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Decoding the Biological Diversity (Amendment) Act, 2023

06 October 2023 | Views | By Kapil Kumar, Senior Associate K&S Partners; and Dr Deepa K. Tiku, Partner at K&S Partners

Indian biodiversity holds vast potential, significantly influencing sectors like agriculture, forestry, fisheries, and biopharmaceuticals, among many others



During the Monsoon Session, 2023 of Parliament, both Houses of Parliament have passed the Biological Diversity (Amendment) Bill, 2023 that seeks to (i) reduce the pressure on wild medicinal plants by encouraging cultivation of medicinal plants; (ii) encourage Indian system of medicine; (iii) facilitate fast-tracking of research, patent application process, transfer of research results while utilising the biological resources available in India without compromising the objectives of United Nation Convention on Biological Diversity and its Nagoya Protocol. Let's delve into the legislative evolution of the amendment Act, examining the initial amendments proposed in the 2021 Bill, insights from the Joint Parliamentary Committee (JPC), and the conclusive provisions of the 2023 amendment Act.

India has updated its 2002 Biological Diversity Act (BDA) by passing the Biological Diversity (Amendment) Act, 2023 (the Amended Act). The BDA originated from the United Nations Convention of Biological that India signed at Rio de Janeiro. The Act was designed to safeguard India's diverse biological resources, ensuring their conservation and sustainable utilisation.

The modifications hold paramount importance as they influence research and innovation across sectors reliant on biodiversity such as pharmaceuticals, agriculture, cosmetics, and traditional medicine, among others. Furthermore, they bolster domestic endeavours in this domain, propelling India towards its ambitious target of a $300 billion bio-economy.

These changes affect a range of sectors, from domestic and international biotech and pharma corporations harnessing biological resources to traditional medicine realms encompassing AYUSH disciplines, research and bio-surveying entities, indigenous communities with time-honoured knowledge, and IPR sectors with a keen focus on biological assets.

Legislative journey

The Biological Diversity Amendment Bill, 2021 (Bill) was introduced in the Lok Sabha on December 16, 2021, to amend the erstwhile Biological Diversity Act, 2002 (erstwhile Act) provision. This Bill was introduced to address various prevalent issues being raised by stakeholders for years since the erstwhile Act came into effect. The invitation for public comments, kept open for a month, received a total of 1,217 comments. The Bill was then scrutinised by a Joint Parliamentary Committee (JPC) which submitted its report in August 2022, with several recommendations.

The government accepted most of the JPC's recommendations and introduced a revised Bill in the Lok Sabha on July 20, 2023. This revised Bill was passed by the Lok Sabha on July 25, 2023, and by the Rajya Sabha on August 1, 2023. It was then signed by the President on August 3, 2023, and became an Act.

Progression of amendments till enactment

The journey of the amendments to the Biological Diversity Act, 2002, has been a meticulous one. In the Biological Diversity (Amendment) Bill, 2021, several proposals were put forth. The Bill proposed exemptions for users of codified traditional knowledge and AYUSH practitioners, ensuring they wouldn't need to share benefits with local communities. Interestingly, the term "Codified traditional knowledge" wasn't explicitly defined in this context. The Bill also sought to exempt certain research and bio-survey activities from benefit-sharing requirements and aimed to decriminalise offences under the Act.

Upon review, the JPC report made several recommendations. They proposed that the Bill should be revised to protect the interests of local communities and traditional knowledge holders, all while simplifying access to biological resources. They also suggested a change in phrasing: from "Associated traditional knowledge thereto" to "traditional knowledge associated thereto," to narrow down the meaning, focusing the associated knowledge strictly on the biological resource and excluding other incidentally associated knowledge, like details in research papers. The JPC also recommended introducing a definition for "Codified Traditional Knowledge," in relation to authoritative texts under systems like Ayurveda, Siddha, and Unani. However, this definition seemed to overlook the traditional knowledge held by local communities.

The Amended Act considered many of the JPC's recommendations, leading to significant changes in the BDA.

Notable areas of change

Definitions in Section 2

Expanded Access: The definition of "access" now covers a wider array of activities, the definition of "benefit claimants" has been clarified.

Addition of "Derivative": The term "derivative" has been introduced, broadening the scope of by-products derived from primary biological resources. However, this can be a potential area of confusion as it blurs the lines between primary resources and their subsequent forms, making it crucial for industries to understand what qualifies as a derivative.

Codified Traditional Knowledge: The Act now recognises "codified traditional knowledge", ensuring protection of established practices. For sectors like AYUSH, this means that traditional practices documented in ancient texts are acknowledged and safeguarded, promoting their authentic use and preventing misappropriation.

Standardising "Non-Indian Entity" Definition: The "non-Indian entity" definition has been synchronised with other Indian statutes such as the Companies Act, 2013.

Compliance provisions

The process for obtaining Intellectual Property Rights (IPR) on biological resources and associated traditional knowledge has been clarified as per Section 6. Foreign entities must obtain prior approval to secure IPR on Indian biological resources. In contrast, Indian entities need only register with the National Biodiversity Authority (NBA). However, if these entities intend to commercialise the IPR, NBA’s prior approval becomes necessary.

Powers & Functions of NBA/SBB

The State Biodiversity Boards (SBBs) have been empowered by the amendments under Section 7 which mandates Indian entities to pay Access and Benefit Sharing (ABS) fees. Section 20, concerning the transfer of research results, no longer requires dual approval for transferring biological resources or associated knowledge but maintains the prior approval requirement for the transfer of research results. However, the powers of the NBA and SBB have been further delineated. Section 23 clarifies the powers of the SBBs, especially regarding the Benefit Sharing Fee (ABS). Section 36A, a new addition, authorises the NBA to oversee and regulate access to biological resources from foreign countries.

Exemptions

Section 40 has expanded the exemptions for Normally Traded as Commodities (NTAC) to include derivatives of NTAC bioresources, agricultural wastes, and cultivated medicinal plants, but this is limited to Indian entities.

Penalties

Penalties have been revised under Section 55, shifting from imprisonment to increased financial penalties. Section 55A introduces the appointment of an adjudicating officer to oversee inquiries and impose penalties. This officer, along with authorities under Section 55B, has the authority to conduct searches, seizures, and collect evidence. Section 61 now permits any individual to file a complaint for potential infractions under the Act.

Implications for various sectors

The changes are expected to simplify the process for Indian entities to access and use biological resources for research and IPR purposes. The roles of SBBs are clearer, and while fines for violations have increased, the process is more transparent. Additionally, the ability for any individual to file a complaint might increase vigilance but could also open doors to potential misuse.

For the biotech and pharmaceutical sectors, these amendments provide clarity. The streamlined process for Indian entities to access biological resources for research and IPR is evident. The roles of the SBBs are now more defined, simplifying the ABS determination process for Indian entities. However, while penalties for infractions have increased, the process aims for equity.

The exemptions for Indian entities are notable, but foreign collaborative research may still encounter challenges.

Achieving a bioeconomy target of $300 billion by 2030

Indian biodiversity holds vast potential, significantly influencing sectors like agriculture, forestry, fisheries, and biopharmaceuticals, among many others. The recent amendments to the Biodiversity Act aim to streamline access to these resources, potentially propelling India towards its ambitious $300 billion bioeconomy target by 2030. While these changes simplify processes, they also ensure the conservation of biological resources, sustainable utilisation, and fair benefit-sharing with local communities.

However, the amendments also introduce concerns, notably the enhanced authority, powers, and potential for unfair competition. Continuous oversight will be essential for balanced implementation.

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