

Biological Diversity (Amendment) Bill, 2021

December 24, 2021

Manifest pedagogy:

The Biological Diversity Amendment Bill 2021, introduced in the Lok Sabha, exempts Ayush practitioners from the ambit of the Biological Diversity Act, 2002, and facilitates access to biological resources and traditional knowledge by the Indian traditional medicine sector. Legal experts have, however, expressed concerns that easing the norms for the sector could be detrimental to ecology and go against the principle of sharing commercial benefits with indigenous communities.

In news: Why legal experts are concerned about the Biological Diversity Amendment Bill 2021

Placing it in syllabus: Law & Policy

Static dimensions:

- Biological Diversity Act, 2002
- Cartagena protocol and Nagoya protocol

Current dimensions:

- Provisions of the amendment Bill
- How the amendment to act would benefit the biopharmaceutical industry in India?
- Challenges to the biodiversity

Content:

Biological Diversity Act, 2002:

- The Biological Diversity Act, 2002 was passed by the Indian Parliament passed on February 5, 2003

- It provides for the conservation of biological diversity, the sustainable use of its components, the fair and equitable distribution of benefits arising from the usage of biological resources, and related matters.
- The Act refers to the Convention on Biological Diversity, adopted by the United Nations in 1992, which India is a signatory to.

Definitions of 'biological diversity', 'sustainable use' and 'biological resources' as per the Act:

- 'Biological diversity' refers to the "variability among living organisms from all sources and the ecological complexes of which they are part." It includes diversity among and within species' and ecosystems.
- 'Sustainable use' means the use of components of biological diversity in a manner and rate that does not lead to their 'long-term decline'.
- 'Biological resources' refer to plants, animals, micro-organisms and their genetic materials, which have actual or potential use or value. The term does not include human genetic material.

What does the Act say about regulating access to biological diversity?

Without the approval of the National Biodiversity Authority, no organisation or person – an Indian citizen or otherwise – shall obtain any biological resource occurring in India, or any associated knowledge for research or commercial utilisation.

What is the National Biodiversity Authority?

- The Act directs the central government to set up the National Biodiversity Authority.
- The Authority may:
- advise the central government on matters relating to the conservation of biodiversity and the sustainable use of

its components;

- the selection of biodiverse areas to be notified as heritage sites and the management of such sites; or
- undertake any other activity necessary as per this Act.
- The Authority, on behalf of the central government, may also oppose the grant of intellectual property rights on any biological resource obtained from India in foreign countries.

What are the central government's duties under this Act?

- The central government shall develop plans and strategies for the conservation and sustainable use of biodiversity, including identifying and monitoring areas rich in biological resources and incentives for research.
- If the central government believes that an area rich in biological diversity and resources is being threatened by overuse, abuse or neglect, it shall issue directives to the concerned state government to take immediate measures to tackle this.
- The central government shall integrate the conservation, promotion and sustainable use of biological diversity into its plans, programmes and policies.
- It shall take measures to assess the environmental impact of a project likely to have adverse effects on biological diversity.
- The government shall also endeavour to respect and protect the knowledge of local people relating to biological diversity, in the manner recommended by the National Biodiversity Authority.
- Apart from this, the central government may notify areas as biological diversity sites; recognise any species on the brink of extinction as threatened; designate repositories for different categories of biological resources; and exempt biological resources from falling

under the provisions of this Act.

What are State Biodiversity Boards?

- The Act says that state governments may appoint their own Biodiversity Boards.
- Their functions shall be to
- advise the state government on matters related to the conservation of biological diversity, the sustainable use of its components,
- the fair and equitable distribution of benefits arising from the use of biological resources;
- regulating requests by Indian citizens for the commercial utilisation of any biological resource; and
- to undertake any other activity necessary as per this Act.

Cartagena Protocol and Nagoya Protocol

The Cartagena Protocol on Biosafety (CPB):

- The Cartagena Protocol on Biosafety (CPB), the first international regulatory framework for safe transfer, handling and use of Living Modified Organisms (LMOs) was negotiated under the aegis of the Convention on Biological Diversity (CBD).
- It is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.
- It governs the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another.
- The protocol was adopted on 29th January 2000. The Protocol entered into force on 11 September 2003. Currently 169 countries are Parties to the Protocol.
- The Protocol promotes biosafety by establishing rules

and procedures for the safe transfer, handling, and use of LMOs.

- It includes Advance Informed Agreement (AIA) procedures for imports of LMOs for intentional introduction into the environment, and also incorporates the precautionary approach, and mechanisms for risk assessment and risk management.
- The Protocol establishes a Biosafety Clearing-House (BCH) to facilitate information exchange, and contains provisions on capacity building and financial resources, with special attention to developing countries and those without domestic regulatory systems
- The Protocol attempts to reconcile the respective needs of trade and environmental protection in the light of the rapidly growing biotechnology industry.
- The Protocol addresses the obligations of Parties in relation to the transboundary movements of LMOs to and from non-Parties to the Protocol.

Nagoya Protocol:

- **Nagoya Protocol** is formally known as The ***Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity***
- It is a supplementary agreement to the Convention on Biological Diversity.
- It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: i.e. the fair and equitable sharing of benefits arising out of the utilization of genetic resources.
- The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014.
- The Nagoya Protocol creates greater legal certainty and

transparency for both providers and users of genetic resources by:

- Establishing more predictable conditions for access to genetic resources.
- Helping to ensure benefit-sharing when genetic resources leave the country providing the genetic resources
- As it helps to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.
- The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization.
- The Nagoya Protocol also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.
- Under the Convention of Biological Diversity, and the Nagoya Protocol on Access and Benefit Sharing to which India is a party, it is mandated that **benefits derived from the use of biological resources** should be **shared in a fair and equitable manner among the indigenous and local communities.**
- When an Indian or foreign company or individual accesses biological resources such as medicinal plants and associated knowledge, it has to take prior consent from the national biodiversity board.
- The board can impose a benefit-sharing fee or royalty or impose conditions so that the company shares the monetary benefit from commercial utilisation of these resources with local people who are conserving biodiversity in the region.

Convention on Biological Diversity:

- The Convention on Biological Diversity is a multilateral treaty with 193 parties
- The convention was opened for signature at the Earth Summit in Rio de Janeiro on 5 June 1992 and entered into force on 29 December 1993.
- The United States is the only UN member state which has not ratified the convention.
- It has two supplementary agreements, the Cartagena Protocol and Nagoya Protocol.

The three objectives of the convention are:

- the conservation of biological diversity
- the sustainable use of its components, and
- the fair and equitable sharing of the benefits arising from the use of genetic resources.

Provisions of the amendment Bill:

The Biological Diversity Act, 2002 was enacted for the conservation of biological diversity and fair, equitable sharing of the monetary benefits from the commercial use of biological resources and traditional knowledge.

According to the statement of objectives of Biological Diversity (Amendment) Bill, 2021, it seeks to:

- reduce the pressure on wild medicinal plants by encouraging the cultivation of medicinal plants;
- exempts Ayush practitioners from intimating biodiversity boards for accessing biological resources or knowledge;
- facilitates fast-tracking of research, simplify the patent application process, decriminalises certain offences;
- bring more foreign investments in biological resources, research, patent and commercial utilisation, without compromising the national interest.

Proposals in the Amendment Bill:

- The role of state biodiversity boards has been strengthened and better clarified in the bill.
- There are also significant changes proposed in the offences section
- Violations of the law related to access to biological resources and benefit-sharing with communities, which are currently treated as criminal offences and are non-bailable, have been proposed to be made civil offences.
- The bill facilitates access to biological resources and traditional knowledge by the Indian traditional medicine sector.

How the amendment to act would benefit the biopharmaceutical industry in India?

- The bill focuses on regulating who can access biological resources and knowledge and how access will be monitored.
- Ayush practitioners have been exempted from the ambit of the Act, a huge move because the Ayush industry benefits greatly from biological resources in India.
- Registered Ayush practitioners who have been practising indigenous medicine can access any biological resource and its associated knowledge for commercial utilisation, without giving prior intimation to the state biodiversity board.
- It will also bring more foreign investments in biological resources, research, patent and commercial utilisation, without compromising the national interest.

- Ayush companies have been seeking relaxation of the **benefit-sharing provisions**.
- A case in point is the case relating to Divya Pharmacy founded by Swami Ramdev and Acharya Balkrishna in Uttarakhand.
- The Uttarakhand Biodiversity Board (UBB) sent a notice

to Divya Pharmacy in 2016 stating that the company was in violation of the Biodiversity Act for using biological resources from the state for its ayurvedic formulations, without intimating the board and that it was liable to pay an access and benefit-sharing fee.

- Challenging the board's notice, the company filed a writ petition before the Uttarakhand high court in December 2016 challenging the powers of the biodiversity board to determine benefit-sharing by Indian companies.
- The court in 2018 upheld the powers of the biodiversity board in its judgement.

Concerns / Challenges to the biodiversity

- **Contrary to the aim and objective of the Biological Diversity Act:** The amendment seems to be done with the sole intention of providing benefit to the Ayush industry. The main focus of the bill is to facilitate trade in biodiversity as opposed to conservation, protection of biodiversity and knowledge of the local communities. The amendments are completely contrary to the aim and objective of the Biological Diversity Act, 2002
- **Exclusion of the term "bio-utilisation."** "Bio-utilization is an important element in the Act. Leaving out bio utilization would leave out an array of activities like characterization, inventorisation and bioassay which are undertaken with commercial motive
- **Exclusion of Cultivated Medicinal Plants:** The bill also exempts cultivated medicinal plants from the purview of the Act but it is practically impossible to detect which plants are cultivated and which are from the wild. This provision could allow large companies to evade the requirement for prior approval or share the benefit with local communities under the access and benefit-sharing provisions of the Act.

Mould your thought:

1. What is biodiversity? Critically evaluate the provisions of the Biological Diversity Amendment Bill 2021.

Approach to the answer-

- Define biodiversity
- Write about the provisions of Biological Diversity Amendment Bill 2021
- Discuss how the bill helps the biopharmaceutical industry
- Comment on the criticisms of the bill
- Conclusion