

Bill Summary

The Biotechnology Regulatory Authority of India Bill, 2013

- The Biotechnology Regulatory Authority of India Bill, 2013 was introduced in the Lok Sabha on April 23, 2013 by the Minister for Science and Technology, Mr. S. Jaipal Reddy. The Bill aims to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures.
- **Biotechnology Regulatory Authority:** The Bill establishes the Biotechnology Regulatory Authority of India (Authority). The Authority will consist of a chairperson, two full time members, and two part time members.
- **Functions of the Authority:** The functions of the Authority shall include regulating the research, transport, import, containment, environmental release, manufacture and use of organisms and products of modern biotechnology. The Authority has the power to call for information, conduct an inquiry and issue directions for the safety of products or processes of modern biotechnology.
- Field trials for certain organisms or products cannot be conducted unless the Authority permits them as aiding the development of modern biotechnology such as genetically engineered plants, animals used in food or any animal clones that can be applied in agriculture, fisheries or food products. The Bill will not apply to the clinical trials of drugs, under the Drugs and Cosmetics Act, 1940, and food or food additives or any material under the Food Safety and Standards Act, 2006.
- The Authority will not disclose confidential commercial information made available in an application to the Authority. However, the Authority may disclose it in public interest or if this disclosure will not harm any person.
- **Divisions under the Authority:** Regulatory divisions of the Authority have been created for the implementation of safety assessment procedures and processes. The divisions are: (i) agriculture, forest and fisheries, (ii) human health and veterinary products, and (iii) industrial and environmental applications.
- A Risk Assessment Unit will appraise applications for proposed research, transport or import of an organism or product, before final approval is granted. The Product Rulings Committee will make recommendations to the Authority for the manufacture or use of organisms or products. The Environmental Appraisal Panel will make recommendations on environmental safety of organisms and products.
- **Other bodies:** An Inter-Ministerial Governance Board has been established to promote inter-ministerial or departmental co-operation for the effective discharge of the functions of the Authority.
- A Biotechnology Advisory Council will render strategic advice to the Authority regarding developments in modern biotechnology and their implications in India.
- **State level body:** A State Biotechnology Regulatory Advisory Committee will act as a nodal agency between the state government and the Authority with regard to the regulation of modern biotechnology.
- **Appellate Tribunal:** A Biotechnology Regulatory Appellate Tribunal will hear appeals against the decisions, orders or directions of the Authority. The Tribunal will consist of a full-time chairperson, who has been a judge of the Supreme Court of India or a Chief Justice of a High Court, and five part time expert members.
- **Penalties under the Bill:** The Bill imposes a penalty for providing false information (imprisonment for three months and fine extending to Rs five lakh) and conducting an unapproved field trial (imprisonment for six months to one year and a fine extending to Rs two lakh).

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