared with other agencies, as may be required.

(xvi) Compliance with the terms and conditions of the agreement by the applicant shall be monitored by the Authority by involving State Biodiversity Board or Union territory Biodiversity Council, Biodiversity Management Committee or any other agency, as deemed appropriate.

(xvii) Compliance with the terms and conditions of the agreement by the applicant shall also be monitored by the State Biodiversity Board or Union territory Biodiversity Council by involving Biodiversity Management Committee or any other agency, as deemed appropriate in the cases where approval has been granted by State Biodiversity Board or Union territory Biodiversity Council concerned.

13. Reporting compliance with the terms and conditions of approval. –

The applicant may submit a compliance report to the Authority or State Biodiversity Board or Union territory Biodiversity Council in accordance with the terms and conditions under which approval is granted.

14. Certain activities or persons exempted from obtaining approval.-

The following activities or persons shall not require approval of the Authority or State Biodiversity Board or Union territory Biodiversity Council, namely:-

(1) any person covered under section 7 of the Act for accessing biological resource including digital sequence information and/or knowledge associated thereto, occurring in or obtained from India, for the purposes of conducting research or bio-survey and bio-utilisation in India;

(2) the activities and persons mentioned under sub-clause (iv) of clause (a) of sub-regulation (2) of regulation 4;

(3) collaborative research projects under section 5 of the Act;

(4) accessing biological resource for conventional breeding or traditional practices in use in agriculture, horticulture, poultry, dairy farming, animal husbandry or beekeeping, in India.

Explanation — The conventional breeding and traditional practices for the purposes of these Regulations shall mean developing more genetic variability or improvement of animal and plant species by facilitating meiotic combination of genes expressing themselves in the subsequent generations that are practiced in agriculture, aquaculture, horticulture, sericulture, poultry, dairy farming, animal husbandry or bee keeping, etc., by the growers, cultivators, farmers or individuals based on their traditional knowledge associated with such resources. The activities of exchange or sale of indigenous, folk, landraces by farmer producer organizations, farmer producing company farmers, tribal

groups, civil society organisations, self-help groups, etc., are also exempted. However, when practiced for commercial purpose, it will not be considered as conventional breeding and traditional practices.

(5) publication of research papers or dissemination of knowledge, in any seminar or workshop, involving financial benefits, if such publication is in conformity with the guidelines issued by the Central Government from time to time;

(6) accessing value added products, which contain portions or extracts of plants and animals in unrecognisable and physically inseparable form:

(7) for accessing biological resources such as, pests, insects, pathogens, microorganisms, plants or animals for testing or trial on any invention and product including for statutory regulatory requirements:

Provided that this exemption will not be applicable if such biological resource is a part of the invention or ingredient of the product being developed or tested.

(8) biological resource, products, and items derived from it, normally traded as commodities notified by the Central Government under section 40 of the Act.

(9) Accessing the crops from amongst the crops listed at Annex-I of the International Treaty on Plant Genetic Resources for Food and Agriculture, as notified by the Department of Agriculture and Cooperation, Ministry of Agriculture, Government of India from time to time, is exempted from the provisions of section 3 and 4 of the Act, for the purpose of utilization and conservation for research, breeding and training for food and agriculture.

15. Appeal against the decisions or orders of the Authority or State Biodiversity Board or Union territory Biodiversity Council under these Regulations. —

Any person aggrieved by any determination of benefit sharing or order of the Authority or State Biodiversity Board or Union territory Biodiversity Council under these Regulations, may file an appeal before the National Green Tribunal within a period of thirty days from the date of communication of the impugned order or decision.

16. Authority or any other organization authorized by the Central Government to act as checkpoint for purposes of implementation of Nagoya Protocol. -

(1) Any person who intends to use in India the biological resource or traditional knowledge associated thereto obtained from a foreign country, irrespective of being a Party or non-Party to the Nagoya Protocol, for research or for commercial purpose or for obtaining intellectual property rights, shall submit a declaration on the web-portal of the Authority in Form 10 of the Rules or in the manner prescribed by any other organization authorized by the Central Government in this behalf.

(2) The Authority, as per the provisions of the section 36A of the Act, after obtaining relevant information from the user of such biological resource or traditional knowledge

associated thereto, shall notify the same on the Access and Benefit-Sharing Clearing-House of the Convention on Biological Diversity.

(3) Based on the request of the provider country, the Authority shall take appropriate measures on such use, as per the provisions of the section 36A of the Act.

Annex

Fair and equitable benefit sharing options

(See regulation 10)

The following options, either one or more, may be applied in accordance with mutually agreed terms between the applicant and the National Biodiversity Authority or State Biodiversity Board or Union territory Biodiversity Council, on case-by-case basis, in accordance with the provisions of sections 21 and 23 of the Act. These options are indicative in nature and other options, as approved by the National Biodiversity Authority 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 / Union territory or Local Biodiversity Funds;
- (vii) Funding for research and development in India;
- (viii) Joint ventures with Indian institutions and companies;

(b) Non-monetary benefits options:

- (i) Providing institutional capacity building, including training on sustainable use practices, creating infrastructure (including disposal of waste/composting for a clean environment, providing safe drinking water/solar powered lights) and undertaking development of works 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; providing green technologies to the local people/communities;
- (iii) Remediation and restoration activities to prevent habitat destruction or pollution or contamination of areas;
- (iv) Strengthening of capacities for developing technologies and transfer of technology to India and/or collaborative research and development programmes with Indian institutions/individuals/entities;
- (v) Contribution/collaboration related to education and training in India on conservation and sustainable use of biological resources;
- (vi) Setting up of production, research, and development units/facilities contributing to the local economy and income generation for the local communities;
- (vii) Taking appropriate measures for conservation and protection of species including rare, endangered and threatened species by raising nurseries and/or plantations in the area from where biological resources have been accessed.

- (viii) Instituting studies/projects on inventorisation and resource assessment of biodiversity
- (ix) Sharing of scientific information relevant to conservation and sustainable use of biological diversity including biological inventories and taxonomic studies;
- (x) Conducting research directed towards priority needs in India including for food, health and livelihood security focusing on biological resources;
- (xi) Providing scholarships including living costs, etc., to individuals and financial aid to Indian institutions preferably to regions, tribes/sects contributing to the delivery of biological resources and subsequent profitability, if any;
- (xii) Setting up of venture capital fund for aiding the cause of benefit claimers;
- (xiii) Joint ownership of relevant intellectual property rights.
- (xiv) Salaries and preferential terms where mutually agreed.

FORM-A
{See regulation-9}

Application for giving prior intimation to the National Biodiversity Authority for deposition of microorganism by an Indian researcher in repositories outside India for claim of discovery of novel strain from India for publication

1.	Name of the applicant (depositor)	
2.	Category of the applicant	a) Individual researcher b) Institution
3.	Complete address with contact details (Postal address including PIN code, email, mobile and alternate mobile numbers and or landline number)	
4.	Name of the microorganism to be deposited in the foreign repository	
5.	Geographical location from where the microorganism was/ were collected	
6.	Name and contact details of the foreign repository from where the biological resource are to be deposited (Postal address including PIN code, email, mobile and alternate mobile numbers and or landline number)	
7.	Name and contact details of the Indian repository where the biological resources are deposited (Postal address including PIN code, email, mobile and alternate mobile numbers and or landline number)	
8.	Accession number allotted by the Indian repository to the deposited microorganism	

Declaration

I/Wedeclare that I will inform the foreign repository that any non-Indian user to access the microorganism so deposited with the repository for undertaking research or for bio-survey and bio-utilisation or for commercial utilisation shall obtain prior approval from the National Biodiversity Authority as per the provisions of the Act.

I declare that I am not a person covered under sub-section (2) of section 3 of the Act.

I further declare and solemnly affirm that the information provided above is true and correct to the best of my knowledge and belief.

Place:

Date:

Signature of the applicant (depositor)

File no....
National Biodiversity Authority
