

A Quick Guide to the Biological Diversity Rules, 2024, notified through Gazette notification dated October 25, 2024

The Ministry of Environment, Forest and Climate Change, Government of India, has notified the Biological Diversity Rules, 2024 (Rules), defining the procedures to be followed while seeking approval or registering before the National Biodiversity Authority (NBA). The Rules will come into force effective from December 25, 2024 (from the expiry of 60 days from the date of notification in the Official Gazette).

The Rules provide for new forms and fees required to be complied with by the applicants, and introduce a few additional aspects that are essential to be kept in mind, such as:

- Provision carved out for regularizing past violations/non-compliances in view of possession of Indian biological resource prior to April 1, 2024;
- Additional obligations on foreign entities for accessing research results based on Indian biological resource;
- Inclusion of digital sequence information (DSI) of a biological resource within the purview of this Act when employed in an invention for obtaining intellectual property rights (IPR);
- Obligations on an entity for using foreign biological resources within the territory of India;
- Obligations on use of Indian biological resource for non-commercial research outside India; and
- Clarity on adjudication of penalties in case of non-compliance/contravention of provisions of the Act.

These Rules are issued in furtherance to the amendments made in August 2023 to the original Biological Diversity Act, 2002 (Act), namely, the Biological Diversity (Amendment) Act, 2023, which came into force from April 1, 2024.

Key Rules that impact Indian and foreign applicants for seeking approval or registering before the NBA are summarized below:

Relevant Rules	Relevant Entity Type	Purpose of the Rule	Gist of the Primary Rule	Brief Comments
Rule 13(1)	Foreign entity ¹	Prior approval for accessing an Indian biological resource and knowledge associated thereto for any purpose.	For seeking prior approval for accessing an Indian biological resource and knowledge associated thereto, a foreign entity will have to file the following forms with the NBA: <ul style="list-style-type: none"> • Form 1: for research or for bio-survey and bio-utilization • Form 2: for commercial utilization 	Separate forms must be filed by the foreign entity for research and commercial utilization, respectively.
Rule 13(2)	Foreign Entity	Possession of an Indian biological resource prior to April 2024, for the purpose of research, commercial utilization, bio-survey, and/or bio-utilization.	A foreign entity who was/has been in possession of an Indian biological resource before coming into effect of the Biological Diversity (Amendment) Act, 2023, can now seek approval of the NBA for research, commercial	This allows foreign entities, including Indian entities who were considered foreign prior to effect of the Biological Diversity (Amendment) Act, 2023 i.e., April 1, 2024 to file for

¹ As defined by section 3(2) of the Act

			<p>utilization, bio-survey and bio-utilization.</p> <p><u>Additional Aspects under Rule 13:</u></p> <ul style="list-style-type: none"> • Application to be processed by the NBA within 90 days; • Any information requested by the NBA – needs to be made available within 30 days of NBA’s request – otherwise application will be closed by the NBA; • Approval will be in the form of an agreement which needs to be executed within 60 days from receipt of the draft agreement from the NBA – otherwise file will be closed by the NBA; • Revival of the application will be possible with 50% additional fees – within 90 days of closure by the NBA; • Application not to be rejected by the NBA unless the applicant has been given a reasonable opportunity of being heard; and, • Expedious processing of applications possible in present or imminent emergency situations 	<p>retrospective approval for accessing Indian biological resources, to remedy any violations prior to April 2024.</p>
Rule 14	All Entities	Restricting access to certain biological resources and knowledge associated with such biological resources.	<p>The NBA may restrict or prohibit access to Indian biological resources where the request for access:</p> <ul style="list-style-type: none"> • Is of threatened and/ or endemic species; • May result in an adverse impact on the livelihood and/ or socio-cultural aspects of the local communities; • May result in adverse environmental impact(s) which may be difficult to control and mitigate; 	<p>The NBA could be restrictive in giving approval for certain categories of biological resources.</p>

			<ul style="list-style-type: none"> • May cause genetic erosion or affect the ecosystem functions; • Is for use of resources for purposes contrary to national interest and other related international agreements entered into by India; and/or, • Is for any other reasons recorded in writing. 	
Rule 15(1)	All Entities	Sharing or transferring results of research to a foreign entity.	<p>For sharing or transferring research results relating to an Indian biological resource or traditional knowledge associated thereto, to a foreign entity, following forms will need to be filed with the NBA:</p> <ul style="list-style-type: none"> • Form 3: for seeking prior approval for sharing or transferring results of research to a foreign entity; • Form 4: for registration by the transferee [foreign entity] to use the results of research for further research; • Form 5: for seeking prior approval by the transferee to use the results of research for commercial utilization; and/or, • Form 6: for seeking prior approval by the transferee to use the results of research for obtaining IPR. <p><u>Additional Aspects under Rule 15:</u></p> <ul style="list-style-type: none"> • Application to be processed by the NBA within 90 days; • Any information requested by the NBA – needs to be made available within 30 days of NBA’s request – otherwise application will be closed by the NBA; • Approval will be in the form of an agreement which needs to be executed within 60 days 	Independent forms are made applicable to the transferee (foreign entity) for seeking prior approval/registration for using results of research for the purpose of further research, commercial utilization or obtaining IPR.

			<p>from receipt of the draft agreement from the NBA – otherwise file will be closed by the NBA;</p> <ul style="list-style-type: none"> • Revival of the application will be possible with 50% additional fees – within 90 days of closure by the NBA; • Application not to be rejected by the NBA unless the applicant has been given a reasonable opportunity of being heard; and, 	
Rule 16(1)(a)	Foreign Entity	Prior approval for use of an Indian biological resource and knowledge associated thereto, before grant of IPR,	<p>A foreign entity will need to seek prior approval of the NBA under Form 7 before grant of IPR in or outside India. based on research or information including DSI on an Indian biological resource, including those deposited in repositories outside India.</p> <p><u>Additional Aspects under Rule 16(1):</u></p> <ul style="list-style-type: none"> • Decision on approvals by the NBA within 180 days; • Any information requested by the NBA – needs to be made available within 90 days of NBA’s request – otherwise application will be closed by the NBA; • Approval will be in the form of an agreement which needs to be executed within 90 days from receipt of the draft agreement from the NBA – otherwise file will be closed by the NBA; • Revival of the application will be possible with 50% additional fees – within 90 days of closure by the NBA; and, • Application not to be rejected by the NBA unless the applicant has been given 	The Rules now consider DSI of a biological resource within the purview of this Act when employed in an invention for obtaining IPR. Thus, if a foreign entity applies for a patent covering an invention using DSI of any Indian biological resource, it must seek prior approval of the NBA before grant of patent in or outside India.

			a reasonable opportunity of being heard.	
Rule 16 (1)(e)		Need for intimating the NBA post grant of a patent application.	<ul style="list-style-type: none"> A foreign entity will need to intimate the NBA about the grant of the patent application using an India biological resource, including DSI on the biological resource, within 45 days of the grant of said patent application. 	A requirement is imposed to intimate the NBA about grant of the patent application using biological resource from India including DSI of the biological resource.
Rule 16 (2)(a)	Indian Entity	Registration for use of an Indian biological resource and knowledge associated thereto, before grant of IPR.	An Indian entity will need to register with the NBA under Form 8 before grant of IPR in or outside India based on research or information including DSI on an Indian biological resource, including those deposited in repositories outside India.	The Rules now consider DSI of a biological resource within the purview of this Act when employed in an invention for obtaining IPR. Thus, if an Indian entity applies for a patent covering an invention using DSI of any Indian biological resource, it must register with the NBA before grant of patent in or outside India.
Rule 16 (2)(d)		Need for intimating the NBA post grant of a patent application.	An Indian entity will need to intimate the NBA about the grant of the patent application using an Indian biological resource, including DSI of the biological resource, within 45 days of the grant of said patent application.	A requirement is imposed to intimate NBA about grant of the patent application using biological resource from India including DSI of the biological resource.
Rule 16 (3)(a)		Prior approval for use of an Indian biological resource and knowledge associated thereto, upon commercialization of IPR.	<p>An Indian entity will need to obtain prior approval of the NBA under Form 9 for commercialization of an invention covered in a patent application using an Indian biological resource including DSI on the biological resource.</p> <p><u>Additional Aspects under Rule 16(3):</u></p> <ul style="list-style-type: none"> Decision on approvals by the NBA within 180 days; Any information requested by the NBA – needs to be made available within 90 days of NBA’s request – 	Procedure is outlined for seeking prior approval from the NBA by an Indian entity for commercializing an invention covered in a patent application/granted patent.

			<p>otherwise application will be closed by the NBA;</p> <ul style="list-style-type: none"> Approval will be in the form of an agreement which needs to be executed within 90 days from receipt of the draft agreement from the NBA – otherwise file will be closed by the NBA; and, Revival of the application will be possible with 50% additional fees – within 90 days of closure by the NBA. 	
Rule 17	All Entities	Revocation of access or approval provided by the NBA.	<p>The NBA may withdraw approvals granted under Rules 13, 15, 16, and 20 – on the basis of complaint or <i>suo moto</i> under the following conditions:</p> <ul style="list-style-type: none"> Declaration of false or misleading information or violation of any of the provisions of the Act or the conditions on which the approval was granted; Failure to comply with any of the terms and conditions of the agreement; Larger public interest or for the protection of environment and conservation of biological diversity; and/or On the basis of new facts or information brought to the notice of the NBA. 	The onus is on the applicants to continue abiding by the terms and conditions of the agreement with the NBA, to ensure that approvals once granted are not revoked by the NBA.
Rule 18(1)	All Entities	Monitoring and regulating the use in India, of a biological resource or associated traditional knowledge obtained from any foreign country.	Any person who intends to use, in India, a biological resource or traditional knowledge associated thereto, obtained from foreign country, for research or for commercial purpose or for obtaining IPR, will need to submit a declaration in Form 10 with the NBA.	When a biological resource obtained from a foreign country is used in India by an Indian/Foreign entity, a declaration in Form 10 must be filed by such an entity. This is considered to meet the international obligations under Convention on Biological Diversity (to which India is a signatory).
Rule 18(2)			<ul style="list-style-type: none"> Upon receiving the declaration in Form 10 from any person referred to in Rule 18(1) above, the NBA 	

			<p>shall notify the same on the Access and Benefit-Sharing Clearing-House of the Convention on Biological Diversity.</p> <ul style="list-style-type: none"> Based on the request of the provider country (foreign country from which the biological resource is obtained), the NBA shall take appropriate measures as per section 36(A) of the Act. 	
Rule 18(3)			Based on the request of the provider country (foreign country from which the biological resource is obtained), the NBA shall take appropriate measures as per section 36(A) of the Act.	
Rule 19(1)	Indian Entity	Obtaining a certificate of origin for cultivated medicinal plants, for seeking exemption under section 7.	An Indian entity who intends to claim an exemption for accessing cultivated medicinal plants under section 7(2) of the Act will need to submit self-declaration under Form 11 to obtain a certificate of origin from respective Biodiversity Management Committee (BMC).	Procedure is outlined for seeking exemption for using cultivated medical plants by an Indian entity. However, onus of providing proof of source of origin of the cultivated medical plant is levied on the end-user of the cultivated medicinal plant.
Rule 19(5)			For claiming exemption under section 7(2) of the Act, the onus of proof of source of origin of the medicinal plants will lie on the end user (Indian entity claiming the exemption).	
Rule 20(1)	Indian Entity/ Foreign Institution	Prior approval for use of an Indian biological resource for non-commercial research or research for emergency purposes outside India by Indian researcher or institution.	An Indian researcher or institution who intends to carry or send an Indian biological resource outside India to undertake non-commercial research including carrying out urgent studies to address any emergencies, will need to apply to the NBA under Form 13. In case the traditional knowledge associated thereto is also transferred or carried along with the biological resource, approval of the NBA must be sought by the foreign institution under Rule 13.	<ul style="list-style-type: none"> Carrying or transferring of Indian biological resource by an Indian researcher/institution to foreign country for non-commercial research requires prior approval of the NBA, and; If traditional knowledge along with the biological resource is transferred or carried to a foreign institution, the foreign institution must seek

				approval of the NBA for carrying out research or commercial utilization using said traditional knowledge.
Rule 20(4)			On receipt of NBA's approval, the applicant will need to deposit voucher specimens in the designated national repositories, wherever required, before carrying or sending the said biological resource outside India and a copy of proof of such deposits will need to be endorsed to the NBA.	
Rule 23	All Entities	Process for enquiry and imposition of penalty by an adjudicating officer for non-compliance, contravention or violation of provisions of the Act.	<ul style="list-style-type: none"> • Adjudicating Officer shall inquire into a complaint of non-compliance or contravention of the provisions of the Act based on the complaint filed by or on behalf of an authorised officer of the NBA; • Based on all relevant facts and circumstances, the adjudicating officer within 30 days of receipt of the complaint will issue a 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 is alleged, and; • Thereafter, based on the enquiry and findings, the adjudicating officer will issue a speaking order to either dismiss the matter or impose an appropriate penalty. 	Detailed procedure is outlined for the adjudicating officer to enquire and levy penalty for non-compliance or contravention of section 3, section 4, section 6 or section 7 of the Act.

In addition to the above, the Rules provide detailing on administrative aspects under the Act, including the Chairperson and Members of the NBA, their general functions, powers and duties; and management and utilization of the National Biodiversity Fund. The Rules also prescribe fees for filing each prescribed form for all activities listed above.

insights@knspartners.com | www.kandspartners.com

Bangalore | Chennai | Gurgaon | Hyderabad | Mumbai | New Delhi | Pune

