

## IN BRIEF

### IMPLICATIONS OF BIOLOGICAL DIVERSITY LAWS ON NON-INDIAN ENTITIES OBTAINING BIOLOGICAL RESOURCES FOR COMMERCIAL UTILIZATION



#### Introduction

The United Nations Convention on Biological Diversity was signed at Rio on June 5, 1992 (CBD), which was subsequently ratified by India as well. In pursuance of the CBD, India enacted the Biological Diversity Act, 2002 (BD Act 2002) to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. The BD Act 2002 was amended by the Biological Diversity (Amendment) Act, 2023. The BD Act 2002 and the Biological Diversity (Amendment) Act, 2023 are collectively referred to as the ‘BD Act’).

India also notified the Biological Diversity Rules, 2004 (BD Rules 2004) for carrying out the purposes of the BD Act 2002. The BD Rules 2004 have been replaced by the Biological Diversity Rules, 2024 (BD Rules 2024) to carry out the purposes of the BD Act.

The Nagoya Protocol was signed at Nagoya on November 5, 2011, and it deals with Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol), which was also subsequently ratified by India. In pursuance of the BD Act 2002 and Nagoya Protocol, India issued the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 (ABS Guidelines). The BD Act, the BD Rules 2024 and the ABS Guidelines are collectively referred to as the ‘Biological Diversity Laws’.

This article gives a brief overview of the Biological Diversity Laws to the extent applicable to a non-Indian entity (covered under Section 3(2) of the BD Act) that obtains any biological resource occurring in India for commercial utilization.

#### Biological Resources Obtained from India

A body corporate incorporated or registered in India under any law for the time being in force, which is controlled by a foreigner within the meaning of Clause (27) of Section 2 of the Companies Act, 2013<sup>1</sup> and that obtains biological resources<sup>2</sup> occurring in India and uses the same for commercial utilization<sup>3</sup>, is required to obtain the prior approval of the National Biodiversity Authority (NBA) under Section 3 of the BD Act.

The user of the biological resource is required to obtain the prior approval of the NBA, which approval is to be applied for in Form I and Form A. The approval process requires the NBA to enter into a negotiation with the applicant, upon the finalization of which an agreement for payment of access and benefit sharing is executed.

Any entity covered under Section 3(2) of the BD Act, which was in possession of a biological resource prior to April 1, 2024, is required to take approval of the NBA for the purpose of commercial utilization.

<sup>1</sup> “Control” means the right to appoint majority of the directors or to control the management or policy decisions exercisable by a person or persons acting individually or in concert, directly or indirectly, including by virtue of their shareholding or management rights or shareholders agreements or voting agreements or in any other manner. (Section 2 (27) of the Companies Act, 2013)

<sup>2</sup> “Biological resources” means plants, animals and micro-organisms or parts of their genetic material and derivatives (excluding value added products), with actual or potential use or value for humanity, but does not include human genetic material. (Section 2 (c) of the BD Act).

<sup>3</sup> Commercial utilization’ means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavors, fragrance, cosmetics, emulsifiers, oleoresins, colors, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping. (Section 2 (f) of the BD Act).

**Biological Resources Obtained from a Foreign Country**

The biological resources obtained from a foreign country by any entity covered under Section 3(2) of the BD Act for processing in India and that are neither of Indian origin nor mixed in India with biological resources of Indian origin are outside the purview of the Biological Diversity Laws.

In case the abovementioned entity, while processing biological resources that are obtained from a foreign country and not of Indian origin, also includes biological resources of Indian origin in such processing, then the mixed end product for commercial utilization (containing biological resources both of Indian origin and not of Indian origin) would fall under the purview of the Biological Diversity Laws.

Further, if the aforesaid entity intends to use in India the biological resource obtained from a foreign country for commercial purpose, it is required to submit a declaration in Form 10 to the NBA.

**Penalties**

If any entity covered under Section 3(2) of the BD Act contravenes or attempts to contravene or abets the contravention of the provisions of Section 3, such entity is liable to pay a penalty which would not be less than INR 1 lakh, but which may extend to INR 50 lakhs, but where the damage caused exceeds the amount of the penalty, such penalty would be commensurate with the damage caused, and in case, the failure or contravention continues, an additional penalty may be imposed, which would not exceed INR 1 crore and such penalty shall be decided by the adjudicating officer appointed under Section 55A of the BD Act.

**Determination of Benefit Sharing**

If any entity covered under Section 3(2) of the BD Act falls under the purview of the Biological Diversity Laws, the benefit sharing can be determined based on either the purchase price of biological resources or the ex-factory sale price of the product:

- Benefit sharing obligations calculated on the purchase price of the biological resource accessed for commercial utilization:
  - (1) where the applicant/trader/manufacturer has not entered into any prior benefit sharing negotiation with the Joint Forest Management Committee/Forest dweller/ Tribal cultivator/Gram Sabha, and purchases any biological resources directly from these persons, the benefit sharing obligation:
    - on the trader is in the range of 1% to 3% of the purchase price of the biological resources; and
    - on the manufacturer is in the range of 3% to 5% of the purchase price of the biological resources.

Provided that where the trader sells biological resource purchased by him to:

- another trader, the benefit sharing obligation on the buyer, if he is a

trader, is in the range between 1% to 3% of the purchase price; and

- a manufacturer, the benefit sharing obligation on the buyer, if he is a manufacturer, is in the range between 3% to 5% of the purchase price.

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

- (2) Where the applicant/trader/manufacturer has entered into any prior benefit sharing negotiation with the Joint Forest Management Committee/Forest dweller/ Tribal cultivator/ Gram Sabha, and purchases any biological resources directly from these persons, the benefit sharing obligation on the applicant:
  - is not less than 3% of the purchase price of the biological resources in case the buyer is a trader; and
  - is not less than 5% of the purchase price of the biological resources in case the buyer is a manufacturer.

- Option of benefit sharing on sale price of the biological resources accessed for commercial utilization:

When the biological resources are accessed for commercial utilization, the applicant has the option to pay the benefit sharing ranging from 0.1% to 0.5% at the following graded percentages of the annual gross ex-factory sale of the product minus government taxes:

Annual gross ex-factory sale of product	Benefit sharing component
Up to INR 10,000,000	0.1%
INR 10,000,001 up to 30,000,000	0.2%
Above INR 30,000,000	0.5%

Further, the benefit sharing may be done in monetary and/or non-monetary mode, as agreed upon by the applicant and the NBA in consultation with the Biodiversity Management Committee/benefit claimers etc. The monetary and non-monetary benefit sharing options may take the following forms:

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

- Non-Monetary Benefits Options:

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

## Conclusion

Any non-Indian entity that falls under the purview of the Biological Diversity Laws has benefit sharing obligations. It is, however, important to note that there is significant dissonance in the approaches adopted by industry and the NBA. While key stakeholders in the private sector advocate for the calculation of benefit sharing on the purchase price of biological resources, the NBA prefers to utilize the annual gross ex-factory sale of the product minus government taxes as the base for these calculations.

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