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Available at: https://works.bepress.com/saravanan_a/1/
India and the international biosafety law: a critical legal appraisal of the Biotechnology Regulatory Authority of India Bill, 2013

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Abstract: In the case of biotechnology, one of the major challenges in the process of regulation is to establish and maintain an appropriate balance between potential benefits of the technology and environmental and health risks posed by it. Though this dilemma has been resolved to a certain extent, owing to the provisions of the Cartagena Protocol on Biosafety in the evaluation and the management of risks, the contracting parties face several difficulties and challenges in the development of the legal framework implementing the international obligations at the national level. It is in this connection, the paper attempts to find out how biotechnology is currently regulated in India and how it is proposed to be regulated under the Biotechnology Regulatory Authority of India (BRAI) Bill, 2013.

Keywords: biotechnology regulation; biosafety; Biotechnology Regulatory Authority of India; BRAI; India; Cartagena Protocol on biosafety; international law; international obligations; precautionary principle; Indian law; Supreme Court; environment; GM; genetically modified organisms; risk assessment.


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1 Introduction

Regulating any technology is not an easy task, as it presents both opportunities and challenges. In the case of biotechnology, one of the major challenges in the process of regulation is to establish and maintain an appropriate balance between potential benefits of the technology and environmental and health risks posed by it, both known and unknown. Though this dilemma has been resolved to a certain extent, owing to the provisions of the Cartagena Protocol on Biosafety in the evaluation and the management of risks, in view of the deferential language of the Protocol, the contracting parties face several difficulties and challenges in the development of the legal framework implementing the international obligations at the national level.

India is a party to the United Nations Convention on Biological Diversity and its Cartagena Protocol on Bio-safety. The Convention on Biological Diversity, in particular, requires that ‘each Contracting Parties, as far as possible and as appropriate, inter alia, establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology’. Similarly, the Protocol also mandates that each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol. Though these provisions collectively require that a legal framework governing the regulation, management and control of living modified organisms should be in place in each of the contracting parties, it is pertinent to note that the above provisions do not require a new or dedicated framework to be established in each of the contracting states post-ratification. In the case of India, most of its current rules and regulations related to biosafety are contained in the bygone Environment (Protection) Act, 1986 and in the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms and Genetically Engineered Organisms or Cells, 1989. However, as India is endeavouring to promote the safe use of biotechnology on a large scale and plans to invite the private capital and foreign players, it intends to de-regulate the biotechnology sector through the creation of an autonomous and independent regulatory authority so that it can better convince prospective business interests.

In fact, the need for creating such a mechanism was initially proposed by the Task Force on Application of Agricultural Biotechnology, commissioned by the Ministry of Agriculture. In its report, the Task-Force headed by Dr. M.S. Swaminathan had
underlined the need for creation of a ‘National Biotechnology Regulatory Authority’. Similarly, the Report of the Task-Force on Recombinant Pharma headed by Dr. R.A. Mashelkar also proposed the establishment of a ‘National Biotechnology Regulatory Authority/Commission’. As a consequence, several legislative proposals for the establishment of a national-level biotechnology regulator started emerging since 2008. Reflecting the real contentious nature of this regulation, especially in view of the vast farming community in India, the proposal went through several drafts, in 2008, 2009, 2011 and finally in 2013. The current version of the Bill, titled the Biotechnology Regulatory Authority of India (BRAI) Bill, 2013, was introduced on 22nd April, 2013.

It is in this connection, the paper attempts to find out how biotechnology is currently regulated in India and how it is proposed to be regulated under the BRAI Bill, 2013. For this purpose, it begins with the overview of the present regulatory mechanism of the biotechnology industry, as contained in the Environment (Protection) Act, 1986. This is followed by the discussion on the biotechnology regulation in India, as proposed by the BRAI Bill, 2013. However, the major focus of the paper will be devoted to the critical review of the BRAI Bill, 2013, especially in the light of India’s international commitments arising out of the UN Convention on Biological Diversity and the Cartagena Protocol on Biosafety. Finally, in the light of the above analyses, the paper underscores the achievements and the deficiencies of the proposed regulatory framework.

2 Present regulatory mechanism

Currently, the issues relating to the promotion and utilisation of biotechnology in India are not handled by any one Ministry or agency. While promotion of biotechnology is the responsibility of the Department of Biotechnology under the Ministry of Science and Technology, the responsibility for safe use of the technology is shared between a number of government ministries or departments.

The legal framework governing the safe use of biotechnology is primarily contained in the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms and Genetically Engineered Organisms or Cells, 1989 made under Sections 6, 8 and 25 of the Environment (Protection) Act, 1986. The Rules have defined the terms, biotechnology, genetic engineering and microorganism and brought them under their control. It paved the way for creation of number of bodies for the purpose of assessing the risks and monitoring the safety. In particular, it had created the Recombinant DNA Advisory Committee (RDAC), the Review Committee on Genetic Manipulation (RCGM), Institutional Bio-safety Committee (IBSC), Genetic Engineering Appraisal Committee (GEAC), State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC).

The Rules stipulates that the RDAC functioning under the Department of Biotechnology shall review developments in biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. On the other hand, the RCGM under the same ministry composed of representatives of the Indian Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR) and other independent experts shall review all ongoing research projects involving high risk category and controlled field experiments...
with a view to ensure safety. The Committee shall also lay down procedures restricting or prohibiting production, sale, importation and use of such genetically engineered organisms of cells as described in the Schedule to the Act.

At the apex of the entire framework, the Rules have created the GEAC, comprising of mostly officials of the government departments and councils and headed by the Additional Secretary of the Ministry of Environment and Forests. Over the years, this Committee became a very influential body in the area of biotechnology regulation in India, as it is endowed with the power of approval for activities involving large scale use of micro-organisms and recombinants in research and industrial production. The Committee also had the power to accord approvals for release of genetically engineered organisms and products into the environment including experimental field trials.

The regime, keeping the federal structure of the Indian governance in mind, created certain state-level and district level machinery for various regulatory needs. The SBCC is composed of officials of the state government and the Chairman of the State Pollution Control Board. The Committee had been given the power to inspect, investigate and take punitive action in case of violations of statutory provisions through the nodal department and the State Pollution Control Board/Directorate of Health or Medical Services. The machinery in the district is known as the DLC. The DLC is chaired by the District Collector and it will monitor the safety regulations in installations engaged in the use of GM organisms/hazardous micro-organisms and its applications in the environment. Also, the DLC/or any other person authorised in this behalf shall have the power to visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, and find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. It is also provided that it is not only the function of the DLC, but the duty of DLC to prepare an off-site emergency plan detailing how emergencies relating to a possible major accident at a site will be dealt with. The regime also ensured that a line of hierarchy runs between the SBCC and the DLC, by requiring that the DLC ‘shall regularly submit its report to the State Biotechnology Co-ordination Committee/Genetic Engineering Approval Committee’.

Additionally, the regime also required that an IBSC is to be established by every occupier handling micro-organisms or GM organisms as an internal body. The IBSC will assist the occupier in the development of an up-to-date on-site emergency plan according to the manuals/guidelines of the RCGM and make available the above information to the state and DLC.

The rules made it illegal to import, export, transport, manufacture, process, use or sell any hazardous micro-organisms or GM organisms or substances or cells without the approval of the GEAC. Similarly, approval or consent of GEAC is required in cases of

a commencement of production in which genetically engineered organisms or cells or micro-organisms are generated or used

b production, sale, import or use of substances and products, which contain genetically engineered organisms or cells or micro-organisms
Moreover, the Rules prescribe that such approval or consent may also be subject to certain terms and conditions as may be imposed by the GEAC\textsuperscript{23} and in any case not exceeding four years at the first instance,\textsuperscript{24} besides the responsibility to notify interruptions or accidents involving the GM substances to the SBCC/DLC concerned.\textsuperscript{25} The authorities also have the right to carry out inspection of public and private premises for the purposes of the Act.\textsuperscript{26}

The Rules as such does not criminalise the violation of the orders passed by any authority in accordance with the Rules. It merely focuses on the measures to be taken to prevent any damage to the environment, nature or health at the expense of the person responsible for the damage, ostensibly proceeding on the ‘polluter’s pays principle’.\textsuperscript{27} However, in such cases, the prescriptions of Section 15 of the Environment (Protection) Act, 1986 cannot be lost sight off which criminalises the contraventions and failures of the provisions of the Act as well as the Rules, orders and directions which are made under it. Section 15 prescribes that every instance of the violation will attract an imprisonment for a term which may extend to five years or a fine of one lakh rupees or with both. The Rules also had a skeleton provision for appeal from the orders of GEAC or SBCC to the authority notified by the Ministry of Environment and Forests.\textsuperscript{28}

However, several major issues were identified in the operationalisation of the above regulatory system.\textsuperscript{29} The chief among them is the lack of independence of the decision-making bodies from the governmental set-up. For instance, the apex body under the Rules (GEAC) is headed by the Additional Secretary of the Ministry of Environment and Forests. Thus, a need was felt for the creation of an independent regulator for regulation of bio-safety issues in India. Later, the point was also echoed by certain other committees.\textsuperscript{30} It is also pointed out that the SBCC or DLC mechanisms were either inoperative or ineffectual in several states leading to the ineffective implementation of GM regulation.\textsuperscript{31} Moreover, the biotech companies, both Indian and overseas, are not in favour of GM regulation under the exclusive control of the Ministry of Environment and Forests, who felt that the strict environmental standards and policies will affect the promotion of biotechnology and the business opportunities created by it.\textsuperscript{32} Also, the decisions of GEAC were also not free from the allegations of bureaucratisation, corruption, and nepotism.\textsuperscript{33}

Moreover, though the above Rules have attempted to regulate all activities relating to GMOs and their products, several agencies and organisations continue to regulate or have the potential to regulate certain aspects of GM organisms and products. For instance, the notification requiring the mandatory labelling for GM products had been interestingly issued by the Ministry of Consumer Affairs under the Legal Metrology Act, 2009,\textsuperscript{34} though with the passage of the Food Safety and Standards Act, 2006, regulation of GM food had come under the purview of the Food Safety and Standards Authority of India (FSSAI).\textsuperscript{35} However, as FSSAI had not so far come out with the regulation for GM foods, the issue continues to be regulated under the Rules of 1989.\textsuperscript{36}
Table 1  Comparison of current and proposed biotechnology regulatory approval process

<table>
<thead>
<tr>
<th>Sl. no.</th>
<th>Criterion</th>
<th>Current regulation</th>
<th>Proposed regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Legal foundation</td>
<td>The Environment (Protection) Act, 1986 – S. 6, 8 and 25</td>
<td>The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013</td>
</tr>
<tr>
<td>2</td>
<td>Key features</td>
<td>The Genetic Engineering Appraisal Committee (GEAC) and five other authorities, responsible for safety assessment and regulation of GMOs (Rule 4).</td>
<td>BRAI shall be an autonomous statutory regulatory agency of the Government of India to ensure comprehensive safety assessment and regulation of organisms (Preamble of the BRAI Bill).</td>
</tr>
<tr>
<td>3</td>
<td>Applicability</td>
<td>To manufacture, produce, transport, release, use, store, and handle GMOs (Rule 2).</td>
<td>To regulate the research, transport, import, environmental release, manufacture and use of organisms and products of modern biotechnology (Preamble of the BRAI Bill).</td>
</tr>
<tr>
<td>4</td>
<td>Ministries/agencies involved in the regulation</td>
<td>4 MoHFW – ICMR</td>
<td>6 MoCI – IMGB</td>
</tr>
<tr>
<td>5</td>
<td>Competent authorities involved in the regulation</td>
<td>GEAC: Total 30 members.</td>
<td>BRAI: Total five members.</td>
</tr>
<tr>
<td>6</td>
<td>Organisational structure</td>
<td>This composition consists of scientific and departmental members from various ministries (Rule 4(1)).</td>
<td>Consists of a Chairperson, two whole-time members and two part-time members to be appointed by the Central Government (Clause. 5).</td>
</tr>
</tbody>
</table>

**Notes:**
- BRAI – The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013
- GEAC – Genetic Engineering Appraisal Committee
- BRAI – The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013
- Notes: Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989; The Environment (Protection) Act, 1986; The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013; Damodaran, A. (2005) ‘Re-engineering biosafety regulations in India: towards a critique of policy, law and prescriptions’, 1 Law, Environment and Development Journal, p.1; and Seuba, X. and Correa, C. (2010) Biotechnology in India: Its Policy and Normative Framework, Catalonia Competitiveness Agency, Government of Catalonia, Ministry of Innovation, Universities and Enterprise; Ministry of Health and Family Welfare (MoHFW); Ministry of Agriculture (MoA); Ministry of Food Processing Industries (MoFPI); Ministry of Commerce and Industry (MoCI); Ministry of Environment and Forests (MoEF); Ministry of Science and Technology (MoST); National Bureau of Plant Genetic Resources (NBPGR); Ministry of External Affairs (MEA); National Productivity Council (NPCI); National Biotechnology Authority (NBA); National Academy of Agricultural Sciences (NAAS); National Agricultural Research System (NARS); National Academy of Sciences, Indian (NASI); National Academy of Sciences, US (NAS); National Academy of Sciences, Japan (NASJ); National Academy of Sciences, Korea (NASK); National Academy of Sciences, China (NASC); National Academy of Sciences, Brazil (NASB); National Academy of Sciences, Australia (NASAA); National Academy of Sciences, India (NASI); National Academy of Sciences, Alexandria (NASAL); National Academy of Sciences, India (NASI); National Academy of Sciences, Alexandria (NASAL); National Academy of Sciences, Alexandria (NASAL); National Academy of Sciences, Alexandria (NASAL); National Academy of Sciences, Alexandria (NASAL).
Table 1  
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| 7       | State level committee | • State Biosafety Committee to regulate the violation of GMOs through SPCBs at State level. It has power to inspect, investigate and take punitive action in case of violations of statutory provisions.  
• The composition consists of Chairman and eight members [R. 4(4)]. | • State Biotechnology Regulatory Advisory Committee acts as a nodal agency between State and the Authority in regulating modern biotechnology  
• Composition consists of eight representatives from different ministries (Clauses 35 and 36). |
| 8       | District level committee | • District Level Biosafety Committee to monitor the safety regulations at district level.  
• The composition consists of Chairman and seven members [Rule 4(5)]. | No such composition |
| 9       | Management structure or regulatory branches | No such divisions | BRAI have three regulatory divisions,  
1 Agriculture, forest and fisheries  
2 Human and animal health  
3 Industrial and environmental applications (C.21). |
| 10      | Regulation of agricultural biotechnology (field trials) | • Aforementioned committees play an important role in regulating agricultural biotechnology.  
• Particularly RCGM and GEAC are important, because they are responsible for release of GMOs in the environment and for biosafety research levels I and II trials [Rule 4(2) and 4(3)]. | BRAI is the sole regulator in approving Modern Biotechnology. It comprises following three units,  
1 RAU – to undertake science based safety assessment (Clause 22).  
2 PRC – for the purpose of making recommendations to the authority for manufacture or use of organisms and products (C.25).  
3 EAP – to make recommendations on environmental safety of organisms and products (Clause 26). |

Notes: BRAI – The Biotechnology Regulatory Authority of India or the Authority; CDSCO – Central Drugs Standard Control Organization; CSIR – Council of Scientific and Industrial Research; DIBT – Department of Biotechnology; DGGCI – Drug Controller General of India; DILC – District Level Committee; EAP – Environment Appraisal Panel; EPA Rules, 1989 – Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989; EPA Act, 1986 – The Environment (Protection) Act, 1986; GEAC – Genetic Engineering Appraisal Committee; GMOs – Genetically Modified Organisms; BSC – Institutional Biosafety Committee; ICAR – Indian Council of Agricultural Research; ICMR – Indian Council for Medical Research; MEA – Ministry of External Affairs; MoA – Ministry of Agriculture; MoCI – Ministry of Commerce and Industry; MoEF – Ministry of Environment and Forests; MoFPI – Ministry of Food Processing Industries; MoHFW – Ministry of Health and Family Welfare; MoST – Ministry of Science and Technology; NBPGR – National Bureau of Plant Genetic Resources; PRC – Product Rulings Committee; RAU – Risk Assessment Unit; RCGM – Review Committee on Genetic Manipulation; RDAC – Recombinant DNA Advisory Committee; SBCC – State Biotechnology Co-Ordination Committee.

Table 1

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<tr>
<td>11</td>
<td>Regulation of medical biotechnology (clinical trials)</td>
<td>• CDSCO and DGCI are responsible for approval of clinical trials, drug application and application for importation of drugs.</td>
<td>While CDSCO will forward the application to BRAI for assessment, CDSCO will regulate the clinical trial under the Drugs and Cosmetics Act, 1940, based on the BRAI’s recommendation (Clause 34.2)</td>
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<td></td>
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<td>• Medical Biotechnology is primarily controlled by DGCI.</td>
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<td></td>
<td>• DCGI is in charge of authorising clinical trials with recombinant products conducted with humans; these products must get final clearance from GEAC (Rule 7, 10 and 11).</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Other units</td>
<td>• National Bureau of Plant Genetic Resources (NBPGR) – controls importation of transgenic seeds and plants for research purposes.</td>
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<td></td>
<td></td>
<td>• No such Environment Unit.</td>
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</tr>
<tr>
<td>13</td>
<td>Adjudicating authority and appeals</td>
<td>Person aggrieved by decision of the GEAC or SBCC may appeal to such authority appointed by MoEF within 30 days from the date on which decision is communicated to him (Rule 19).</td>
<td>Any person aggrieved by decision of the Authority may appeal to Biotechnology Regulatory Appellate Tribunal, within 30 days from the date on which decision communicated to him (Clause 43).</td>
</tr>
<tr>
<td>14</td>
<td>Penalties</td>
<td>Few penalties are mentioned in Rule 5, but not specifically defined.</td>
<td>1 Punishment for providing false information – three months imprisonment and Rs. 5 lakh fine.</td>
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<td></td>
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<td>2 Punishment for conduct of un-approved Field trial – 1 year imprisonment and Rs. 2 lakh fine.</td>
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<tr>
<td></td>
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<td></td>
<td>3 Punishment for abetor – two years imprisonment and Rs. 10 lakh fine (Clauses 60 to 69).</td>
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</table>
3 Proposed BRAI regime

3.1 Institutional framework

The proposed framework is the first attempt to create a comprehensive legislative framework covering all aspects of the utilisation of biotechnology. The preamble of the Bill expressly declares that it is seeking to establish regulatory framework in accordance with the requirements of the Cartagena Protocol on Bio-safety. The Bill also made it clear that it was brought for the purpose of consolidation of the existing regulatory policies, rules and services made under statutory and autonomous agencies.

The proposed framework seeking to create a national-level independent and autonomous regulator charged with the ‘duty’ of regulating the research, transport, import, manufacture and use of GM organisms and products, known as the BRAI (The details of comparison between the current framework and the proposed framework can be found in Table 1). It is provided that the body shall comprise of one chairperson, two full-time members and two part-time members who are either accomplished biologists or medical scientists. The proposed body is envisioned as the apex authority for all scientific and technical advice, policy formulation and regulatory guidance relating to biotechnology. It shall also monitor, review, and analyse national and international policies which may affect priorities, and develop and implement guidelines for safety assessment methodologies for products and processes. The Authority is also empowered to make regulations relating to the all processes and other new products of modern biotechnology, in particular, import, transport, research, field trials, pre-clinical evaluation and environmental release.

It is submitted that as biotechnology has both benefits and risks, the creation of an independent regulator to harness the technology subject to conditions and safeguards will not be a faulty decision. In fact, it is a laudable initiative and is to be welcomed. However, with regard to the composition of the BRAI, it is desirable to make it more representative than the existing five members. This would be particularly necessary as the body had to adjudicate on enormously complex issues, including questions on scientific evidence taking into account the entire spectrum of scientific opinions. However, the Bill tried to moderate this need by creation of an advisory body called, the Biotechnology Advisory Council comprising of 15 members to render strategic advice to the Authority. Though the Bill provided that the Council membership will reflect, as far as possible, the broadest geographical representation within the country, there is no provision for consultation (especially with States) as provided in Section 100 of the Australian Gene Technology Act, 2000.

The proposed law also provided for the constitution of Inter-Ministerial Governing Board with representatives from concerned Ministries, Departments, Councils, Directorate, authorities and officers of the Central Government, such as Ministry of Science and Technology, Ministry of Environment and Forests, Ministry of Health and Family Welfare, and Ministry of Agriculture. It will be presided by the Secretary in the Department of Science of Technology. This new body is expected to promote Inter-Ministerial or Departmental coordination among the various governmental units dealing with the issues of biotechnology. The Board is also given the substantive power to recommend the appointment of all members of the Biotechnology Advisory Council (except the Presiding Officer of the Council). As the frequency of meetings and the required quorum for the Board will be known only after the making of the rules in this
regard, a clear picture on the utility of the forum will be known only after the operationalisation of the Board.

The statute also brings the biotechnology product development within the purview of the BRAI. Accordingly, the statute provides for the creation of Products Rulings Committee for the purpose of making recommendations to the Authority in respect of authorisations for manufacture or use of organisms and products. Though the procedures for the functioning of the Committee were left to the delegated legislation, the Bill itself prescribes the composition of the Committee. The Committee shall be chaired by one of the members of the Authority nominated by the Chairperson of the Authority with the membership of all Chief Regulatory Officers of the Divisions, one representative from the Central Drugs Standards Control Organization (CDSCO) to be nominated by the Central Government, at least three and not exceeding five scientific experts from out of the roster of experts appointed by the Authority and at least one of such expert shall be nominated by the Ministry of Environment and Forests.

The proposed regime also provides that the environmental appraisal will become an integral part of the BRAI regime. This is quite in contrast to the current system of environmental impact assessment being directly handled by the Ministry itself. The Bill proposes that the Authority shall constitute an EAP consisting of a representative of the Ministry of Environment and Forests, Government of India (who shall be the chairperson of the Panel) and such other members not exceeding five whose qualification and experience will be as prescribed by the Authority. The Panel will make recommendations on matters referred to it by the Authority. Thus, it becomes clear that the final authority on questions of environmental appraisal will rest with the Authority. However, under the current system, the states are also given a crucial role through the State-level Environmental Impact Assessment Authority (SEIAA).

It is interesting to note that while states have been denied the role in the decision-making as above-mentioned, on questions of enforcement of decision, BRAI has been empowered to delegate the powers of enforcement on any State Governments or any other authority. However, the Bill provides for the creation of its own Enforcement Unit consisting of Monitoring Officers.

3.2 Jurisdictional framework

The Bill has divided the jurisdictional subject-matter of BRAI into three categories. While the subjects mentioned in the Part I of Schedule I of the Bill will constitute the exclusive domain of the BRAI in so far as they are relating to the research, transport, import, manufacture and use of organisms and products therein, the Authority can exercise only a limited power in respect of the items mentioned in Part II. It is empowered to make regulations only in respect of transport, containment, research including pre-clinical evaluation and environmental release of organisms and products mentioned in Part II. Especially, with regard to import of organisms and products mentioned in Part II, it is provided that jurisdiction will be restricted to research and development purposes.

It is stipulated that the Authority mainly functions through three Divisions. These Divisions have been structured on the lines of the Schedule I. In other words, each Division will be responsible for the subjects covered under each Part of the Schedule I. Each regulatory division will be presided over by a Chief Regulatory Officer and will be assisted by a panel of scientific experts.
3.3 Risk assessment and approval process

The proposed statute also prescribes the procedure for the conduct of risk assessment. The scrutiny by the Risk Assessment Unit has been made mandatory for all applications of authorisations.\(^46\) However, different procedures will apply depending on whether the application is for purposes of ‘research, transport or import’ or ‘manufacture or use’. In case of the former, ‘the Authority shall forward every application to the Risk Assessment Unit which shall undertake a science-based evaluation and submit a clear assessment as to the safety of the proposed research, transport or import of organisms or products to the Authority’.\(^47\) In addition, the Authority is also obligated to consider ‘all other relevant matters’ and shall have the power to grant or refuse the authorisation, depending on its conclusion on the safety or otherwise of the organism or product. The Authority is also competent to impose conditions while granting authorisations.

On the other hand, in the case of the applications for ‘manufacture or use’ of organisms or products, the risk assessment report prepared by the Risk Assessment Unit is to be forwarded to the Product Rulings Committee for its recommendations, instead of directly sending it to the Authority. Moreover, the Authority shall also obtain the opinion of the Environmental Appraisal Panel (EAP) in cases of potential environmental impact. However, in cases of difference of opinion between the Environmental Appraisal Panel (EAP) and the Authority, the Authority shall pass an order. In cases of refusal, the Authority shall pass orders after recording the reasons and shall furnish the copy to the applicant for pursuit of legal remedies. As a novel feature, the statute also provides that the Authority shall invite suggestions or objections from the public before the final decision.

3.4 Field trials and clinical trials

Currently, in India field trials are governed by the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms and Genetically Engineered Organisms or Cells, 1989,\(^48\) made under the Environment (Protection) Act, 1986 and subject to the regulation of the RCGM and the GEAC. These provisions are supplemented by the Guidelines for the Research in Transgenic Crops, 1998 and the recent Guidelines for the Conduct of Confined Field Trials of Regulated, GE Plants in India, 2008 along with a host of other guidelines applicable to bio-safety.\(^49\) The Guidelines of 2008 referred to above provides for the procedure to be followed for the approval or authorisation for field trial in the following terms:\(^50\)

> “The initial assessment of an application for a confined field trial begins at the institutional level itself. Based on information generated by the applicant in the laboratory and the greenhouse, an application is made to the IBSC for permission to conduct a confined field trial. The IBSC evaluates the proposal for conducting a field trial and, if recommended by the IBSC, the applicant may submit the application to RCGM.

RCGM, functioning in the DBT, is the Regulatory Authority for Bio-safety Research Level I (BRLI) trials. These trials are limited in size to no more than 1 acre (0.4 ha) per trial site location and a maximum cumulative total of 20 acres (8.1 ha) for all locations for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.
GEAC, functioning in the MoEF, is the Regulatory Authority for Bio-safety Research Level II (BRLII) trials. These are limited in size to no more than 2.5 acres (1 ha) per trial site location and number of locations to be decided on a case by case basis for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season."

However, under the proposed BRAI regime, the Authority will have the power to permit field trials in respect of items specified in Part I and III of Schedule I with such safeguards as it may consider necessary and which may be specified by the regulations. Thus, the future direction of the clinical trials in India will be known only after the formulation of regulation by the Authority in this regard.

On the question of clinical trials, the current framework for clinical trial is contained in the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. The primary objective of the Act is to, *inter alia*, ensure that the drugs available in India are safe and efficacious and conform to standards of quality. The Act had established CDSCO and designated its principal officer as Drugs Controller General of India (DCGI). The Drugs and Cosmetics Rules of 1945, in particular, Schedule Y establishes a set of regulatory guidelines and requirements for clinical trials. It defines the requirements for import or manufacture of new drugs for sale or for clinical trials. The CDSCO had issued certain guidelines in the form of Good Clinical Practices (GCP) Guidelines for Clinical Research in India. This is supplemented by the Indian Council for Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants, 2006.

Though the BRAI Bill does not intend to alter this scheme, it provides that in respect of organisms and products specified in Part II of Schedule I, the Authority may evaluate and ‘recommend’ clinical trials only after the applications are forwarded by the Central Drugs Standard Control Organization in accordance with the provisions of Drugs and Cosmetics Act, 1940 and the rules and regulations made there-under. It is also further clarified that the Authority shall not ‘grant’ any permission or authorisation to conduct any clinical trial but at the same time, it shall have the power to authorise any trial in laboratory or in containment for pre-clinical testing preceding clinical trial.

### 3.5 Mechanisms in the states

The BRAI Bill proposes that every state shall constitute a State Biotechnology Regulatory Advisory Committee, comprising mostly officials of the state government and presided over by the Head of the Department of Biotechnology or in its absence by the Department of Science and Technology in the states. The reading of the provisions of the Bill show that the Committee has been envisaged for purposes of interaction between the Authority and the State Government, to facilitate inter-departmental coordination in the states, capacity-building and information dissemination of activities and programs of the Authority. However, it would be prudent to entrust the Committee with certain regulatory, decision-making and inspection functions, as it is name implies.
3.6 Biotechnology regulatory appellate tribunal

The BRAI Scheme also intends to establish a statutory appellate tribunal entrusted with the jurisdiction ‘over all civil cases where a substantial question relating to modern biotechnology is involved and such question arises out of the safety and use of organisms, products and processes referred to in any one of the part of the Schedule I of the Act’.54

It is provided that the Tribunal shall consist of one full-time Chairperson and not exceeding five part-time members. While the Chairperson may be current or former judge of the Supreme Court of India or the Chief Justice of the High Court, the part-time members may be drawn from the community of scientists or former bureaucrats. In the case of former bureaucrats, it is provided that they should have held the post of Joint Secretary either in the Central or State Government for a period of not less than three years. In this connection, a question arises as to the desirability of appointing former officials who might have involved in the formulation of policies or rules and regulations relating to the application of biotechnology in the recent past. It is interesting to note that the statute does not have any provision on the requirement of conflict of interest, even as a requirement for consideration of names by the Selection Committee. On the contrary, Clause 7(5) stipulates that ‘before recommending any person for appointment as a Chairperson or a Member of the Authority, the Selection Committee shall satisfy itself that such person does not have any financial or other conflict of interest, which is likely to affect prejudicially his functions as Chairperson or Member’.55 It is submitted that in view of the highly contentious nature of the cases to be handled by the Tribunal, the Tribunal should be envisioned as a strong institution.

However, it is gratifying to note that the independence of the office of the Chairperson of the Tribunal in the matter of appointment is adequately secured through the provision of consultation with the Chief Justice of India. Similarly, it is provided that ‘any person’ who is aggrieved by the decision or order or direction of the Authority may file an appeal to the tribunal. Thus, it can be argued that even a member of the general public who is aggrieved by the decision etc may prefer an appeal to the Tribunal.

Besides, the Bill also makes provision for notification of accredited laboratories or research institutions.56 This is expected to solve the problems associated with the testing facilities. The Bill also enables the Authority to constitute one or more Scientific Advisory Panels to provide scientific advice, information and recommendations on issues relating to the actions of the Authority and safety of human and animal health and the environment.57

3.7 The legal appraisal

The first and foremost objection for the BRAI Bill, 2013 is that it is against the provisions of the Cartagena Protocol on Bio-safety, especially its precautionary approach.58 It is pertinent to remember that a number of provisions of the Protocol expressly recognise the precautionary approach.59 Also, India has ratified the Protocol and it has entered into force on 11th September, 2003.60 However, it is pointed out that the Preamble of the Bill merely refers to the Protocol as a formality and it contradicts the provisions and the spirit of the Protocol.61 It is argued that if the government is serious in implementation of the Protocol and wanted to make the precautionary approach as the major focus of the new regulatory regime, it should have expressly declared that
precautionary approach will be the basis of any bio-safety decision making, as it was done under Section 4 (aa) of the Australian Gene Technology Act, 2000. The Bill also does not adequately make use of the provisions contained in Article 26 of the Protocol which gives the Parties the right to take into account socio-economic considerations, consistent with the international obligations. However, the Authority at the time of grant of authorisation either under Clause 24 or 27, has not been specifically mandated to look into the ‘socio-economic considerations, as required under Article 26 of the Protocol.

Moreover, it is contended that the Bill does not provide for any public consultation (or consultation with interests likely to be affected by it), as required under Article 23 of the Protocol. Article 23 provides that the ‘parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21’. The IUCN Explanatory Guide to the Cartagena Protocol on Biosafety considers this provision as laying down ‘affirmative obligations on Parties’ and opined that the obligation applies to ‘all decision-making processes regarding LMOs, including the making of decisions on import of LMOs’. However, Clause 27 (5) merely enables the Authority ‘to obtain objections or suggestions from the public’ during the grant of authorisation for manufacture or use of organisms or products. It is needless to observe that obtaining objections or suggestions is not the same thing as public consultation. It is to be noted that though the scope of public consultation will itself be determined by domestic laws and regulations in terms of the Protocol, the invitation of objections or communication of decisions cannot be considered to constitute public consultation. Hence, it is suggested that the Bill should be modified to provide a public consultation mechanism.

Also, it is relevant to note that India is a signatory to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, though it has not ratified it so far. The Supplementary Protocol contains the rules and procedures in the field of liability and redress relating to living modified organisms. However, the proposed legislation is completely silent on how to determine the liability in cases of damage relating to the LMOs or GMOs. Though it is true that India has not undertaken any obligation under the Supplementary Protocol, the Indian legislation is at least expected to have a clause on liability and redress as such issues are bound to arise even under the proposed regime.

Though the Bill is in accordance with the established notions of corporate criminal liability by making the ‘the person who at the time the offence was committed was in charge of, and responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence’, it exempts that person from the liability ‘if he proves that the offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence’. This is understandable given the need for commercialisation of certain genetically modified food or crops with the investment and support of private players, application of the same exemption to the civil liability will be having disastrous consequences. In this connection, it is pertinent to remember the principle of absolute liability laid down by the Indian Supreme Court in the case of M. C. Mehta v Union of India, popularly known as the Shri Ram Food and Fertilizer case.
The Supreme Court was of the opinion that:

“an enterprise which is engaged in a hazardous or inherently dangerous industry which poses a potential threat to the health and safety of the persons working in the factory and residing in the surrounding areas owes an absolute and non-delegable duty to the community to ensure that no harm results to anyone on account of hazardous or inherently dangerous nature of the activity which it has undertake.”

It also explained the rationale of the rule in the following terms:

“If the enterprise is permitted to carry on an hazardous or inherently dangerous activity for its profit, the law must presume that such permission is conditional on the enterprise absorbing the cost of any accident arising on account of such hazardous or inherently dangerous activity as an appropriate item of its overheads. Such hazardous or inherently dangerous activity for private profit can be tolerated only on condition that the enterprise engaged in such hazardous or inherently dangerous activity indemnifies all those who suffer on account of the carrying on of such hazardous or inherently dangerous activity regardless of whether it is carried on carefully or not. This principle is also sustainable on the ground that the enterprise alone has the resource to discover and guard against hazards or dangers and to provide warning against potential hazards.”

The court also remarked that:

“[The above principle of liability will] not [be] subject(ed) to any of the exceptions which operate vis-à-vis the tortious principle of strict liability under the rule in Ryland v. Fletcher.” And

“The measure of compensation in the kind of cases referred to in the preceding paragraph must be correlated to the magnitude and capacity of the enterprise because such compensation must have a deterrent effect.”

Though there is no decisive reply to the question of whether GM technology is ‘hazardous’ or ‘inherently dangerous’, especially, in view of the decision of US Food and Drugs Administration that ‘foods developed through genetic modification’ are not inherently dangerous’, morality require that corporations should accept the liability for such environmental harm.

Moreover, Clauses 62 to 66 of the Bill enable the imposition of heavy penalties as a part of the criminal law machinery to deter violations of the provisions of the law. However, it is significant to note that the above provisions are silent on the question of the award of ‘compensation’ for the harm resulted and the cost of restoration of damaged environment. But in view of the law declared by the Supreme Court in the case of Vellore Citizen Welfare Forum v Union of India enunciating the ‘polluter pays’ principle, it is inherent that the cost of restoration of the damaged ecology due to introduction of genetically modified food or crops should be recovered from the polluter. Moreover, even Rule 15 of the existing Rules of 1989 can be considered to reflect upon this principle, as it provides that the expenses incurred in taking the necessary steps in preventing any damage to the environment, nature or health, will be payable by the person responsible for such damage. Thus, there is a clear imperative to provide for recovery of the cost of restoration of damaged ecology from the GM producers.

The role of state governments in the existing and the proposed biotechnology regulatory systems has already been discussed. The examination of the provisions of Clause 35(6) discloses that states are not given any role in the process of decision-making
or even in independent inspection and verification. On the contrary, states are just given certain powers of coordination and collaboration and nothing more. Also, no representation for states in the proposed regime either in the selection process of the Chairperson or any member of the Authority or even in the constitution of the proposed Biotechnology Advisory Council. Thus, state governments are completely kept out of the process. Though Clause 2 of the Bill declares that in view of the expediency in the public interest, the Union Government decides to control the regulation of organisms, products and process of modern biotechnology industry, ostensibly in exercise of Entry 52 of List I of Schedule 7 of the Indian Constitution, owing to the fact that ‘agriculture’ being a State subject, the states would want to be heard or have some powers over the growth and cultivation of GM crops. Thus, it is suggested that state governments should be given an appropriate role in the proposed regulatory regime.

4 Conclusions

In the overall assessment, the Bill tries to bring out a skeleton mechanism on regulating the biotechnology in India, without a crucial commitment and decision as to the vital principles of regulation, such as precautionary approach, polluter pays principle and absolute liability for hazardous activities. This also cast a shadow of doubt on the fulfilment of India’s international commitments, especially under the Cartagena Protocol on Bio-safety. Consequently, the current form of the Bill failed to build a broad consensus among the industry, scientists and the non-governmental organisations on the nature and extent of regulation. While it is true that efficiency of the technology regulation is desirable, it should not be at the cost of genuine bio-safety concerns. However, the positive contributions of the Bill cannot be under-estimated. The Bill tries to institutionalise an autonomous regime which is free from direct government control. Also, the Bill makes an attempt for greater involvement of scientists at a number of levels and stages of decision-making through the Scientific Advisory Panels and the Biotechnology Advisory Council. The Bill also seeks to create an Inter-Ministerial Governing Board and thereby attempts to solve many of the issues of the public administration relating to the regulation of the biotechnology. It is emphasised that a stronger biotechnology regulatory regime in India can be built only by striking a finer balance between efficiency and the goals of safety.

Notes


Paragraph 16.1 recommended that “keeping in view the rapid strides being taken in the area of agro- and food biotechnology research and application, there is a need for setting up a National Biotechnology Regulatory Authority”.


For details, see Government of India (Allocation of Business Rules), 1961.


Act No. 29 of 1986.


Rule 4(1).

Rule 4(2).

Rule 4(3).

Rule 4(4).

Rule 4(5).

Rule 4(6).

Rule 17.

Rule 7(1).

Rule 8.

Rule 10.

Rule 11.

Rule 13.

Rule 13(2).

Rule 16.

Rule 18.

Rule 15.

Rule 19.

In the case of Aruna Rodrigues v Union of India (Writ Petition (Civil) No. 260 of 2005), the Supreme Court-appointed Technical Expert Committee (TEC) had recommended a ten-year moratorium on open field trials of transgenic food crops until adequate regulatory mechanisms and safety standards are put in place.

Supra, notes 5 and 6.

Biswajit Dhar, Globalization and the International Governance of the Modern Biotechnology: Regulating Biotechnology in India, Research and Information System for the Non-Aligned and Other Developing Countries, New Delhi, p.19 (‘although a decentralized structure has been provided for carrying out the regulatory functions, no real attempt seems to have been made to make it respond to the problem at hand’).
The proposed system received a strong support from a number of biotech business organisations. See Koul, R. (2013) ‘BRAI bill deadline extension fails to dampen biotech industry’s spirits’, *BioSpectrum*, 11 July.


Act No. 34 of 2006.

Notification No. S.O. 1519 (E), dated 23rd August 2007 of the Ministry of Environment and Forests exempting the “food stuffs, ingredients in foodstuffs and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organism” had been stayed by the Ministry as the FSSAI had not so far formulated the necessary rules for the purpose.

Paragraph 5 of the Statement of Objects and Reasons (“In order to implement the recommendations of the aforesaid Task Forces, and to give effect to certain provisions of the aforesaid Convention and Protocol”).

Clause 18.

Clause 16.

Clause 15.

Clause 25.

S.O. 1533 (E) of the Ministry of Environment and Forests, Government of India, dated 14th September 2006 and amendments issued to the above notification.

Clause 26.

Paragraph 3 of the S.O. 1533 (E) of the Ministry of Environment and Forests, Government of India, dated 14th September, 2006. However, still it might be possible for the Authority to give a decisive role to the states, if it makes use of the provisions contained in Clause 38 of the Bill rightly. It provides that the Authority shall establish such mechanisms, in consultation with the concerned State Governments, State Biotechnology Regulatory Advisory Committees or any other authority, as may be considered necessary to facilitate enforcement of the provisions of the Act.

Clause 23.

Clauses 24 and 27.

Clause 24(2).

Rule 4(4).

The other guidelines include


b Guidelines For Generating Preclinical and Clinical Data for r-DNA Vaccines, Diagnostics and Other Biologicals, 1999.

c Standard Operating Procedures (Sops) for Confined Field Trials of Regulated, Genetically Engineered Plants, 2008.


At pages 2 and 3.

Clause 34(1).
India and the international biosafety law


53 Clause 34(2). The organisms and products over which the BRAI will have authority to recommend for field trial, as mentioned in Part II of Schedule I are: (a) re-combinant proteins and combinations thereof; (b) DNA vaccines intended to induce or increase an antigen specific immune response for prophylactic or therapeutic immunization, regardless of the composition or method of manufacture; (c) vaccines for use in humans or animals that contain living genetically engineered organisms; (d) cellular products, including products composed of human, bacterial or animal cells (such as pancreatic islet cells for transplantation), or from physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines); (e) recombinant gene therapy products including nucleic acids, viruses, or genetically engineered micro-organisms that mediate their effect by transcription and/or translation of the transferred genetic material, and or by integrating into the host genome and cells may be modified in these ways ex vivo for subsequent administration to the recipient, or altered in vivo by gene therapy products administered directly to the recipient; (f) transgenic blood or plasma derived products; (g) stem cell based products; (h) RNA interference (RNAi) based products; (i) products of synthetic biology for human or animal use; (j) any products that include as a component of a product from categories (a) to (i) above”.

54 Clause 56. Also, see National Green Tribunal Act, 2010.

55 Again, Clause 6(1) of the Bill lays down ‘integrity’ as a qualification for appointment as Chairperson of the Authority. In this connection, it is pertinent to keep in mind the decision of the Supreme Court in the case of Centre for PIL and Another v Union of India and Another [2011) 4 SCC 1], expounding the concept of institutional integrity. Also See Clause 21(7) of the Bill, on conditions of the office of Chief Regulatory Officer of the Authority.

56 Clause 41.

57 Clause 29.


59 For instance, Article 1 of the Protocol stipulates that the objective of the instrument is to be achieved ‘in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development’. Also, Articles 10(6) and 11 (8) provide that lack of scientific certainty relating to the potential adverse effects of a living modified organism shall not prevent the Party of import from taking the decision relating to the trans-boundary movement or intended for feed or food or for processing. Also see Mackenzie, R., Burhenn-Guilmin, F. and La Viña, A.G.M. et al., An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN Environmental Policy and Law Paper No. 46, IUCN Environmental Law Centre, UK.


61 Centre for Legislative Research and Advocacy, Policy Brief for Parliamentarians: The BRAI Bill, 201: A Threat to Our Food and Farming, No. 19, 2013.

62 Section 4 (aa), inter alia, provides that “the object of this Act is to be achieved through a regulatory framework which; provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost effective measures to prevent environmental degradation”.

63 See Note 54 above.
Article 26: “The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities”.

It is opined that the expression ‘all other relevant matters’ found in Clause 24(3) and Clause 27(6) may not be quite sufficient to address these considerations.


Paragraph 594 at p. 150.

Clause 27(5) of the Bill.

The status of Supplementary Protocol is available at http://bch.cbd.int/protocol/parties/#tab=1 (accessed 14 April 2014). Also see Article 18 for the entry-into-force clause which provides that the instrument shall enter into force on ninetieth after date of deposit of fortieth instrument of ratification or acceptance or approval or accession.

The only obligation on a state which has signed the international instrument pending ratification is that it would refrain from acts that would defeat the objects and purposes of a treaty in accordance with the good faith principle in international law. Advisory Opinion on the Legality of the Threat or Use of Nuclear Weapons, 8 July 1996, ICJ Rep. (1996).

Proviso to Clause 67(1).


(1996) 5 SCC 647.

Ibid. at p.659 (The ‘Polluter Pays’ principle as interpreted by this Court means that the absolute liability for harm to the environment extends not only to compensate the victims of pollution but also the cost of restoring the environmental degradation. Remediation of the damaged environment is part of the process of ‘Sustainable Development’ and as such polluter is liable to pay the cost to the individual sufferers as well as the cost of reversing the damaged ecology’).

However, this will be a requirement only if the producers of the GM products considered to fall within the expression ‘polluter’.

Also, Rule 18(3) provides that “the Genetic Engineering Approval Committee may fix fees to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervisions and control”.


Entry 14 of List II, Schedule 7 of the Indian Constitution (agriculture, including agricultural education and research, protection against pests and prevention of plant diseases).