

Biological Diversity Rules, 2024

The Biological Diversity (Amendment) Act, 2023 (hereinafter referred to as “Amendment Act”) to amend the Biological Diversity Act, 2002 (hereinafter referred to as “BD Act”) has come into force from April 1, 2024. Subsequently, the Biological Diversity Rules, 2024 (hereinafter referred to as “BD Rules”) dated October 22, 2024, were notified on October 25, 2024, in the Official gazette. The Rules have come into force from December 25, 2024.

The BD Rules have brought in changes in the procedures for the compliance of access of biological resource for several purposes by Section 3(2) entities and Section 7 entities with more clarity. Section 3(2) and Section 7 entities defined under the BD Act is as shown below.

Section 3(2)	Section 7
1. Person who is <i>not</i> a citizen of India	Section 7 does not explicitly define an entity, however, excludes the entities that are not covered under Section 3(2); i.e. Persons other than Section 3(2). 1. Indian citizens 2. Indian citizen who is a resident of India
2. A citizen of India who is <i>non-resident</i> of India as defined in clause (30) of section 2 of Income tax Act, 1961 India.	
3. Body corporate, association or organization <i>not</i> incorporated or registered in India; or	3. Body corporate, association incorporated or registered in India which is not controlled by a foreigner within the meaning of clause (27) of Section 2 of Companies Act, 2013
4. Body corporate, association or organisation incorporated or registered in India under any law for the time being in force, <i>which is controlled by the foreigner within the meaning of clause (27) of section 2 of Companies Act, 2013.</i>	

Some of the key amendments to the Rules are as follows:

RULE 13: Procedure for access to biological resources and knowledge associated thereto.

- ✓ Rule 13(1) requires **Section 3(2) entities** required to obtain prior approval to access biological resources and knowledge associated thereto for research/bio-survey/bio-utilization and commercial utilization.

- **Prior approval** from the National Biodiversity Authority (NBA) is required.
- **Relevant Form**: Form 1 for research /bio-survey/bio-utilization.
Form 2 for commercial utilization.
- **Official Fee**: Individual: INR 10000
Entity: INR 20000
- **Approval Timeline**: Approval to be granted within Ninety days by the authority from the receipt of complete application.
- ✓ Rule 13(2) requires Section 3(2) entities to seek approval from NBA for research, commercial utilisation, bio-survey and bio-utilisation if it possesses a biological resource by person/entity covered under Section 3(2) before the coming into force of the Biological Diversity (Amendment) Act, 2023.
- ✓ **Closure and revival of the application**:
 - After filing the application, the NBA may seek additional information. The application shall be closed if the Applicant fails to respond **within 30 days** from the date of seeking information.
 - The application is deemed to be closed if the applicant does not sign the agreement within a period of **60 days** from the date of communication of the draft agreement by the Authority to the applicant.
 - Such closed application may be revived on receipt of payment of half of the prescribed fee for fresh application within a period of **90 days**

RULE 14: Restricting access to biological resources and knowledge associated with such biological resources.

- ✓ The Authority shall take steps to restrict or prohibit access to biological resources or knowledge associated with such biological resources namely:
 - the request for access is for any threatened and/ or endemic species including those notified under section 38 of the Act.
 - the request for access may result in an adverse impact on the livelihood and/ or socio-cultural aspects of the local communities;
 - the request for access may result in adverse environmental impact(s);
 - the request for access may cause genetic erosion or affect the ecosystem functions including in the areas notified under section 37 of the Act;
 - the request for the use of resources for purposes contrary to national interest and other related international agreements entered into by India;
 - for any other reasons to be recorded in writing.

RULE 15: Procedure for seeking approval for sharing or transferring results of research to persons covered under subsection (2) of section 3 of the Act.

- ✓ Rule 15(1) requires any persons who intends to share or transfer results of research based on biological resources (or) traditional knowledge associated thereto from India to a Section 3 (2) entity should meet the following requirements of the act:

(i) Any person who intends to share or transfer results of research for commercial purpose or otherwise:

- Any person who intends to share or transfer results of research based on biological resources (or) traditional knowledge from India should obtain **Prior approval** from National Biodiversity Authority (NBA).
- Relevant Form: Form 3
- Official Fee: Individual: INR 5000
Entity: INR 10000
- Approval Timeline: Approval to be granted within Ninety days by the authority from the receipt of complete application.
- Other Obligations:
 - The Applicant must inform the transferee to register with the NBA if it intends to use the results of the research for further research.
 - The Applicant must inform the transferee to seek prior approval from NBA if it intends to use the results of research for commercial utilization or for obtaining intellectual property rights.

(ii) For transferee (i.e. Section 3(2) entity) to use the results of research for further research:

- Transferee is required to **Register before** National Biodiversity Authority (NBA).
- Relevant Form: Form 4
- Official Fee : Individual: INR 2000
Entity: INR 5000
- Approval Timeline: Approval to be granted within Ninety days by the authority from the receipt of complete application.
- Other Obligations:
 - The transferee to update the NBA about the research activities progress at the end of every calendar year.

- The transferee to seek prior approval from the NBA if it intends to use the results of research for commercial utilization or for obtaining intellectual property rights as per Section 4 or Section 6 of the Act.

(iii) For transferee to use the research results for commercial utilisation

- Transferee is required to obtain **prior approval** from National Biodiversity Authority (NBA).
- Relevant Form: Form 5
- Official Fee : Individual: INR 10000
Entity: INR 20000
- Approval Timeline: Approval to be granted within Ninety days by the authority from the receipt of complete application.

(iv) For transferee to use the research results for obtaining Intellectual property rights

- Transferee is required to obtain **prior approval** from the NBA.
- Relevant Form: Form 6
- Official Fee : Individual: INR 5000
Entity: INR 10000
- Approval Timeline: Approval to be granted within Ninety days by the authority from the receipt of complete application.

✓ Closure and revival of the application:

- Same as that given under Rule 13

RULE 16: Procedure for registration and obtaining prior approval from Authority before grant of intellectual property rights (IPR)

✓ Rule 16(1): Prior approval for Section 3 (2) entities:

- To obtain IPR for any invention based on research *or information including digital sequence* information on biological resource, which is accessed from India, including those deposited in repositories outside India, or traditional knowledge associated thereto
- **Prior approval** from National Biodiversity Authority (NBA) is required.
- Relevant Form: Form 7
- Official Fee : Individual: INR 5000
Entity: INR 10000

- Approval Timeline: Approval to be granted within one hundred and eighty days by the authority from the receipt of complete application.
 - Form of Approval: Approval shall be granted in the form of an agreement on mutually agreed terms duly signed by an authorised officer of the Authority and the applicant:
 - Other Obligations of the applicant:
 - To sign the agreement within **Ninety days from the date of communication** of draft agreement.
 - To intimate NBA the grant of IPR within **Forty-five days of date of grant of IPR**.
- ✓ Rule 16(2): Registration for Section 7 entities:
- To obtain IPR for any invention based on research or information including digital sequence information on biological resource, which is accessed from India, including those deposited in repositories outside India, or traditional knowledge associated thereto
 - **Registration** with NBA before grant of the IPR in India or abroad is required.
 - Relevant Form: Form 8.
 - Official Fee: Individual: INR 2000
Entity: INR 5000
 - Other obligations of the applicant:
 - To obtain prior approval from the NBA before commercialisation of the IPR.
 - To intimate NBA the grant of IPR within **45 days of date of grant of IPR**.
- ✓ Rule 16(3)): Prior approval for commercialisation of IPR by Section 7 entities:
- Need to obtain Prior approval of the NBA at the time of commercialization in the form of licensing, assignment, self-manufacture, transfer of patent rights or any other mode.
 - Relevant Form: Form 9
 - Official Fee: Individual: INR 5000 and
Entity: INR 10000
 - Approval Timeline: Approval to be granted within **180 days** by the authority from the receipt of complete application.

- Form of Approval: The approval shall be granted in the form of an agreement on mutually agreed terms duly signed by an authorised officer of the Authority and the applicant.

- Other obligation of the applicant:

The Applicant is required to provide a declaration that prior intimation to the concerned State Biodiversity Board (SBB) or Union territory Biodiversity Council (UBC) shall be provided for accessing the biological resource and/or traditional knowledge associated thereto for commercial utilization as per the Section 7 of the Act.

✓ Closure and revival of the application:

- After filing the application, the NBA may seek additional information. The application shall be closed if the Applicant fails to respond **within 90 days** from the date of seeking information.
- The application is deemed to be closed if the applicant does not sign the agreement within a period of **90 days** from the date of communication of the draft agreement by the Authority to the applicant:
- Such closed application may be revived on receipt of payment of half of the prescribed fee for fresh application within a period of **90 days**.

RULE 17: Revocation of access or approval

- ✓ On the basis of a complaint or suo moto, the Authority may withdraw the approvals granted under rules 13, 15, sub-rule (1) and (3) of rule 16 and rule 20, revoke the agreement or any part thereof, for the reasons namely
 - That the person who has been granted approval:
 - has declared false or misleading information or violated any of the provisions of the Act or the conditions on which the approval was granted;
 - has failed to comply with any of the terms and conditions of the agreement; or in public interest or for the protection of environment and conservation of biological diversity, or on the basis of new facts or information brought to the notice of the Authority

RULE 18: Measures for monitoring and regulating the use in India of biological resource or associated traditional knowledge obtained from any foreign country.

- Any person (Section 3(2) as well as Section 7 entities) who intends to use in India the biological resource or traditional knowledge associated thereto obtained from any foreign country for research or for commercial purpose or for obtaining intellectual property rights, should-
- Submit a Declaration to NBA.
- Relevant Form: Form 10.
- Fee: No Official Fee.

Rule 19: Procedure for obtaining a certificate of origin for cultivated medicinal plants.

Rule 19(1): Section 7 entity intending to claim an exemption for accessing cultivated medicinal plants under sub-section (2) of section 7 needs to obtain a certificate of origin from the Biodiversity Management Committee concerned. As per the Gazette notification dated May 6, 2025, Rule 19 (Biological Diversity Rules, 2025) will be amended. It shall come in force from 1st day of November 2025. The key aspects of Rule 19 are as follows:

Biological Diversity Rules, 2024	Biological Diversity Rules, 2025
• Self-declaration is to be submitted at the NBA. • <u>Relevant Form</u>: Form 11 • <u>Official Fee</u>: Rs. 200.	• Needs to obtain a certificate of origin from the Biodiversity Management Committee • <u>Relevant Form</u>: Form 11A <u>Official Fee</u>: Rs. 200.
• The entries made in the books maintained in Format 12	• Books containing the details of cultivated medicinal plants shall be maintained by the Biodiversity Management Committee: • Relevant Form: Form 11 • Official Fee: No Official fee
• No relevant form for issuance of certificate of origin	• On the basis of the entries made in the books, the certificate of origin will be generated on the web portal. • Relevant Form: Form 12 • Official Fee: No Official fee

• <u>Approval Timeline:</u> Based on the application submitted by the applicant and the entries made in the books maintained in Format 12, the Authority will issue a certificate of origin of the cultivated medicinal plants within a period of 15 days.	NIL
• In case the certificate of origin is not issued within 15 days, the Applicant shall approach the concerned State Biodiversity Board and same may be disposed of within a period of 7 days.	NIL
• <u>Other obligations:</u> • For claiming exemption, the onus of proof of source of origin of the medicinal plants shall lie on the end-user.	NIL

Rule 20: Procedure for conducting non-commercial research or research for emergency purposes outside India by Indian researcher or institution

- For any Indian researcher or institution to carry or send the biological resource outside India to undertake non-commercial research or research for emergency purpose should obtain prior approval of NBA.
- In case the associated traditional knowledge is also to be transferred or carried along with the biological resources, the prior approval of the Authority shall be

taken by the concerned foreign institution also under Rule 13. (See Section 3(2) Rule 13)

- Relevant Form: Form 13
- Official Fee: Rs. 1000.
- Approval Timeline: 45 days from the date of receipt of the application.
- Other Obligations of the applicant:
 - On receipt of approval the applicant shall deposit voucher specimens in the designated national repositories before carrying or sending the biological resource outside India and a copy of proof of such deposits shall be endorsed to the Authority.
 - The biological resources shall be used only for the purposes stated in the application.
 - The Applicant shall not share/provide/part with/ leave behind any biological resource at the collaborator's facility/ laboratory without the approval of the National Biodiversity Authority.
 - The Applicant or its' supervisor and collaborator, individually and severally shall not put to commercial utilization, nor shall seek any intellectual property rights claim based on the biological resources and traditional knowledge associated thereto used in the research.
 - In case such a situation arises, they should seek prior approval of NBA.
 - Results, process, products, or other outcomes arising out of this activity shall be shared with the NBA during and upon completion of research intended along with copies of the relevant documents and publications.
- Obligations of the Recipient/Collaborator:
 - The Recipient/Collaborator must declare that the biological resources shall be destroyed in full after the completion of the studies 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 maybe, or as decided by the National Biodiversity Authority.
 - The Recipient/Collaborator shall not claim any ownership nor shall claim any intellectual property rights over the biological resources, derivatives or other such components without prior approval of the applicant, institution affiliated and the National Biodiversity Authority.

Section 55; Rule 25: Penalties:

- Applicable to Section 3(2) and Section 7 entities.
- In case any person or entity fails to comply with the provisions of the Act and the contravention is proved before the adjudicating officer, such person/entity shall be liable to pay penalty.
- The penalty may be **one lakh rupees extending to fifty lakh rupees**. Further, if the damage caused exceeds the amount of penalty, then such a penalty shall be commensurate with the damage caused (damage includes damage to the environment and value of the biological resources used and value of the products derived from it by violating provisions of Act).
- If the person or entity continues such contravention, the adjudicating officer may impose an additional penalty not exceeding **one crore rupees**.
- The penalties imposed shall be in addition to the liability of the applicant to pay relief or compensation under Section 55 of the Act and Section 17 of the National Green Tribunal Act, 2010.

Rule 23: Manner of inquiry by the Adjudicating Officer

- The Adjudicating Officer will not inquire into a complaint of non-compliance or contravention of the provisions referred to in Section 55 of the Act (penalties), unless the complaint is filed by or on behalf of the authorised officer, along with all necessary documents, either on its own motion or on receipt of a representation.
- Complaint may be represented by a presenting officer who shall be a legal practitioner.
- Notice: The Adjudicating Officer within **30 days** of the receipt of the complaint, shall issue notice to the person against whom non-compliance or contravention to the provisions of Section 3 or Section 4 or Section 6 or Section 7 of the Act has been alleged under Section 55A of the Act.
- Appearance before the Officer: Such person may appear personally or through an authorized representative on such date as specified, within **15 days** from the date of service thereon not exceeding **30 days**.
- Sub-rule (6): If the person or his representative admits to the allegations, the Adjudicating Office shall-
 - State in his order such admission and impose a penalty;

- Send a copy of the order to the concerned presenting officer and the person against whom complaint was filed;
- Sub-rule (7): For cases not covered under sub-rule (6), the adjudicating officer shall fix a date for inquiry and communicate the same to the concerned presenting officer for presentation of matter.
- On the date fixed, the adjudicating officer shall give an opportunity to the person to produce documents or evidence as he may consider relevant to the inquiry and if the person fails or refuses to appear without sufficient cause, the adjudicating officer may proceed with the inquiry in the absence of such person.
- While holding inquiry, the Adjudicating Officer shall having the following powers of a Civil Court, as specified in the Civil Procedure Code, 1908, namely:-
 - (a) summoning and enforcing the attendance of any person and examining him on oath;
 - (b) requiring the discovery and production of documents or other electronic records; and
 - (c) receiving evidence on affidavits.
- Time period to complete adjudication of matter: Within **90 days** from the date fixed under sub-rule (7), which is extendable upto a further period of **90 days** if sufficient cause exists.
- Sub-rule (16): If the subject-matter of a complaint received under this rule is already in question before the National Green Tribunal or any other Court of competent jurisdiction on the date of receipt of the matter, the proceedings under this rule shall not be initiated unless such latter case is finally disposed of.
- If the adjudicating officer is satisfied that the person concerned has failed to comply with the provisions of section 3 or section 4 or section 6 or section 7 of the Act, he shall impose a penalty as deemed fit in accordance with the provisions of section 55 of the Act.
- The Adjudicating Officer shall not pass an order for penalty if the Tribunal or Court has already passed an order to that effect in a proceedings referred to in under sub-rule (16).
- **Any person or a benefit claimer who intends to make a complaint** before any court about any offence under this Act-

- shall give a notice of not less than **30 days** about his intention to make a complaint to the Central Government or authority or officer authorised in that behalf, under section 61 of the Act, through online or registered post with acknowledgement due or speed post.

Relevant Form: Form 16

Official Fee: Nil

- Upon expiry of a period of **30 days** from the recipient of notice and not being satisfied with the action taken by authority or Central Government, such person or the benefit claimer may file a written complaint before a court having jurisdiction to take cognizance of the offence under the Act.
 - Provided that the Central Government or any authority or officer authorised by that Government may under clause (a) of section 61 of the Act make a written complaint to court for taking cognizance of any offence under the Act.

Rule 24: Appeals from Order of Adjudicating Officer

- Any person aggrieved by the order of the Adjudicating Officer may prefer an **appeal to the National Green Tribunal** established under section 3 of the National Green Tribunal Act, 2010 (19 of 2010), under section 52A of the Act.

Rules 3 to 12 provide for administrative provisions under the Act, including term of office, pay allowance, meetings of authority, general functions of the authority etc., Further, Rules 21 to 22 provide for management and utilisation of National Biodiversity Fund, settlement of disputes. Rule 26 states that all amounts of penalties shall be deposited in the National Biodiversity Fund and all amounts of penalties relating to offences under Section 7 of the Act shall be deposited in the Biodiversity Fund of the State Biodiversity Board or the Union territory Biodiversity Council concerned, as the case may be.
