

The Biotechnology Regulatory Authority of India (BRAI) is a proposed regulatory body to regulate the use of genetically modified organisms (GMOs) as per the provisions of the Bill introduced in the Parliament in 2013. BRAI was needed as India had signed the Cartagena Protocol and it mandates setting up a Regulatory Body.

What is the need for the Biotechnology Regulatory Authority of India?

1. Currently, the Genetic Engineering Approvals Committee, a body under the Ministry of Environment and Forests (India) is responsible for approval of genetically engineered products in India.
2. In January 2003, India ratified the Cartagena Protocol which protects biodiversity from potential risks of genetically modified organisms, the products of modern biotechnology.
3. As per the **Cartagena Protocol**, **India** needs to set up a **Regulatory Body**.

Biotechnology Regulatory Authority of India Bill, 2013 - Introduced in Parliament

1. The Biotechnology Regulatory Authority of India Bill was introduced in the Lok Sabha on April 22, 2013 by the Ministry of Science and Technology.
2. This Bill was referred to the Standing Committee on May 17, 2013.
3. The Standing Committee was supposed to submit its report in June 2014.

Biotechnology Regulatory Authority of India Bill, 2013 - Key Features

1. To regulate the products of modern biotechnology an independent authority named Biotechnology Regulatory Authority of India (BRAI) will be established.
2. BRAI will provide the necessary certification and approval whether it is safe for use.
3. Biotechnology Regulatory Authority of India (BRAI) will only grant regulatory approval after a multi-level process of assessments are undertaken by scientific experts in the field.
4. BRAI will impose penalties for conducting field trials without its approval.
5. A Biotechnology Regulatory Appellate Tribunal will hear civil cases that involve a substantial question relating to modern biotechnology and hear appeals on the decisions and orders of BRAI.

Biotechnology Regulatory Authority of India Bill, 2013 - Criticisms

Biotechnology Regulatory Authority of India Bill, 2013 faced stiff opposition from farmers and anti-Genetically Modified Organisms activists.

Some of the criticisms voiced by different stakeholders on the Biotechnology Regulatory Authority of India Bill, 2013 are listed below

1. The Bill proposes new institutes without clearly defining the boundaries of their responsibilities and powers.
2. The bill was introduced without consulting the stakeholders who would be affected by the introduction of the bill.
3. As per opinion voiced by some people, the bill is considered to be unconstitutional as agriculture comes under the domain of State Governments.
4. In the Bill, the term “confidential commercial information” has been kept out of the Right to Information (RTI) Act.
5. As per one of the experts in the field, the bill uses vague wordings which would criminalize sequencing or isolation of DNA and PCR techniques, requiring approval for each usage. This would hinder education and research in the field.
6. The bill has no provision for mandatory labelling of Genetically Modified (GM) foods.
7. One of the bones of contention is that it gives powers to the BRAI, to punish parties if misleading or false statements are made against GM foods.
8. As per the Bill, Biotechnology Regulatory Appellate Tribunal will consist of just 1 judicial member and 5 technical members which is against directives of Supreme Court that a bench of tribunal cannot have more technical members than judicial members.
9. The Bill does not specify any liability for damage caused by a product of biotechnology.
10. The Tribunal has jurisdiction over a ‘substantial question relating to modern biotechnology’. However, the Bill does not define this term. Leaving a term undefined increases ambiguity.

Cartagena Protocol on Biosafety - Important Facts

1. Cartagena Protocol on Biosafety is an international agreement on biosafety as a supplement to the Convention on Biological Diversity.
2. The Biosafety Protocol seeks to protect biological diversity from the potential risks posed by genetically modified organisms resulting from modern biotechnology.
3. The Protocol entered into force on 11 September 2003.
4. 172 countries are party to the Cartagena Protocol on Biosafety.
5. 103 countries are signatories to the Cartagena Protocol.
6. The Protocol applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health
7. The Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of LMOs, with specific focus on transboundary movements of LMOs.
8. LMO's are Living Modified Organisms. Examples are agricultural crops like tomatoes, corn, cassava, soybeans, cotton etc; that have been genetically modified for greater productivity or for resistance to pests or diseases.

Convention on Biological Diversity (Biodiversity Convention) Treaty - Important Facts

1. Convention on Biological Diversity is a multilateral treaty that came into effect in December 1993.
2. The Convention was opened for signature at the Earth Summit in 1992 held at Rio De Janeiro, Brazil.
3. 30 countries have ratified the Biodiversity Convention Treaty.
4. 196 countries are party to the Biodiversity Treaty.
5. Convention on Biological Diversity has 2 Supplementary Agreements - **Cartagena Protocol** and **Nagoya Protocol**.

Convention on Biological Diversity (Biodiversity Convention) - 3 Objectives of Multilateral Treaty

The 3 main objectives of this treaty are mentioned below.

1. Conservation of biodiversity.
2. Sustainable use of components.
3. Fair and equitable sharing of benefits arising from genetic resources.

Consider the following statements:

1. BRAI is already in existence.
2. BRAI is a regulatory body for nuclear weapons.

Which of the above statements are correct?

- a) 1 only
- b) 2 only
- c) Both 1 and 2
- d) None of the above

Answer: d