

### HIGHLIGHTS OF THE INDIAN BIOLOGICAL DIVERSITY REGULATIONS, 2025

The National Biodiversity Authority (NBA) on 29th April 2025, issued the Biological Diversity Regulations, 2025 known as the “Access to Biological Resources and Knowledge Associated thereto and Fair and Equitable Sharing of Benefits” (“Regulations”), to implement the revised Biological Diversity (BD) Act (2023) and Rules (2024). The Regulations outline the

mechanisms for benefit sharing under the BD Act and Rules by foreign and Indian entities for accessing Indian biological resources for research, commercialization with or without claiming intellectual property rights (IPR) and transfer of research results. These Regulations replace the 2014 Access and Benefit Sharing Guidelines.

#### A. For Foreign Entity/Applicant covered under Section 3 of the BD Act:

##### A QUICK SNAPSHOT

Regulation	Relating to	Type of Biological Resource	Mode of Benefit Sharing	Comments
Regulation 3	Prior approval of NBA for research, bio-survey and bio-utilization	Conservation value, high economic value, threatened species, DSI	Upfront payment	No benefit sharing obligation for academic research, NBA to decide on case-to-case basis
Regulation 4	Commercialization without IPR	Biological resource including DSI	Based on annual gross ex-factory sale price of the product	No benefit sharing obligation if the annual turnover is less than INR 5 crores (INR 1 Cr = Approx. US 12,000)
Regulation 7(2)	Use of research results for commercial utilization	Biological resource	Based on annual gross ex-factory sale price of the product	No benefit sharing obligation if the annual turnover is less than INR 5 crores (INR 1 Cr = Approx. US 12,000)
Regulation 7(3)	Use of research results for obtaining IPR	Biological resource	Up to 1% based on annual gross ex-factory sale price of the product if commercialized by applicant; up to 5% each of license and royalty fees if licensed/assigned	Sectoral and case to case based approach to be taken by NBA on deciding the %

## DETAILS OF THE KEY REGULATIONS

**Regulation:** Regulation 3

**Relating to:** Prior approval of the NBA for research, bio-survey and bio-utilization.

**Type of biological resource:**

- Having conservation value<sup>1</sup>, high economic value, such as red sanders, sandalwood, agarwood or threatened species as notified under Section 38 of the BD Act; and
- Certain biological resource<sup>2</sup>, including DSI or knowledge associated thereto.

**Mode of Benefit Sharing:** Upfront payment

**Comment:**

- No benefit sharing required for accessing biological resource, including digital sequence or knowledge associated thereto, for conducting academic research;
- NBA to make assessment of waiver on case-to-case basis.

**Regulation:** Regulation 4

**Relating to:** Access to biological resource or associated knowledge for commercialisation (without IPR)

**Mode of Benefit Sharing:**

- Based on the annual gross ex-factory sale price of the product, excluding Government taxes:

Annual Turnover (INR)	Benefit Sharing
Up to 5 crores* (*1cr = Approx. USD 120,000)	Nil
Above 5 crores to 50 crores	0.2%
Above 50 crores to 250 crores	0.4%
Above 250 crores	0.6%

- For biological resources with conservation value, high economic value, such as red sanders, sandalwood, agarwood or threatened species as notified under Section 38 of the BD Act,
  - upfront payment of not less than 5% of the auction, sale amount or the purchase price; and
  - Additional benefit sharing amount of 20% to be levied in case the biological resource is of conservation value, high economic value or threatened species and includes DSI or knowledge associated thereto.
- Person/entity having annual turnover more than INR 1 crore must submit an annual statement in Form A containing information regarding the biological resource consumed in the financial year within 3 months of the finalization of annual income tax or corporate tax return for that financial year.

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<sup>1</sup> not particularly indicated/defined in the Regulations

<sup>2</sup> not particularly indicated/defined in the Regulations

**Regulation:** Regulation 7(2)

**Relating to:** Use of research results of biological resource received by an entity covered under Section 3 of the BD Act for commercial utilization.

**Mode of benefit Sharing:** Based on the annual gross ex-factory sale price of the product, excluding Government taxes:

Annual Turnover (INR)	Benefit Sharing
Up to 5 crores (*1cr = Approx. USD 120,000)	Nil
Above 5 crores to 50 crores	0.2%
Above 50 crores to 250 crores	0.4%
Above 250 crores	0.6%

**Regulation:** Regulation 7(3)

**Relating to:** Use of results of research of biological resource received to obtain IPR

**Mode of benefit sharing:**

- When an applicant commercializes the IPR, up to 1% based on annual gross ex-factory sale price of the product; and
- When the applicant licenses/assigns the IPR -
  - up to 5% of the license or assignee fee; and
  - up to 5% of the royalty fees received.

**Regulation:** Regulation 8

**Relating to:** Commercialization of the IPR

**Mode of benefit sharing:** Monetary benefit sharing or non-monetary benefit sharing.

- When an applicant commercializes the IPR, up to 1% based on annual gross ex-factory sale price of the product;
- When the IPR involves traditional knowledge, an additional 25% to be paid
- When the Applicant licenses/assigns the IPR-
  - up to 5% of the license or assignment fee; and
  - up to 5% of the royalty fees received.

**Comments:**

- In case of commercializing an active IPR, benefit sharing rules to be as per Regulation 8;
- Upon cessation/revocation of the patent, the mode of benefit sharing to be considered as 'commercialization without IPR' as per Regulation 4; and
- Any person accessing a biological resource for IPR commercialization to apply for approval separately as per Section 3 of the BD Act.

**B. For Indian Entity/Applicant covered under Section 7 of the BD Act:**

- No benefit sharing obligation for accessing biological resource for research;

- Benefit sharing applicable only for commercialization with or without IPR.

### A QUICK SNAPSHOT

Regulation	Relating to	Type of Biological Resource	Mode of Benefit Sharing	Comments
Regulation 5	Prior intimation to SBB or Council for commercialization without IPR	Biological resource including DSI	Based on annual gross ex-factory sale price of the product	Intimation under Form-B; Fees: INR 2,000 for individual / INR 5,000 for entity
Regulation 7(1)	Sharing or transfer of research results	Biological resource	Monetary or non-monetary benefit sharing	Up to 5% of monetary consideration
Regulation 9	Commercialization of IPR	Biological resource	Monetary or non-monetary benefit sharing Up to 1% annual gross ex-factory sale price of the product if commercialized by applicant; up to 5% each of license and royalty fees, if licensed/assigned	Sectoral and case to case based approach to be taken by NBA on deciding the %  Additional 25% if IPR involves traditional knowledge
Regulation 10	Deposition of novel microbial strain outside India	Microbial strain	NA	Prior intimation to NBA under Form-E. Exemption in case of reference for taxonomic identification

### DETAILS OF THE KEY REGULATIONS

**Regulation:** Regulation 5

**Relating to:** Prior intimation to State Biodiversity Board (SBB) or Council (Union territory Biodiversity Council) for commercialization without IPR

**Mode of benefit sharing:**

- Pertaining to biological resource including DSI - based on the annual gross ex-factory sale price of the product, excluding Government taxes:

Annual Turnover (INR)	Benefit Sharing
Upto 5 crores (*1cr = Approx. USD 120,000)	Nil
Above 5 crores to 50 crores	0.2%
Above 50 crores to 250 crores	0.4%
Above 250 crores	0.6%

- Biological resources having conservation value, high economic value, such as red sanders, sandalwood, agarwood or threatened species as notified under Section 38 of the BD Act:
  - Upfront payment, not less than 5% of the auction, sale amount or the purchase price.

- Additional benefit sharing amount of 20% to be levied in case the biological resource is of conservation value, high economic value or threatened species and includes DSI or knowledge associated thereto.

**Comments:**

- Prior intimation must be applied under Form B with requisite fees;
- The SBB or the Council to dispose of the matter within 15 days under Form C (approval, with or without modification of mutually agreed terms) or under Form-D (rejection). No rejection to be made without giving an opportunity of a hearing to the applicant;
- In case of lack of response from the SBB or the Council within 15 days towards the filed prior intimation Form B, the approval is deemed provided for a period of one year;
- Applicant to sign the modified agreement within 15 days of notice, otherwise the application will be considered closed;
- Revival of the closed application may be possible within 90 days upon receipt of half of the prescribed fees;
- Person/entity having annual turnover of more than INR 1 crore to submit annual statement in Form A containing information regarding the biological resource consumed in the financial year within 3 months of finalization of annual income tax or corporate tax return for that financial year; and
- No benefit sharing obligation for manufacturing products containing both cultivated and non-cultivated medicinal plants, notified by the Ministry of Environment, Forest and Climate Change, in consultation with the NBA and the Ministry of Ayush.

**Regulation:** Regulation 7(1)

**Relating to:** Sharing or transfer of results of research under Rule 15 of the Biological Diversity Rules.

**Mode of Benefit Sharing:** Monetary benefit sharing or non-monetary benefit sharing.

- In case of monetary benefit received by the applicant - up to 5% of the monetary consideration.

**Comment:**

- For sponsored projects allowed before April 29, 2025 (date of commencement of the Regulations) where no budget was earmarked for benefit sharing, sponsoring organization to give an undertaking that in case the results of research are used for commercialization later, the benefit shall be shared with the NBA. An Indian person availing sponsorship to inform the sponsoring organization of this requirement.

**Regulation:** Regulation 9

**Relating to:** Commercialization of IPR

**Mode of Benefit Sharing:** Monetary benefit sharing or non-monetary benefit sharing.

- When the applicant commercializes the IPR - up to 1% based on the annual gross ex-factory sale price of the product, excluding Government taxes;
- When the IPR involves traditional knowledge- additional 25% over the benefit sharing that is due; and

- When the applicant licenses/assigns the IPR-
  - up to 5% of the license or assignee fee; and
  - up to 5% of the royalty fees received.

**Comments:**

- Applicant accessing biological resource for the purpose of commercialization of active IPR- mode of benefit sharing is as per Regulation 9; and
- Upon cessation/revocation of the patent, the mode of benefit sharing to be considered as 'commercialization without IPR', as per Regulation 5.

**Regulation:** Regulation 10

**Relating to:** Deposition of novel microbial strain in the repositories outside India for publication

**Comments:**

- Applicant intending to deposit the novel microbial strain in the repositories outside India must apply to the NBA under Form E;
- Applicant must deposit one voucher specimen in the designated repository according to Section 39(3) of the BD Act;
- Prior approval of the NBA is necessary for accessing the strains for research or bio-survey and bio-utilization or commercial utilization as per Section 3 of the BD Act;
- Designated repositories in India and outside India shall inform the user about the requirement for prior approval as per Section 3 of the BD Act;
- No prior approval is required if the researcher refers to the voucher specimen for taxonomical identification purposes; and
- The applicant must submit a copy of the acknowledgement of the receipt of voucher specimen issued by the designated repository to the NBA.

**Regulation:** Regulation 11

**Relating to:** Criteria for determination of benefit sharing

**Comments:**

- The amount of benefit sharing will remain the same whether the product contains one or more biological resources;
- Monetary benefits and non-monetary benefits are as provided in Form-F of the Regulations;
- Special consideration (lower percentage of benefit sharing) to be given for cases where the access of the biological resource, including DSI, is for technologies or innovations or products that are developed leading to IPR for controlling epidemics, mitigating environmental pollution affecting human, animal or plant health or for food securing or conservation of biodiversity; and
- NBA to specify the formula for determining percentage of benefit sharing component, including upfront payment to be levied.