

Legislative Brief

The Biological Diversity (Amendment) Bill, 2021

The Biological Diversity (Amendment) Bill, 2021 was introduced in Lok Sabha on December 16, 2021. The Bill was referred to a Joint Parliamentary Committee on December 20, 2021.

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Highlights of the Bill

- ◆ The Bill amends the Biological Diversity Act, 2002 to simplify compliance requirements for domestic companies.
- ◆ Users of codified traditional knowledge and AYUSH practitioners will be exempted from sharing benefits with local communities.
- ◆ The Bill removes research and bio-survey activities from the purview of benefit sharing requirements.
- ◆ Benefit sharing will be based on terms agreed between the user and the local management committee represented by the National Authority.
- ◆ The Bill decriminalises all offences under the Act.

Key Issues and Analysis

- ◆ The term codified traditional knowledge has not been defined. A broad interpretation might exempt all local traditional knowledge from benefit sharing requirements.
- ◆ The Bill removes the direct role of local communities in determining benefit sharing provisions.
- ◆ The Bill decriminalises offences under the Act and instead provides for a wide range of penalties. Further, the Bill empowers government officials to hold inquiries and determine penalties. It may be questioned whether it is appropriate to confer such discretion to government officials.

PART A: HIGHLIGHTS OF THE BILL

Context

Biodiversity refers to the variety of life forms that exist on the planet.¹ Human activities on the planet have created challenges for biodiversity such as loss of habitat, deterioration of ecological systems, and extinction or threat of extinction for species.² There have also been concerns around bio-piracy which involves unauthorised appropriation of biological resources and related knowledge belonging to indigenous communities.³ A key multilateral treaty to address these concerns is the United Nations Convention on Biological Diversity (CBD) from the year 1992.⁴ It recognises sovereign rights over biological resources and permits countries to regulate access to these resources as per their national legislation.⁴ It recognises contributions of local and indigenous communities to conservation and sustainable use through traditional knowledge, practices, and innovations.¹ It provides for equitable sharing of benefits arising from the utilisation of these resources with such people.¹ India became a signatory to CBD in 1994.⁵ Under CBD, two protocols have been adopted: (i) Cartagena Protocol on biosafety (2003), and (ii) Nagoya Protocol on access and benefit sharing (2014).⁶ India ratified the Cartagena Protocol in 2003 and the Nagoya Protocol in 2014.⁵

In light of India's commitments under CBD, the Biological Diversity Act, 2002 was passed by Parliament. The Act regulates access to biological resources and associated traditional knowledge. It specifies distinct frameworks for regulating access by foreign and domestic entities. It sets up a three-tier structure for regulation: (i) National Biodiversity Authority at the national level, (ii) State Biodiversity Boards at the state level, and (iii) Biodiversity Management Committees at the local body level. The Act provides for sharing of benefits with conservers of biodiversity and holders and creators of associated knowledge. Benefits may be shared in various forms such as: (i) monetary compensation, (ii) sharing of intellectual property rights, or (iii) technology transfer.

In December 2021, the Biological Diversity (Amendment) Bill, 2021 was introduced in Lok Sabha, and was subsequently referred to a Joint Parliamentary Committee.⁷ The Bill seeks to amend the Biological Diversity Act, 2002 to: (i) encourage the Indian system of medicine and cultivation of wild medicinal plants, (ii) facilitate fast-tracking of processes for research, patent application, and transfer of research results, (iii) decriminalise offences, and (iv) encourage foreign investment in the sector. The Bill also amends the Act to include references to the Nagoya Protocol.

Key Features

- **Access to biological resources and associated knowledge:** The Act requires prior approval or intimation to the regulatory authority based on the origin of the entity for obtaining biological resources occurring in India or associated knowledge. The regulatory authorities under the Act for these purposes are National Biodiversity Authority (NBA) and State Biodiversity Boards (SBB). The Bill amends the classification of entities, list of activities requiring intimation, and adds exemptions as listed in Table 1.

Table 1: Approval/Intimation requirement for accessing biological resources or associated knowledge

The Biological Diversity Act, 2002	Changes made by the Bill
<ul style="list-style-type: none"> ▪ Approval required from NBA (for certain foreign entities) <ul style="list-style-type: none"> • Entities: (i) foreign individuals, (ii) non-resident Indians, (iii) companies not registered in India, and (iv) companies registered in India and having non-Indian participation in share capital or management • Activities: obtaining biological resources occurring in India or associated knowledge for: (i) research, (ii) commercial utilisation, or (iii) bio-survey and bio-utilisation ▪ Prior intimation required to SBB (for certain domestic entities) <ul style="list-style-type: none"> • Entities: (i) Indian citizens, and (ii) companies registered in India except those which require NBA approval • Activities: obtaining biological resources occurring in India for commercial utilisation • Exemptions: use by local people and communities including growers and cultivators of biodiversity, and v aids and hakims practising indigenous medicine 	<ul style="list-style-type: none"> ▪ Approval from NBA <ul style="list-style-type: none"> • Entities: changes the last category to companies registered in India which are “foreign-controlled” companies as under the Companies Act, 2013 ▪ Prior intimation to SBB <ul style="list-style-type: none"> • Activities: access to associated knowledge for commercial utilisation will also require prior intimation • Exemptions: adds exemptions for: (i) codified traditional knowledge, (ii) cultivated medicinal plants and their products, (iii) AYUSH practitioners; limits the exception to v aids and hakims, and AYUSH practitioners to use for sustenance and livelihood

Sources: The Biological Diversity Act, 2002; The Biological Diversity (Amendment) Bill, 2021; PRS.

- **Approval for Intellectual Property Rights (IPR):** The Act specifies that approval of NBA is required before: (i) applying for IPR involving biological resources obtained from India, or (ii) sealing of patent. The Bill provides that approval will be required before the grant of IPR instead of before the application itself. The Bill specifies distinct approval processes based on the origin of the entity. Foreign entities as specified above will require approval from NBA whereas domestic entities will be required to register with NBA. However, domestic entities will need approval from NBA at the time of commercialisation of IPR. The Bill also extends the approval requirement to IPR on associated knowledge.
- **Benefit sharing:** Under the Act, NBA is required to determine terms of benefit sharing while granting approvals for various activities. Benefit sharing refers to requiring applicants to share monetary and non-monetary benefits with benefit claimers and local people. Benefit claimers are conservers of biodiversity, or creators or holders of associated traditional knowledge. The Act makes benefit sharing provisions applicable to research, commercial utilisation, as well as bio-survey and bio-utilisation for certain entities. The Bill removes its applicability from research, and bio-survey and bio-utilisation. The Bill adds that SBB will determine benefit sharing while granting approvals to domestic entities as per the regulations by NBA. The Act provides that the terms for benefit sharing should be in accordance with the mutually agreed terms and conditions between the applicant, local bodies concerned, and the benefit claimers. The Bill instead provides that the terms should be in accordance with the mutually agreed terms between the applicant and the Biodiversity Management Committee (BMC) represented by NBA.
- **Offences and Penalties:** Under the Act, offences include failing to take approval or providing prior intimation for various activities. These offences are punishable with imprisonment of up to five years, or a fine, or both. The Bill decriminalises the offences and makes offences punishable with a penalty between one lakh rupees and Rs 50 lakh. Continuing contravention may attract an additional penalty of up to one crore rupees. An adjudicating officer of at least the rank of Joint Secretary of the central government or the rank of Secretary of the state government will hold the inquiry and determine the penalty.

PART B: KEY ISSUES AND ANALYSIS

Ambiguity in the exemption for codified traditional knowledge

Bill: Clause 6, 9, 17, 19, 21, 30

The 2002 Act requires users of biological resources and associated knowledge to share benefits with local communities. The Bill exempts users of “codified traditional knowledge” from this requirement. The Bill has not defined the term ‘codified traditional knowledge’. The Convention on Biological Diversity and Nagoya and Cartagena protocols under it also do not define this term. A broad interpretation of this term might exempt almost all traditional knowledge from benefit sharing requirements.

Act: Section 4, 7, 19, 21, 23, 41

The World Intellectual Property Organisation (WIPO) defines codified traditional knowledge as “traditional knowledge which is in some systematic and structured form, in which the knowledge is ordered, organised, classified and categorised in some manner”.⁸ The Act requires every local body in India to create a Biodiversity Management Committee (BMC). The Biological Diversity Rules, 2004 state that the main function of BMC is to prepare the People’s Biodiversity Register.⁹ The Register will contain comprehensive information on the availability and knowledge of local biological resources, their medicinal or any other use, or any traditional knowledge associated with them. Therefore, all local traditional knowledge may be captured in these registers, and thus fulfil the definition of codified traditional knowledge by WIPO. If this definition were used, all local traditional knowledge would be exempt from benefit sharing provisions.

Biological Diversity Rules, 2004: Rule 22 (6)

Local communities may not have a direct say in benefit sharing

Bill: Clause 2 (b), 19, 30

The Bill removes the direct role of local bodies and benefit claimers in determining mutually agreed terms. The Act states that while granting approvals for various activities, National Biodiversity Authority (NBA) will determine terms for benefit sharing. Such approval should be in accordance with the mutually agreed terms between the applicant, concerned local bodies, and benefit claimers. Benefit claimers are persons who are conservers of biological resources, or creators or holders of associated traditional knowledge. The Bill amends this to require that approvals should be in accordance with mutually agreed terms between the applicant and the concerned Biodiversity Management Committee represented by NBA. Thus, benefit claimers and local people will not be directly involved in setting the terms and conditions.

Act: Preamble, Section 21, 41

Nagoya Protocol: Article 6 (2), 7

Further, there is no provision for a mechanism for obtaining prior informed consent of the local and indigenous communities. This may be in contrast with the framework under Nagoya Protocol. Nagoya Protocol requires a signatory country to ensure that prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources and traditional knowledge.⁶ In *Divya Pharmacy vs Union of India (2018)*, the Uttarakhand High Court had observed that under the Nagoya Protocol, the concept of fair and equitable benefit sharing is focused on the benefits for local and indigenous communities.¹⁰

Offences and Penalties

Bill: Clause 38

Under the Act, offences are punishable with imprisonment of up to five years or a fine, or both. The Bill decriminalises the offences and makes them punishable with a penalty. The penalty is between one lakh rupees and Rs 50 lakh, and in case of continuing contravention, there may be an additional penalty of up to one crore rupees. The Bill adds that an adjudicating officer will hold an inquiry and decide the penalty. The adjudicating officer will be of at least the rank of Joint Secretary in the central government or Secretary in the state government. We discuss certain issues related to the mechanism of penalty below.

Act: Section 55

There is a lack of substantive legislative guidance on adjudging the penalty

There is a wide range of penalties that can be levied, between one lakh rupees and one crore rupees, i.e., the maximum penalty is 100 times the minimum penalty. There is no guidance to the adjudicating officer on how to assess the penalty within this range. The Bill has not made any differentiation based on the type of offence. For instance, the punishment is the same for failing to take approval for either research or commercial utilisation. It does not distinguish whether the offence involves accessing traditional knowledge or obtaining biological resources. Similarly, the punishment for transferring results of research without approval, and failing to take approval for bio-survey or patent is the same.

The question is whether it is appropriate to empower members of the Executive to adjudicate penalty

The Bill changes the adjudicating authority from a Judge to a government official. The penalty decisions will be based on an inquiry instead of a judgement after arguments in an open court. The question is whether it is appropriate to confer such discretion to government officials.

Inconsistencies and Omissions

In the following paragraphs, we highlight certain inconsistencies and omissions in the drafting of the Bill.

It is unclear whether activities under Section 7 require only prior intimation to SBB or its approval

Bill: Clause 9, 21, 22

Clause 9 of the Bill amends Section 7 of the Act. It provides that certain entities are required to intimate State Biodiversity Board (SBB) before accessing any biological resource or associated knowledge for commercial utilisation subject to Sections 23(b) and Section 24(2). However, Section 23(b) (as amended by Clause 21 of the Bill) provides that functions of SBB will include regulating the above activities by granting or rejecting approvals. Also, Section 24(2) of the Act requires SBB to prohibit or restrict activities intimated under Section 7. This raises the question whether the Bill only requires prior intimation or approval of SBB is required for undertaking the specified activities under Section 7.

Act: Section 7, 23, 24

Inconsistency in the definition of “foreign-controlled company”

Bill: Clause 5

The Bill provides that a company “incorporated in India” which is a “foreign-controlled company” will require approval from NBA for specified activities. Under the Bill, a “foreign-controlled company” means a foreign company as per Section 2(42) of the Companies Act, 2013, which is under the control of a foreigner. Section 2(42) of the Companies Act defines a foreign company as a company or body corporate *incorporated outside India*. Hence, the Bill creates a contradiction by requiring NBA approval for a company incorporated in India (Clause 5 of the Bill), which is incorporated outside India (Section 2(42) of the Companies Act).

Companies Act, 2013: Section 2 (42)

Application process not specified for NBA approval in certain cases

Bill: Clause 5, 17

Section 3 of the Act as amended by the Bill requires specified persons to seek approval from NBA for accessing biological resources occurring in India or associated knowledge for: (i) research, (ii) commercial utilisation, or (iii) bio-survey and bio-utilisation. Clause 17 of the Bill specifies the manner of application to NBA for approval. However, it only covers access for commercial utilisation. Manner of application for research, and bio-survey and bio-utilisation activities have not been specified under the Bill.

Act: Section 3, 19

The Bill seeks to remove references to ‘Bio-utilisation’; however, certain references remain

Bill: Clause 3 (iii)

The Act provides for the definition of “Bio-Survey and Bio-Utilisation”. The Bill seeks to remove the reference to “Bio-utilisation” from the definition, and elsewhere in the Act. However, Section 3 of the Act as amended by the Bill still contains the term “Bio-utilisation”.

Act: Section 2 (d), 3

1. [“95th Report: Biodiversity Bill, 2000”](#), the Departmentally Related Standing Committee on Science, Technology, and Environment, Rajya Sabha, December 2001.
2. [“The Global Assessment Report on Biodiversity and Ecosystem Services: Summary for Policymakers”](#), Intergovernmental Science Policy Platform on Biodiversity and Ecosystem Services (IPBES), May 2019.
3. [Parliamentary Debates](#) in Rajya Sabha on December 11, 2002.
4. [Text of the Convention on Biological Diversity](#), United Nations Organisation, 1992.
5. [Country Profile-India](#), Website of the Convention on Biological Diversity as accessed on January 25, 2022.
6. [Text of the Nagoya Protocol](#).
7. [The Biological Diversity \(Amendment\) Bill, 2021](#) as introduced in Lok Sabha.
8. [Glossary of Key Terms Related to Intellectual Property and Genetic Resources](#), Traditional Knowledge and Traditional Cultural Expressions, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, World Intellectual Property Organisation, September 2021.
9. Rule 22 (6), [The Biological Diversity Rules, 2004](#).
10. [Divya Pharmacy vs Union Of India And Others](#), Writ Petition No. 3437 of 2016, Uttarakhand High Court, December 21, 2018.

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