

Legislative Brief

The Biotechnology Regulatory Authority of India Bill, 2013

The Bill was introduced in the Lok Sabha on April 22, 2013.

It was referred to the Standing Committee on Science and Technology (Chairperson: Dr. T. Subbarami Reddy) on May 17, 2013. The Committee is scheduled to submit its report on December 15, 2013.

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Highlights of the Bill

- ◆ The Bill sets up an independent authority, the Biotechnology Regulatory Authority of India (BRAI), to regulate organisms and products of modern biotechnology.
- ◆ BRAI will regulate the research, transport, import, containment, environmental release, manufacture, and use of biotechnology products.
- ◆ Regulatory approval by BRAI will be granted through a multi-level process of assessment undertaken by scientific experts.
- ◆ BRAI will certify that the product developed is safe for its intended use. All other laws governing the product will continue to apply.
- ◆ 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.
- ◆ Penalties are specified for providing false information to BRAI, conducting unapproved field trials, obstructing or impersonating an officer of BRAI and for contravening any other provisions of the Bill.

Key Issues and Analysis

- ◆ The Tribunal has jurisdiction over a 'substantial question relating to modern biotechnology'. However, the Bill does not define this term. Leaving a term undefined could allow for flexibility but could also increase ambiguity.
- ◆ The Tribunal will consist of one judicial member and five technical members. This is not in conformity with a Supreme Court decision that the number of technical members on a bench of a Tribunal cannot exceed the number of judicial members.
- ◆ The Tribunal's technical members shall be eminent scientists or government officials with experience in the field. It is unclear whether the technical expertise of the latter can be equated with the former.
- ◆ The Bill does not specify any liability for damage caused by a product of biotechnology. Therefore, it will remain open to the courts to determine liability arising out of any adverse impact of modern biotechnology.
- ◆ Various committees have recommended that an autonomous statutory regulator having members with expertise in biotechnology be set up.

PART A: HIGHLIGHTS OF THE BILL¹

Context

Biotechnology is the manipulation of the genetic structure of organisms to alter their characteristics and introduce specific traits. For instance, biotechnology has been used to create synthetic human insulin to treat diabetes and Bt Cotton which produces an insecticide that kills certain pests that eat it. Such products could include living modified organisms, genetically modified organisms and genetically engineered organisms. Currently, biotechnology is jointly regulated by the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT) under the Ministry of Science and Technology. Biotechnology is governed by rules notified in 1989 under the Environment (Protection) Act, 1986² (1989 rules) and various guidelines issued by the DBT. A number of committees including the Swaminathan Task Force and the Standing Committee on Agriculture have reviewed the regulatory mechanism and made recommendations.³ Given the benefits and risks associated with the use of this technology, these committees have suggested that a statutory agency be established which will implement a robust science - based review mechanism of biotechnology products by a qualified team. The DBT had held consultations on a draft Bill in 2008 and had circulated a draft establishment plan for the proposed regulatory authority.⁴ The Supreme Court is also examining the efficacious and safe use of biotechnology.⁵

The Ministry of Science and Technology introduced the Biotechnology Regulatory Authority of India Bill, 2013 in the Lok Sabha on April 23, 2013.⁶ The Bill sets up a regulator which aims to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures.⁷

Key Features

The Bill sets up an independent authority, the Biotechnology Regulatory Authority of India (BRAI), to regulate organisms and products of modern biotechnology. BRAI will regulate such organisms and products through a multi-layered process of scientific assessment undertaken by experts in the field of biotechnology.

Biotechnology Regulatory Authority and its functions

- BRAI will consist of a chairperson, two full time members, and two part time members for a three year term. They will have specified scientific qualifications and will be selected by a committee composed of the Cabinet Secretary, secretaries of relevant ministries such as agriculture and biotechnology and two eminent biotechnologists.
- The functions of BRAI shall include authorising and regulating the research, transport, import, containment, environmental release, manufacture and use of organisms and products of modern biotechnology.
- Field trials require permission from BRAI, which will also prescribe safeguards to be followed.
- For a drug or vaccine with elements of biotechnology, the Central Drugs Standard Control Organisation (CDSCO) will forward the application to BRAI to assess whether it is safe to proceed with a clinical trial. Clinical trials will continue to be regulated by the CDSCO under the Drugs and Cosmetics Act, 1940.
- The Bill amends the Food Safety and Standards Act, 2006, which regulates the manufacture, import, sale and distribution of food items. The amendment mandates that food items with elements of biotechnology have to be approved by BRAI as safe for human consumption.
- BRAI will have the power to call for information, conduct an inquiry and issue directions for the safety of products or processes of modern biotechnology. BRAI shall communicate its decisions on applications for authorisation to the public and obtain objections or suggestions.
- BRAI will not disclose confidential commercial information made available to it in an application for authorisation. This is regardless of anything contained in the Right to Information Act, 2005. However, BRAI may disclose the information in public interest or if this disclosure will not harm any person.

Process for approval of applications

- BRAI will comprise of three units: Risk Assessment Unit (RAU), Product Rulings Committee (PRC) and Environmental Appraisal Panel (EAP). BRAI will forward all applications seeking authorisation for research, transport, import, manufacture or use of products and organisms of biotechnology to the RAU. RAU will be composed of scientific officers possessing qualifications as specified in regulations. The RAU will undertake science - based safety assessments of the applications. For research, transport and import, BRAI will take a

decision based on the RAU's assessment. In the case of manufacture or use, the report of the RAU will be forwarded to the PRC. The PRC is composed of members of BRAI and its regulatory divisions, a representative from the CDSCO and between three to five scientific experts. Based on this report, the PRC will make recommendations regarding the safety of the product or organism. Further, BRAI may refer an application to the EAP, in case of products or organisms having an environmental impact.

- BRAI will constitute an Enforcement Unit consisting of monitoring officers for enforcing its decisions. A Scientific Advisory Panel will be created to provide scientific advice and technical support to BRAI.
- Safety assessment procedures for products will be implemented by the three regulatory divisions of BRAI. The divisions pertain to the following areas: (i) agriculture, forest and fisheries, (ii) human health and veterinary products, and (iii) industrial and environmental applications. Each of these will be headed by a Chief Regulatory Officer (CRO) with specified scientific qualifications. The CROs will be a part of the PRC.

Other bodies being established

- The Biotechnology Regulatory Appellate Tribunal will: (a) have jurisdiction over civil cases where a substantial question relating to modern biotechnology is involved and arises from the safety and use of organisms, products and processes specified in the Bill; and (b) hear appeals from the decisions and orders of BRAI. It will consist of a full-time chairperson, who has been a judge of the Supreme Court or a Chief Justice of a High Court, and five part time expert members. Decisions of the Tribunal can be appealed to the Supreme Court.
- An Inter-Ministerial Governance Board has been established to promote inter-ministerial co-operation for the effective discharge of BRAI's functions. A Biotechnology Advisory Council will offer advice to BRAI on developments in modern biotechnology and their implications. State Biotechnology Regulatory Advisory Committees will co-ordinate between the state government and BRAI and identify state-specific needs.

Penalties under the Bill

- The Bill provides imprisonment of up to three months and a fine of up to rupees five lakh for providing false information, conducting unapproved field trials and obstructing an officer of BRAI. Contravention of other provisions would be punishable with imprisonment of up to two years and a fine of up to rupees 10 lakh.

PART B: KEY ISSUES AND ANALYSIS

Regulation of biotechnology

Biotechnology has been the subject of much debate; while it has certain benefits, there could be unintended risks if it is not assessed adequately for safety. Benefits of this technology include the introduction of characteristics such as drought resistance, pest resistance, or high iron content in a plant. Risks include adverse impact on the health of organisms that consume these products, and the environment and biodiversity. Any regulatory structure for the sector will need to balance the benefits with the risks and ensure the safe use of biotechnology.

Several committees have said that the current assessment system in India is not independent and lacks scientific rigour in its assessment.³ The Bill envisages an independent scientific risk assessment to be undertaken by experts in the field of biotechnology. BRAI's role is restricted to certify that the product or organism developed is safe for its intended use. All other laws applicable to the product will continue to apply. For example, use of items such as drugs and seeds would be regulated by the Drugs and Cosmetics Act, 1940 and Seeds Act, 1966 respectively and any applicable state laws.

Table 1 compares differences between the current regulatory approval system under the 1989 rules with the regulatory approval system proposed under the Bill.

Table 1: Comparison of regulatory approval process: current and BRAI Bill, 2013

Parameter	Current regulatory process	BRAI Bill, 2013
Kind of authority	Government departments give approvals.	Independent statutory body will give approvals.
Activities regulated	Manufacture, use, sale, import, export and storage of genetically modified organisms.	Research, transport, import, manufacture and use of genetically modified organisms/products.
Oversight of research process for safety	Every entity conducting research needs to set up an Institutional Biosafety Committee.	No provision.

Parameter	Current regulatory process	BRAI Bill, 2013
Approval bodies	Final approval by Genetic Engineering Appraisal Committee (GEAC); technical review done by Review Committee on Genetic Manipulation.	Single regulator comprising of a number of units such as the RAU, PRC and EAP.
Regulatory divisions	No provision.	Three divisions: (i) agriculture, forests and fisheries; (ii) human health and veterinary; and (iii) industrial and environmental applications.
Assessment of environmental impact	GEAC approves proposals for release of products into the environment including field trials.	EAP shall make recommendations on the environmental safety of products as may be referred to it by BRAI.
Qualification of regulators	Ministry officials and representatives of government scientific/technical bodies.	Individuals with scientific expertise in the area of biotechnology.
Monitoring and enforcement body	No provision.	Enforcement Unit will enforce decisions of BRAI and ensure compliance with rules and regulations.
State and district level bodies	State body investigates and takes action for violation of law through the State Pollution Control Board. District committee monitors safety regulations in installations engaged in the use of such products.	State body is the nodal agency for interaction between the state government and BRAI. No provision for district level body.
Public participation	No provision under the 1989 Rules.	Decisions of BRAI will be made available to the public. Public objections/suggestions will be obtained.
Judicial body	Authority to be notified by MoEF. National Green Tribunal (NGT) has jurisdiction in some cases.	Appeals to be heard by the Biotechnology Regulatory Appellate Tribunal.

Sources: 1989 Rules; BRAI Bill, 2013; PRS.

International Regulation

The Convention on Biological Diversity and the Cartagena Protocol on Biosafety mandate rigorous scientific regulation to ensure safe use of biotechnology. Countries around the world have various mechanisms for regulating biotechnology. In USA and Canada, the government departments of agriculture, health, environment and food regulate biotechnology.⁸ Both countries use existing laws and agencies rather than creating a specialised regulatory mechanism. On the other hand, Australia has set up an independent regulator that conducts risk assessment and authorises activities such as research and transport of products of biotechnology.⁹

Countries have also adopted varying standards for assessing risk. USA and Canada assess the safety of a biotechnology product by applying the principle of establishing substantial equivalence (scientifically establishing that the biotechnology product is the same as the conventional product in terms of its composition and nutritional value).¹⁰ Norway, on the other hand, requires that the product should not lead to any risk of adverse impact on health and the environment.¹¹

Jurisdiction of the Appellate Tribunal

Clauses 43(1) and 56(1)

The Tribunal will have jurisdiction over all civil cases where a 'substantial question relating to modern biotechnology' is involved and these questions arise from the safety and use of organisms, products and processes specified in the Bill. However, the Bill does not define 'substantial question relating to modern biotechnology'. This may lead to uncertainty with regard to the extent of jurisdiction of the Tribunal on matters of modern biotechnology and its consequences. There can be two views on whether 'a substantial question relating to...' can and ought to be defined. On the one hand, defining the term could reduce ambiguity. For example, the NGT has jurisdiction over all civil cases where a 'substantial question relating to environment' is involved. This term is defined within the relevant Act.¹² On the other hand, given the evolving nature of modern biotechnology and its consequences, leaving the term undefined may allow for flexibility. For instance, the term 'substantial question relating to law' has not been defined in any statute and has been developed by the courts over time.

Composition of the Appellate Tribunal and BRAI

Inadequate judicial representation on the Appellate Tribunal

Clauses 45(1), 45(2), 46, 45(4) (c), and 58

In the National Company Law Tribunal judgment of 2010, the Supreme Court laid down that the number of technical members on a bench of a Tribunal cannot exceed the number of judicial members.¹³ The Bill is not in conformity with this principle laid down by the Court. The Bill provides that the Tribunal will consist of a full-time chairperson, who has been a judge of the Supreme Court or a Chief Justice of a High Court, and five part time expert members. Thus, the number of technical members exceeds that of judicial members. In addition, in case the post of the chairperson is vacant, an expert member of the Tribunal shall discharge the functions of this post. This implies that cases before the Tribunal could be heard without a judicial member.

Equivalence of expertise of various technical members

Clauses
45 and 46

The Bill lays down the qualifications for expert members of the Tribunal and equates (a) an eminent scientist in the field of biotechnology with at least 20 years experience, with (b) a Joint Secretary in the central or state government who has held a post dealing with biotechnology for at least three years and possesses special knowledge in the field. It is unclear whether 20 years of technical expertise of an eminent scientist can be equated with the three years of administrative experience of a government official in the field of biotechnology.

Areas of expertise of technical members

Clauses
46 and 56

The Bill requires that the experience of technical members in biological science or biotechnology be related to any of the following fields: (i) healthcare, *or* (ii) agriculture, *or* (iii) environmental, *or* (iv) industrial activities and processes. This implies that a Tribunal could be constituted without representation from each field. Absence of a member from a specified field could impede the Tribunal's ability to examine a technical question related to it.

Qualification of chairperson and members of BRAI

Clauses
6(1), 6(2)
and 21(3)

The chairperson and members of BRAI and Chief Regulatory Officers of the three divisions of BRAI are required to either have a doctorate degree in biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or a university or institute established by law. It is unclear whether candidates who may have obtained similar degrees from reputed universities outside India would qualify to be selected as members of BRAI.

Determination of liability

The primary function of liability regimes is to provide compensation to affected parties and incentivise the industry to minimise the risks of adverse impact. There are different types of liability regimes. In some cases, liability is specified in a law (statutory liability). In other cases, courts decide that the polluter should compensate: (i) regardless of any fault (no fault liability such as strict liability and absolute liability), or (ii) based on proof of fault (fault liability). The Bill does not specify any liability regime. Therefore, it will remain open to the courts to determine the general civil liability arising out of any adverse impact of modern biotechnology.

The Nagoya Supplementary Protocol has stated that countries should have a liability regime for living modified organisms either based on general rules and procedures on civil liability or specific rules of liability developed for biotechnology.¹⁴ USA and Canada have not specified any liability in the relevant Acts.¹⁵ Australia, in its statute regulating biotechnology, has specified strict liability for offences such as dealing with a genetically modified organism without a licence and for breaching conditions of a licence. In addition, causing significant damage to health or safety of people or to the environment is an aggravated offence.⁹ The Norwegian statute imposes strict liability for causing damage, nuisance or loss through the deliberate or unintended release of genetically modified organisms into the environment.¹¹

Notes

1. The brief has been written on the basis of the Biotechnology Regulatory Authority of India Bill, 2013 introduced on April 23, 2013.
2. Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells 1989.
3. Report of the Task Force on Application of Agricultural Biotechnology (Chairperson: MS Swaminathan), Ministry of Agriculture, May 2004, <http://agricoop.nic.in/TaskForce/tf.htm>; Cultivation of Genetically Modified Food Crops –Prospects and Effects (Chairperson: Basudeb Acharya), Standing Committee on Agriculture, August 2012, http://164.100.47.134/lsscommittee/Agriculture/15_Agriculture_37.pdf.
4. Draft National Biotechnology Regulatory Bill, 2008, dbtindia.nic.in/Draft%20NBR%20Act_%2028may2008.pdf.
5. Aruna Rodrigues vs. Union of India, (2012) 5 SCC 331.
6. Clause 2 of the Bill states it is expedient in public interest that the Union regulate organisms, products and processes of the modern biotechnology industry. Hence, the legislative competence of the Parliament to enact this law flows from the Union List Entry 52 of the Constitution, which states that Parliament can regulate industries that it declares by law to be in public interest.
7. Preamble, Biotechnology Regulatory Authority of India Bill, 2013.
8. US Foods and Drugs Administration, <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/default.htm>; Health Canada, <http://www.hc-sc.gc.ca/sr-sr/biotech/about-apropos/index-eng.php>.
9. Gene Technology Act, 2000, <http://www.comlaw.gov.au/Details/C2011C00539>.
10. US Foods and Drugs Administration, <http://www.fda.gov/food/foodscienceresearch/biotechnology/ucm346030.htm>.
11. Gene Technology Act, 1993, <http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031>.
12. Section 2(m), National Green Tribunal Act, 2010.
13. Union of India vs. R. Gandhi, Madras Bar Association, Civil Appeal No. 3067 of 2004, Supreme Court Judgment on May 11, 2010.
14. Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, United Nations, adopted October 15, 2010, https://bch.cbd.int/protocol/NKL_text.shtml. India is a signatory to the Protocol; it is yet to come into force.
15. US: Federal Food Drug & Cosmetic Act, 1983; Federal Insecticide, Fungicide and Rodenticide Act, 1947; Plant Protection Act, 2000. Canada: Food and Drugs Act, 1985; Feeds Act, 1985; Health of Animals Act, 1990; Seeds Act, 1985; Plant Protection Act, 1990.

Comparison of recommendations of various Committees

Table 2: Comparison of recommendations of various committees on biotechnology and its regulation

Swaminathan Task Force (Agriculture)	CD Mayee Sub Committee (Agriculture – Bt Cotton)	Mashelkar Committee (Recombinant drugs)	SC on Agriculture (Agriculture)
Regulatory framework			
An autonomous statutory agency with specialised wings should be established. Members should have expertise in biosafety and biotechnology. Testing, evaluation and approval should be stringent, elaborate and science-based.	Regulatory agencies should have staff with technical expertise and the necessary infrastructure at their disposal to ensure the safety of environment and people.	Overlap in approval process of GEAC and Drugs Controller General of India has led to ambiguity. An independent and technically competent regulator with specialised wings is required. An approval process to deal with biotechnology drugs of varying risk levels should be created.	Independent statutory system is required; due to dearth of scientists in the current system, the approver and developer is the same. An overarching legislation on biosafety to ensure the safety of biodiversity, human and livestock health, and environmental protection is required. Regulators should implement a robust scientific review mechanism through a dedicated and qualified team. Till concerns of the Committee are addressed further research should only be done in strict containment and field trials should be stopped.
Recommendations on role of states			
Since agriculture is a state subject, a body should be established in each state to maintain liaison with the central regulator. State body should supervise trials and prevent the illegal release and proliferation of genetically modified seeds.	As agriculture is a state subject, State Agriculture Departments/Universities should be involved in monitoring. These departments should also be notified about field trials.	No comment.	Mandatory consultation should be held with states to seek permission for field trials. Most of the responsibility for the maintenance and operation at the field level should be given to the states.

Source: Report of the Task Force on Application of Agricultural Biotechnology (Chairperson: MS Swaminathan), Ministry of Agriculture, May 2004, <http://agricoop.nic.in/TaskForce/tf.htm>; Sub-Committee on Bt Cotton and Related Issues (Chairperson: CD Mayee), Ministry of Environment and Forest, June 2006, http://www.envfor.nic.in/divisions/csurv/geac/mayee_report.pdf; Report of the Task Force on Recombinant Pharma (Chairperson: Dr. Mashelkar), Ministry of Environment and Forest, August 2005, http://www.envfor.nic.in/divisions/csurv/geac/tforce_mashelkar_report.pdf; Cultivation of Genetically Modified Food Crops –Prospects and Effects (Chairperson: Basudeb Acharia), Standing Committee on Agriculture, August 2012, http://164.100.47.134/Isscommittee/Agriculture/15_Agriculture_37.pdf; PRS.

Note: A Technical Expert Committee set up by the Supreme Court submitted its report on the regulation and use of GM technology in agriculture in India in July 2013. However, the report is not available in the public domain.

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