Creating an Undemocratic and Unaccountable Biotechnology Regulator

A critique of the Biotechnology Regulatory Authority of India Bill, 2011, with particular emphasis on environmental laws

by

Leo F. Saldanha and Bhargavi S. Rao[1]
Environment Support Group[2]

November 2011

Background:

The Biotechnology Regulatory Authority of India Bill, 2011 (Bill No. 54 of 2011, BRAI Bill, 2011)[3] was proposed by Shri. Vilasrao Deshmukh, Minister of Science and Technology and Earth Sciences, in the Monsoon Session of the Lok Sabha on 27th July 2011. However, it was not taken up as the Parliament was rocked by heated debates and protests against the arrest of Anna Hazare and others who were demanding the institution of the Lokpal. The Bill was withdrawn them only to be re-introduced in for debate and discussion during the Winter Session of the Parliament commencing 22nd November 2011. It appears that this time too, the Bill may not be taken up, as the Parliament is now rocked with protests against the Government's proposal to allow Foreign Direct Investment in single brand retail, amongst other issues.

Introduction:

Ever since the Cartagena Protocol on Biosafety (brought into force as a part of the Convention on Biological Diversity, 1992) came into effect in 2003[4] and the M. S. Swaminathan headed Task Force on Application of Agriculture Biotechnology in its report (henceforth referred to as the Task Force Report)[5] that was accepted by the Union Ministry of Agriculture in 2004 recommended the need for establishment of an independent and autonomous biotechnology regulatory authority, the Government has been under pressure to enact a law to institute such an Authority. In recent years another compelling reason has emerged for regulating biotechnology resulting from the largely unsatisfactory experience with existing regulatory systems established under the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms and Genetically Engineered Orianisms or Cells, 1989 enacted under the Environment Protection Act, 1986 (hereinafter referrred to as 1989 Rules)[6] and monitored by the Union Ministry of Environment and Forests (MoEF). There have also been too many controversies over the lack of transparency and competence in existing decision making processes relating to this sector, especially given the experience with B.t. Brinjal, India's first food GMO awaiting an approval decision.

It is widely known that biotechnology as a sector has crosscutting and complex impacts on various aspects of life and livelihoods in this large and diverse country where a majority of the population farm. The technology also has many implications for the country's biodiversity and public health, and certainly on the economy.

Regulating an high growth sector:

According to Indian Brand Equity Foundation (IBEF)[7], "India is ranked among the top 12 biotech destinations worldwide and third largest in the Asia-Pacific region. The biotechnology sector grew by 21.5 per cent in 2010-11, to

1 The authors may be contacted at leo@esgindia.org and bhargavi@esgindia.org

2 More details of Environment Support Group can be accessed at: www.esgindia.org

3 A copy of the Bill as tabled in the Parliament is accessible at: http://www.prsindia.org/uploads/media/Biotech/Biotech%20Regulatory%20Auhority%20Bill,%202011.pdf

4 The text of the Cartagena Protocol is accessible at: http://bch.cbd.int/database/attachment/?id=10694

5 The entire report can be accessed on the website of Dept. Of Agriculture and Cooperation of the Union Ministry of Agriculture at: http://agricoop.nic.in/TaskForce/index.htm

6 A copy of these Rules can be accessed on MoEF website at: http://envfor.nic.in/legis/hsm/hsm3.html

7 http://www.ibef.org/industry/biotechnology.aspx

cross the US$ 4 billion mark, as revealed by an annual survey conducted by BioSpectrum and Association of Biotech Enabled Enterprises (ABLE)." The Foundation reports that "India's biotechnology industry is expected to reach US$ 10 billion, in terms of revenue from the current US$ 4 billion, by 2015." Clearly, therefore, the biotechnology sector is amongst the most robust growth sectors. The report also reveals that the growth of this sector is uneven across the country and that "the State of Karnataka contributes around 40 per cent of the Indian biotechnology sector". The report cites the former Chief Minister of Karnataka Yeddyurappa as having stated during India Bio 2011, that Bangalore alone "...hosts 52 per cent of the core biotechnology companies in the country and around five top biotech companies are in the city".

For a high growth sector with massive investments from Indian and Foreign corporate sectors, there is quite obviously a strong lobby that would ensure that any required regulation of the sector would be pro-sector. Needless to state, there have been many well coordinated campaigns from the biotech sector to ensure that the regulatory mechanism evolved would not impede the financial expansion of this sector in any manner. Also, the emphasis has been on addressing the high environmental and health risks involved in a rather ritualistic manner.

In such situations, it is for the Government to ensure that a wholistic and balanced view is taken without yielding to lobby induced pressures. Instead the process by which the Bill has been formulated has been highly secretive. A careful review of the Bill leaves one with a disconcerting feeling that an highly calibrated effort has been at play to establish a Biotechnology Regulatory Authority of India (BRAI) as an highly undemocratic authority. As proposed now, BRAI will be accountable mainly to the Centre and absolutely impervious to wider concerns of our society. States have at best been granted an insignificant side role in affecting decisions or monitoring biotechnology initiatives, while the constitutionally guranteed role of Local Governments to be involved in such matters is absolutely disregarded. The BRAI Bill, therefore, is nothing short of an effort to locate all powers of decision making and regulation of biotechnology with a coterie of officials appointed directly by the Cabinet Secretary and other bureaucrats representing various Central Ministies. There is some oversight offered in the form of from an Inter-Ministerial Committee at the Centre, once more filled with bureaucrats. Needless to state there cannot be a more intransparent and undemocratic structure of governance of any sector.

It should have been a bill to democratically and transparently regulate biotechnology respectful of the federal nature of our governance. Such concerns would have backed the legislative proposal were the Government truly interested in safequarding multiple interests and futures of diverse sectors that are affected. The Consitution in fact requires the Centre initiate nation-wide discussions and debates on such a critical Bill with cross-cutting impacts. Instead, the Centre has been exceptionally intransparent and deeply undemocratic. This is indicative by the fact that not even a copy of the Bill is accessible on the Parliament's website[8].

There is little doubt now that the Union Government intends to push this legislation through Parliament, even when States and Local Governments, and the wide public largely constituted by farming communities, have no opportunity whatsoever to comprehend its impacts on their lives, livelihoods and their collective futures. Such efforts echo very strongly of slick tactics that were employed in piloting through Parliament in 2005 the highly controversial and unjust Special Economic Zone Act with hardly any debate. The question looming large now is if the BRAI Bill, 2011 will similarly subordinate wider public interest by yielding to pressures from national and international biotech corporations.

Highly Centralised regulation of a high risk sector

The proposed Bill makes no effort at all to wholistically address a variety of concerns associated with the high risks involved in biotechnology. In fact as a legislative effort it brazenly, controversially and questionably proclaims it as a "Bill **to promote** the safe use of modern biotechnology". The use of the expression "safe use" notwithstanding, there is no mystery whatsoever that the Bill is an unabashed effort to promote biotechnology. This based on a regulatory system designed to accord quick and favouring approvals. To ensure which, sufficient attention seems to have been paid to ensure that decisions affecting this sector are not in any manner subservient to opinions and decisions at State and Local Government levels, thus respecting their rights and obligations in the federated system of governance. (Emphasis supplied)

With such skewed rationale backing the law, it is not at all surprising that there is absolutely no provision for public

8 A copy of the Bill that was introduced in the 2011 Monsoon session of the Parliament was leaked out, and is now being circulated as the main official copy for discussion.

involvement in biotechnology related decision making. Nor is there any possibility of independent review by States and Local Governments in the proposed regulatory process. If anything, States have been provided largely administrative and, thus, marginal roles. Almost every aspect of the power and functioning of the proposed Biotechnology Regulatory Authority is controlled by the Centre, and that too by a committee of bureaucrats directly under the Cabinet Secretary, a process that has no Parliamentary oversight whatsoever.

For all these reasons and more, a review of this legislative proposal is essential in the context of existing national laws and international treaties and agreements.

Mocking the federal polity of the country:

The manner in which this Bill has been promoted, as well as its contents, mocks the very fundamentals of the federal polity of this country. The basis for allotting responsibilities across the Centre and States is contained in the 7th Schedule of Constitution of India, which also lists concurrent responsibilities. Keeping in view the federal polity of the nation, therefore, the Centre has to respect this separation of powers.

The State List in the 7th Schedule of the Constitution of India includes "agriculture, including agricultural education and research, protection against pests and prevention of plant diseases" and also "preservation, protection and improvement of stock and prevention of animal diseases; veterinary training and practice". In addition, "fisheries" and "public health and sanitation; hospitals and dispensaries" are also listed.

Important to note is that "agriculture, including agricultural extension" is listed in the 11th Schedule, thus making it an item directly concerning Panchayat Raj institutions (elected rural local bodies) as well. Meanwhile, the 12th schedule lists "urban forestry, protection of environment and promotion of ecological aspects" as a matter of consideration for Nagarpalikas (elected urban municipal bodies) thus granting a greater role for local governments in such matters even as the Concurrent List of the 7th Schedule require the joint attention of the Centre, States and Local Governments on "protection of wild animals and birds", "prevention of extension from one State to another of infectious or contagious diseases or pests affecting men, animals and plants". The 12th Schedule further lists "public health", thus making urban local bodies jointly responsibly with the State on such matters.

Given that biotechnology has a direct and often irreversible impact on all these items, and also on life, livelihoods and the environment, it is to be expected that any legislative action of the nature of the BRAI Bill, 2011 cannot at all be an exclusive initiative of the Centre. Yet that is exactly what has happenned: no consultation whatsoever with the States and Local Governments during formulation of this Bill.

BRAI in aberration of Swaminathan Task Force recommendations:

The Swaminathan Task Force conceived the need for a Biotechnology Regulatory Authority for several categorical reasons. First and foremost, it recognised that "(b)iotechnology provides an opportunity to convert bioresources into economic wealth. *This has to be done in a manner that there is no adverse impact either on the environment or on human and animal health*. **The bottom line of our national agricultural biotechnology policy should be the economic well being of farm families, food security of the nation, health security of the consumer, protection of the environment and the security of our national and international trade in farm commodities**." Highlighting that "Biodiversity constitutes the feedstock of the biotechnology industry" it left no doubt that the "(r)ecommendations of the Task Force are based on these considerations." (Emphasis supplied)

At the outset, the Task Force admitted that "**(w)ith rapid growth in R & D efforts in biotechnology, a statutory and autonomous National Biotechnology Regulatory Authority will soon become necessary".** But it held that the nature of the authority should be such that it would "**have two wings – one for agricultural and food biotechnology and the other for medical and pharmaceutical biotechnology". Importantly it remarked that such an authority is "essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory mechanism in place in the country**". It further recommended that "**NBRA should be autonomous and professionally led but could be attached for necessary administrative support to an appropriate Ministry/Department."** (All emphasis in original).

The Task Force acknowledged that "(s)ince agriculture is a state subject it will be desirable to establish a State Agricultural Biotechnology Regulatory Advisory Board in each State to maintain liaison with NBRA and to ensure that

steps are taken to prevent the illegal release and proliferation of GM seeds. The State Agricultural Biotechnology Regulatory Advisory Board will also take steps to ensure that farmers are properly educated on the raising of refugia and the adoption of IPM procedures, so that the pest resistance properties of GM crops do not break down. It can also help to supervise the trials conducted with GM strains within the State". In addition, the Task Force recommended the institutional framework of the Authority would be such that it would work within the federated system of governance in India as "a large and agro-ecologically diverse country". Thus proposing a three tier regulatory structure as follows:

a. National Level:National Biotechnology Regulatory Authority (with a separate wing for Agricultural Biotechnology)

b. State Level:State Agricultural Biotechnology Regulatory Advisory Board

c. District Level:Biotechnology Risk Assessment and Communication Committee

The present BRAI Bill, 2011 makes no effort at all to comply with these recommendations.

International Legal Regime regarding biodiversity and biotechnology:

The Stockholm Declaration of the United Nations Conference on the Human Environment, 1972[9], is a fundamental and precedent international agreement for all environmental matters. It cautiously proclaims that "a point has been reached in history when **we must shape our actions throughout the world with a more prudent care for their environmental consequences**. Through ignorance or indifference, we can do massive and irreversible harm to the earthly environment on which our life and well-being depend. Conversely, through fuller knowledge and wiser action, we can achieve for ourselves and our posterity a better life in an environment more in keeping with human needs and hopes. There are broad vistas for the enhancement of environmental quality and the creation of a good life. What is needed is an enthusisastic but calm state of mind and intense but orderly work." Thereby, clearly prescribing the manner in which we need to govern such high risk technologies as biotechnology. (Emphasis supplied)

Building on this precedent Agreement, the largest gathering of heads of government recognised through the historic Rio Declaration on Environment and Development, 1992[10] the increasingly precarious nature of the relationship of human society with planetary ecological systems. In the Rio Declaration a greater specificity was achieved in dealing with the relationships between emerging technologies and the environment. The following Principles are most prescriptive in determining the role of the State and the people in dealing with such concerns as biotechnology presents:

> "Principle 10: **Environmental issues are best handled with participation of all concerned citizens, at the relevant level**. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.
>
> Principle 15: In order to protect the environment, **the precautionary approach shall be widely applied by States according to their capabilities**. Where there are threats of serious or irreversible damage, lack of full scientific certainty **shall not** be used as a reason for postponing cost-effective measures to prevent environmental degradation." (Emphasis supplied)

The Convention on Biological Diversity, 1992[11] was another historic agreement achieved in Rio de Janeiro. Some articles of the Convention directly affecting laws and regulatory systems relating to biotechnology are extracted below:

> *"Article I. Objectives:* The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity.the sustainable use of its components and the fair and

9 http://www.unep.org/Documents.Multilingual/Default.asp?documentid=97&articleid=1503
http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163

10 http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163

11 http://www.cbd.int/doc/legal/cbd-en.pdf

equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article *2. Use of Terms:*
For the purposes of this Convention:
"Biological diversity" means the variability among living organisms from all sources including, *inter alia,* terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems.
'*Biological resources*' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."

Article 6. General Measures for Conservation and Sustainable Use
Each Contracting Party shall, in accordance with its particular conditions and capabilities:
(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, *inter alia,* the measures set out in this Convention relevant to the Contracting Party concerned; and
(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies."

Specifically addressing the risks of biotechnology, the Convention states under *Article 8 relating to In-situ Conservation that, contracting parties are required to:*

"(g) **Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health**"

and also that States would endeavour
"(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices". (All emphasis supplied)

A major step forward in acknowledging the need of deeply democratic and transparent regulation of the biotechnology sector was achieved in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[12] adopted in 2000. This Protocol aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It reaffirms several relevant Principles of the Rio Declaration and asserts its objective as:

"Article **1: OBJECTIVE** In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, **the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.**" (Emphasis supplied)

The importance of making any State effort to decide on matters relating to modern biotechnology transparent and involving the wide public is especially enunciated in this Protocol which is based on a careful assessment of various risks and safeguards that ought to be built in:

"Article **23: PUBLIC AWARENESS AND PARTICIPATION**

12 http://bch.cbd.int/database/attachment/?id=10694

1. The Parties shall:
(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
(b) **Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported**.
2. 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.
3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House." (Emphasis supplied)

An appraisal of the evolution of international law suggests that the thrust is to ensure biosafety in dealing with high risk technologies such as modern biotechnology. The Agreements do not support, as the BRAI Bill intends, the enactment of laws whose intention is to exclusively "promote the safe use of modern biotechnology". Further, international efforts in such matters strongly urge nation states to guarantee highly democratic and people friendly decision making processes that are particularly conscious of the need to fully and meaningfully engage in decision making indigenous and other natural resource dependent communities - with the explicit intention of safeguarding their special interests in conservation and wise use of biological diversity.

India being a signatory to all these international agreements has a great responsibility to comply with treaty obligations in all its policy and legislative efforts. This especially while enacting laws governing biotechnology which is associated with very high environmental and health risks, and replete with scientific uncertainties. Quite in contrast, the BRAI Bill, 2011 fails to meets the high standards prescribed in these binding international agreements.

BRAI Bill, 2011 hardly improves existing regulatory weaknesses:

The Environment Protection Act, 1986, enacted in the aftermath of the Bhopal gas catastrophe and in preparation to the Rio Conference, serves as an umbrella legislation in all matters connected with the environment. It is for this reason that environment is defined in this Act as including "water, air and land and the inter-relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property". The Act defines "environmental pollution" as the "presence in the environment of any environmental pollutant" and especially defines "hazardous substance" as "any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plant, micro-organism, property or the environment".

On this basis, Section 3 of the Act empowers that the "**Central Government[13] shall have the power to take all such measures as it deems necessary or expedient for the purpose of protecting and improving the quality of the environment and preventing, controlling and abating environmental pollution**". (Emphasis supplied)

Powers that especially address the risks involved in the biotechnology sector include "laying down standards for emission or discharge of environmental pollutants from various sources whatsoever", "laying down procedures and safeguards for the handling of hazardous substances", "examination of such manufacturing processes, materials and substances as are likely to cause environmental pollution", "preparation of manuals, codes or guides relating to the prevention, control and abatement of environmental pollution", etc.

Supported by such sweeping responsibilities and powers to regulate, monitor, control, educate and penalise wrong acts as provided in the Environment Protection Act, the *1989 Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms and Genetically Engineered Organisms or Cells* was passed (hereinafter 1989 Rules). A variety of "competent authorities" have been established under these Rules, such as the Recombinant DNA Advisory Committee (IXDAC), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committee (IBSC) and a statutory Genetic Engineering Approval Committee (GEAC) with powers to approve "proposals relating to release of genetically engineered organisms and products into the environment including experiment Field trials".

13 The central government here means the union ministry of environment and forests as per orders issued under the Government of India (Allocation of Business) Rules.

The 1989 Rules require the constitution of State Biotechnology Co-ordination Committee (SBCC) with "powers 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/Medical Services" and "review periodically the safety and control measures in the various industries/institutions handling genetically engineered Organisms/Hazardous microorganisms". In addition, the Rules also mandate that "District Level Biotechnology Committee (DLC) in the districts wherever necessary" will be constituted "under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment". Critically, the District Committee is required to "visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency". Comprehending the high risks involved in biotechnology, the Commitee is required also to "prepare an off-site emergency plan" and "regularly submit its report to the State Biotechnology Co-ordination Committee/Genetic Engineering Approval Committee". (Emphasis supplied)

Centralised biotechnology regulation laws fail to wind public confidence:

All these safeguards, notwithstanding, the processes contained in the Rules empowered the Central Government to effectively control all decisions relating to biotechnology, including genetically modified organisms. The experience has been far from satisfactory, especially because the whole process has been governed with very little transparency and scientific scrutiny. State Governments have been almost entirely ignored in decision making, and rarely, if ever, have District Level Biotechnology Committees been constituted and/or consulted in decisions.

This has resulted in widespread discontents over decisions taken and resulted in massive protests nation-wide against the strong thrust for corporate controlled biotechnology interventions in agriculture and the food sectors, particularly those promoting Genetically Modified Organisms as products (GMO). In the backdrop of such widespread concerns, Aruna Rodrigues and ors. filed a Public Interest Litigation[14] in the Supreme Court of India challenging the unscientific, undemocratic and intransparent decision making of the Centre promoting GMO products. This petition is still under the active consideration of the court. In preliminary hearings, the Court was unconvinced of the Centre's independence and competence in making crucial decisions relating to this high risk sector, and found it necessary to involve itself in closely examining and monitoring the decision making process. Such has been the lack of faith in the Centre's handling of the process, that the Supreme Court appointed leading biotechnologist Dr. Pushpa Bhargava to become a member of the GEAC in an effort to make its decisions less opaque and more scientific.

B.t. Brinjal debates: An attempt at democratising decisions

An unique test of the efficacy of the current decision making system on biotechnology arose when the GEAC approved in October 2009 the environmental and commercial release of B.t. Brinjal, India's first food GMO product and promoted by the American transnational Monsanto through its subsidiary Mahyco[15]. Massive public protests from farmers and consumer groups followed protesting the GEAC decision as unscientific and corrupt.

The protests worked to draw the attention of then Union Minister of State for Environment and Forests (with independent charge) Jairam Ramesh, who promptly ordered a stay on the decision and subjected it to a series of public consultations that he personally held nation-wide late 2009 and early 2010. These consultations were participated by thousands of people from diverse sectors including representatives of farmers movements, scientific establishments, agricultural universities, government departments, civil society organisations, corporate sector, media, etc. The high levels of public participation in the consultations revealed the extensive nature of public concern over genetic engineering, and the weak and intransparent regulation of biotechnology in general.

Towards the end of this highly participatory process[16], Minister Ramesh found substantive evidence that the existing

14 Writ Petition (Civil) No. 260 of 2005 in the Supreme Court of India

15 Monsanto holds about 33% of the equity in Mahyco, even as it has indepently registered in India as Monsanto Holdings, perhaps the only instance of the US TNC registering its independent presence in a foreign nation. The Bt Brinjal project is funded by USAID under the ABSP II project and involves Sathguru (a front company of USAID and Cornell University, USA), University of Agricultural Sciences (Dharwar, Karnataka), Tamilnadu Agricultural University (Coimbatore) and Indian Institure of Vegetable Research (Lucknow, UP).

16 There have been strong misgivings though that the manner in which Jairam Ramesh conducted the proceedings, left a lot to be desired. But overall, this was a unique experience in India where a Central Minister went across the country to hold Hearings on critical issues of public importance.

decision making procedures and agencies connected with it had not thoroughly and sufficiently reviewed the evidence of adverse health and environmental impacts from B.t. Brinjal. He also discovered that trials conducted had not met with the necessary scientific rigour. Consequently, relying on the Precautionary Principle, Ramesh ordered a moratorium on the release of B.t. Brinjal, at least until the time all concerns could be carefully considered, appropriately reviewed and addressed to win public acceptability.

What this decision highlighted was that the existing procedures and safeguards were grossly inadequate in dealing with complex decisions relating to biotechnology and their social, environmental, ecological, economic and political ramifications. In many ways, the consultations revealed that a highly centralised decision making process is not at all sufficient to deal with the complexities that biotechnology decisions present, and strongly argued for a deeply participatory process of decision making. In addition the public consultations exposed a major lacunae in the existing decision making procedure: highly centralised decision making with very weak or no participation of local communities and governments promote bad decisions.

It is clear from this experience that the Centre taking dominant charge of decisions relating to biotechnology is not in the public interest. International treaties and conventions, and national laws are in agreement that such decisions must be deeply democratic as they offer the best guarantee in safeguaring public welfare when employing high risk associated biotechnology.

The Parliament has also repeatedly endorsed this position in various key legislations. In particular, the following laws mandate federated decision making on matters connected to peoples lives and livelihoods, health and environment.

i. Constitutional 73rd (Panchayat Raj) and 74th Amendment (Nagarpalika) Acts, in 1992.
ii. Biological Diversity Act, 2002
iii. Right to Information Act, 2005
iv. Forest Rights Act, 2006

BRAI confronts legitimate roles of Local Governments in health and environmental matters:

The Panchayat Raj and Nagarpalika Acts brought into force an important institutional tier of decision making: that of the District Planning Committee. Article 243 ZD of Part IX A of the Constitution mandates that "(t)here shall be constituted in every State at the district level a **District Planning Committee** to **consolidate the plans** prepared by the Panchayats and the Municipalities in the district and **to prepare a draft development plan for the district as a whole**." In formulating the draft development plan for 5 years, the Committee is required to "have regard to — **matters of common interest between the Panchayats and the Municipalities including spatial planning, sharing of water and other physical and natural resources, the integrated development of infrastructure and environmental conservation**". Similar provisions are made for metropolitan areas by constituting a Metropolitan Planning Committee. (Emphasis supplied)

When this Constitutional provision is read with the 7th, 11th and 12th Schedule of the Constitution, it becomes clear that the Centre cannot exclusively decide on matters relating to agriculture, health, environment, etc. Local Governments have a direct role in engaging with such decisions, especially in developing district plans. Besides consolidating these plans, the States have a role in developing broad policies on how to address such matters. All such progressive provisions that devolve power to the level of government closest to the people would become infructuous if the Centre arrogated to itself the power to regulate biotechnology exclusively, as is now proposed in the BRAI Bill, 2011. This proposal is therefore insidious and will have deep, cross-cutting and probably irreversible impacts on all these sectors.

BRAI sidesteps completely the Biological Diversity Act:

The Biological Diversity Act, 2002 was enacted in compliance with India's ratification of the Convention on Biological Diversity, 2002. According to this Act ""biological diversity" means the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco systems" and ""biological resources" means plants, animals and micro organisms or parts thereof, their genetic material and by products (excluding value added products) with actual or potential use or value, but does not include human genetic material". Further, the Act states ""commercial utilization" means end uses of biological

resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping". All these aspects are invariably affected by biotechnology interventions.

The Act also mandates that any activity that has any impact or implication on biological diversity or biological resource cannot proceed until and unless prior permission is accorded from State Biodiversity Boards (where the projects involve Indian institutions and companies), and from the National Biodiversity Authority (when foreigners, foreign institutions, collaborations and corporations are involved). In both cases, regulatory authorities are allowed to take a final decision only after duly consulting Biodiversity Management Committees that are constituted by the Local Governments. If access is allowed, it shall be based on the protocol of Access and Benefit Sharing, where the "benefit claimers" (typically natural resource dependent communities who have acute knowledge of biodiversity and knowledge associated with it) will have to be provided an appropriate share of the benefits arising – monetary or otherwise.

Such deeply participatory consultative and regulatory provisions have been evolved to ensure private and public corporations and institutions do not commit acts of biopiracy or unjustly deny benefits to local communities through high end commodification interventions such as biotechnology, that also normally tend to mystify knowledge associated with biological resources. It is a fact admitted by former Environment Minister Jairam Ramesh that biopiracy is rampant in India and is the most serious threat to biodiversity conservation. And that regulatory authorities have almost entirely failed in tackling this menace – depriving the country therefore of massive revenues from biological resources. This has also very adversely affecting biodiversity conservation and livelihoods associated with it.[17]

When such is the alarming scale of biopiracy, especially by corporations and institutions, the BRAI Bill, 2011 makes no reference to the Biological Diversity Act. Nor does it explicitly state the critical importance of complying with its binding provisions. In fact it promotes biotechnology decisions as entirely independent of those associated with accessing biological diversity of India.

Can BRAI override Right to Information Act, 2005?

It is settled law that a subject specific legislation overrides any restriction on that subject if made in any other general law. Therefore, any power to regulate access to information would primarily rest within the framework of the Right to Information Act, 2005 – an Act that has revolutionised relationships between the public and authorities of the State.

The authors of the BRAI Bill, however, seem to think otherwise. Controversially, and highly questionably, the BRAI Bill has a provision that gives BRAI the discretion to not disclose "commercial information" even if the same were to be released per the RTI Act. Thousands of decisions of Information Commissioners fly in the face of such exigent thinking that propose powers to special authorities like BRAI to over-ride fundamental Rights.

How BRAI works with the Forest Rights Act

The basic purpose of The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Bill, 2006, (Forest Rights Act) is "to recognise and vest the forest rights and occupation in forest land in forest dwelling Scheduled Tribes and other traditional forest dwellers who have been residing in such forests for generations but whose rights could not be recorded" and that such " recognised rights of the forest dwelling Scheduled Tribes and other traditional forest dwellers include the responsibilities and authority for sustainable use, conservation of biodiversity and maintenance of ecological balance and thereby strengthening the conservation regime of the forests while ensuring livelihood and food security of the forest dwelling Scheduled Tribes and other traditional forest dwellers". (Emphasis supplied)

This unprecedented law recognised that "forest rights on ancestral lands and their habitat were not adequately recognized in the consolidation of State forests during the colonial period as well as in independent India resulting in

17 A rare instance where biopiracy has been tackled is the result of Environment Support Group's investigation and complaint against Monsanto/Mahyco for illegally accessing various local varieties of brinjal (endemic to India) in developing B.t. Brinjal. More information about this ongoing case may be accessed at: www.esgindia.org

historical injustice to the forest dwelling Scheduled Tribes and other traditional forest dwellers who are integral to the very survival and sustainability of the forest ecosystems". Therefore, the Act states in the preamble that "it has become necessary to address the long standing insecurity of tenurial and access rights of forest dwelling Scheduled Tribes and other traditional forest dwellers including those who were forced to relocate their dwelling due to state development interventions". Significantly, this law mandates that the "**Gram Sabha shall be the authority to initiate the process for determining the nature and extent of individual or community forest rights or both that may be given to the forest dwelling Scheduled Tribes and other traditional forest dwellers** within the local limits of its jurisdiction under this Act by receiving claims, consolidating and verifying them and preparing a map delineating the area of each recommended claim in such manner as may be prescribed for exercise of such rights and the Gram Sabha shall, then, pass a resolution to that effect and thereafter forward a copy of the same to the Sub-Divisional Level Committee". (Emphasis supplied).

No other law can trample on these Rights provided under the Forest Rights Act. It would follow then that when the BRAI Bill is read with the Forest Rights Act and Biological Diversity Act together, the latter two would override in all aspects relating to access to forests and biological diversity and the recognition of special rights of Scheduled Tribes and forest dwelling communities. Further, given that both these legislations conform with the Panchayat Raj and Nagarpalika Acts, and with the provisions of the 7th, 11th and 12th Schedules of the Constitution, and that in contrast the BRAI Bill, 2011 makes no such effort whatsoever, raises a critical question of the constitutional validity of the Bill under consideration. Seen in this context, it is shocking, to say the least, that the BRAI Bill, 2011 has come knocking on the doors of the Parliament without any consultation with States and Local Governments. This is also absolutely in contravention with various settled laws and fundamental rights as provided for in the Constitution.

The highly problematic BRAI Bill, 2011

At the outset it must be recognised that the BRAI Bill is proposed "to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for matters connected therewith or incidental thereto". The Preamble recognises that "modern biotechnology offers opportunities to address important needs related to agriculture, health, food production and environment" and claims that the legislation is to ensure conformance with the provisions of the Cartagena Protocol.

Union controls biotechnology: The Bill then quickly promotes the idea that "**it is expedient inthe public interest that the Union should take under its control the regulation of organisms, products and processes of modern biotechnology industry**". To do so, the Bill provides for the constitution of the Biotechnolgy Regulatory Authority of India, which would be a body consisting of 3 full time member, one of who will be the Chairperson, and 2 part-time members. A variety of criteria is determined for qualifying eligibility to be Members of the Authority who will be appointed by a Selection Committee which is Chaired by the Cabinet Secretary and almost entirely filled by senior bureaucrats representing various connected Ministries. Consequently there is a direct intervention of the State in the constitution of such a critical regulatory authority. Thus, grossly limiting the possibility of the Authority functioning autonomously and without being influenced by the Government in any manner. With such a flaw built into the basic structure of the Authority, it is a moot point if the regulator can at all function independently, autonomously and transparently when set up by the approver of biotechnology.

BRAI as regulator and promoter of biotechnology: The problem in such consitution of an Authority becomes deeper when we review its powers. Simply stated, the Authority has unlimited powers to decide about any aspect of biotechnology. In a very rare instance of contradictory powers, the regulatory authority whose basic purpose seems to be to accord or deny clearances for biotechnological interventions, is actually also saddled with the responsibility of promoting biotechnology. Thus raising a fundamental question if a promoter of a technology can be its own judge and jury? Upon this fundamental flaw rests many other critical functions of the Authority, including laying down norms and standards for biotechnology industry and applications in India. This would involve working closely with various biotechnology promoters, and needless to state, discretion in evolving standards, for one, could easily become a process for lowering standards. Nowhere in these list of functions though is there even a whisper of a mention that biotechnology interventions must conform with other laws that affect this sector, such other as the Biological Diversity Act.

Multiple sub-authorities to be created: Based on such highly centralised institutional mechanisms, a variety of assistant agencies are to be created to support BRAI in its work. First and foremost is that three Chief Regulatory Officers will be appointed in dealing with the following items:

a)agriculture, forest and fisheries
b)human health and veterinary
c)industrial and environmental applications

Then there are many specialised units that will be constituted and these include Risk Assessment Unit, Product Rulings Committee, Environmental Appraisal Panel (a sort of nod in weak acknowledgement of the regulatory powers of the MoEF under the Environment Protection Act). Interestingly, should the MoEF have a view divergent to that taken by BRAI on a biotechnological intervention, the Bill states that in such instances BRAI's opinion will supercede. This brings to question if BRAI, as proposed in the BRAI Bill, can at all override the powers vested with MoEF under the Environment Protection Act, as it is settled law that the latter Act is superior on all matters connected with the environment, and should also serve as an umbrella legislation.

Weak safeguards to rein in BRAI: There are some safeguards to review the workings of BRAI that are offered, one of which includes the constitution of an Inter-Ministerial Governing Board that consists of representatives of various Ministries, essentially all bureaucrats. In addition, there is the need to constitute a Biotechnology Advisory Council "to render strategic advise to the Authority on the matters relating to the developments in modern biotechnology and their implications in India". This Council will have inter-disciplinary representation. But the selection of Members to the Council is proposed to be done entirely by the Central Government, thus leaving room for a lot of discretion in ensuring "Yes Men" (as is often the case) are picked up. There is the requirement then to establish at state levels State Biotechnology Regulatory Advisory Committee with the purpose of acting as a nodal agency to "facilitate inter-

departmental coordination within the State" and for "inter-action between the State Government and the Authority". This body is once more filled with bureaucrats and reduces the State body to the status of a glorified postman.

Fraud in securing clearance not a criminal offence? All laws that govern biological diversity, forest rights, environment, etc., make the wrongful submission of information by an applicant seeking clearance, a serious criminal offense. The BRAI Bill, in contrast, does not see the need for similarly punishing fraudsters. It merely provides for the Authority to chide the violator, and at best revoke the clearance granted. (Sec. 27.9)

Mild punishment for violators of clearance conditions: Punishment for not meeting the conditions imposed in clearances, or initiating biotechnology interventions without prior clearances, are shockingly mild. Prison sentences vary from 3 months to 4 years (repeat offenders), at best, and the fines are ridiculously low, pegged at Rs. 2 lakhs to Rs. 5 lakhs even when the offense is of initiating field trials without clearance. That such low fines are proposed for regulating a super-high growth, high profit sector, is clearly indicative that the Union Government proposes to use this law less for regulation and more for promotion of biotechnology. In contrast, the Biological Diversity Act enacted about a decade ago has far more stringent penal powers, both criminal and civil. (Chapter XII)

RTI Act subordinate to BRAI? In a related provision, the BRAI Bill claims that the provisions of the RTI Act will not apply in accessing information if BRAI decides that certain information submitted by the applicant is "confidential commercial information". Thus arrogating to itself a power that cannot be possible when BRAI is read with the RTI Act, as the latter clearly being a special law governing information access supercedes with its *non obstante* clause the limitation imposed in BRAI Bill to regulate regressively information access. (Sec. 28)

Protesting biotechnology a criminal offense? Perhaps an indication of highly reactionary approach that the BRAI Bill contains a provision that allows serious penalisation if "any person contravenes or attempts to contravene or abets the contravention of the provisions of this Act". Such loosely defined language in law gives abundant space for careless and vindictive interpretations, and is a serious attack on human rights as the punishment proposed is 2 years in prison and ten lakh rupees in fine. This language could target all actions resisting introduction of GMO, for instance, as being grossly illegal, and could well see thousands of farmers and activists filling the prisons on the direction of the Authority. (Sec. 66) Another such reactionary provision in the BRAI Bill is punish a "person" who "without reasonable excuse, resists, obstructs, or attempts to obstruct, impersonate, threaten, intimidate or assault an officer of the Authority". (Sec. 64) While protecting public officials is provided for in the Indian Penal Code, the need for claiming special protection to BRAI officials appears rather specious.

Limiting Access to Justice by Setting up a BRAT: In what has now become a dominant trend in establishing Tribunals to resolve disputes, the BRAI Bill too proposes the constitution of the Biotechnology Regulatory Appellate Tribunal (BRAT). BRAT will have powers to deal with all appeals of contestations over biotechnological interventions and explicitly bars civil courts from entertaining such disputes. The Tribunal as proposed is a largely centralised appeals forum that would "sit at such place or places, as the Central Government may, by notification, specify". Which in reality would translate to very poor access to this forum in a large country like India. A further restriction imposed on litigants' access to justice is that BRAT decisions can only be appealed against in the Supreme Court. In other words, it is highly unlikely that this forum will be easily accessible to the wide public, as a similar experiences reveal with the National Green Tribunal constituted by MoEF last year. It also raises the question if this Appellate Authority was at all required and whether a reference could have not been made that appeals connected to biotechnological interventions must be taken up by the National Green Tribunal, which is developing wider presence across the country. (Chapter XI and Sec. 77)

Citizens cannot monitor violations by Regulator: A major omission in the BRAI Bill is that it does not provide for citizen suits. This provision that is contained in all environmental laws allows any person to issue due notice on an authority or violator of the law to remedy the situation. If the violation is not remedied during the notice period, the complainant can move the courts for necessary action and punishment, including criminal prosecution. This powerful provision is completely missing in the BRAI Bill. Was this an effort to ensure the biotechnology industry is totally sheltered from all its risks and liabilities, even when is a high risk sector, next only to nuclear power?

While these are indicative of the deeply problematic nature of this Bill, a close study would reveal many more flaws. Dangerously, the BRAI Bill is replete with provisions that subvert many progressive laws as discussed before. And most certainly does not at all recognise the consitutionally mandated roles of the States and Local Governments to be intrinsically involved in decisions relating to agriculture, food security, health and environment given that

biotechnology has a direct and essentially irreversible impact on all these sectors.

In summary

The BRAI Bill, 2011, therefore, is a deeply problematic legislative proposal. This legislative proposal is best subjected to a detailed and critical public review in a deeply democratic and transparent manner, providing ample opportunity for States and Local Governments to discuss and debate the provisions involved. Such a review could be undertaken under the supervision of a Joint Parliamentary Committee given the cross-cutting and multi-sectoral impact the Bill has on many aspects of governance, including the powers of Local and State Governments. Such an exercise should only be undertaken after the Bill is translated into all languages, so that its impacts on lives and livelihoods of millions may be fully appreciated and deeply introspected upon.

(The authors thank Mallesh K. R. of Environment Support Group for his invaluable research and documentation support.)

Environment Support Group - Trust
[Environmental, Social Justice and Governance Initiatives]
1572, 36th Cross, Ring Road
Banashankari II Stage
Bangalore 560070. INDIA
Tel: 91-80-26713559-61
Fax/Voice: 91-80-26713316
Email: esg@esindia.org Web: www.esgindia.org